



Australian Government

Department of Health

Therapeutic Goods Administration

Recall Action Result Summary

You searched for recall action reports between **01/07/2012 – 16/05/2024**:

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Important information on the System for Australian Recall Actions

The TGA publishes information about therapeutic goods supplied in the Australian market that have been subject to a recall action in a publicly searchable database.

Recall action means action taken by the responsible entity (being the person who is responsible for taking the recall action) to resolve a problem with therapeutic goods supplied in the Australian market that have, or may potentially have, deficiencies relating to safety, quality, efficacy (performance) or presentation.

- Recall actions include: the permanent removal of therapeutic goods from supply in the market, the taking of corrective action in relation to therapeutic goods (such as repair, modification, adjustment or relabelling) and, in the case of medical devices that have been implanted into patients, the issuing of a hazard alert containing information for health practitioners on how to manage patients.
- More information about Australian recall actions is available at <http://tga.gov.au/safety/recalls-about.htm>
- If you are taking a medicine, using a medical device or have had a medical device implanted into you, that is the subject to a recall action, and you have any concerns you should seek advice from a health professional. <http://www.healthdirect.org.au/>

About the release of this information

While reasonable care is taken to ensure that the information is an accurate record of recall actions that responsible entities have reported to the TGA or of which the TGA has become aware, the TGA does not guarantee or warrant the accuracy, reliability, completeness or currency of the information or its usefulness in achieving any purpose.

To the fullest extent permitted by law, including but not limited to section 61A of the Therapeutic Goods Act 1989, the TGA will not be liable for any loss, damage, cost or expense incurred in or arising by reason of any person relying on this information.

The information contained in the SARA database is released under s 61(5C) of the Therapeutic Goods Act 1989.

Copyright restrictions apply to the System of Australian Recall actions (SARA) <http://tga.gov.au/about/website-copyright.htm>.

Recall Action Details

Number of recall actions: 8003

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
16/05/2024	CARESCAPE Monitors	Medical Device	Product Defect Correction	Class II	Hospital
16/05/2024	HeartSine Defibrillators	Medical Device	Product Defect Correction	Class I	Consumer
15/05/2024	A610 Clinician Programmer Application and A620 DBS Patient Programming Application	Medical Device	Product Defect Correction	Class II	Hospital
14/05/2024	fabian HFO Classic and fabian HFOi Neonatal and Pediatric Ventilators	Medical Device	Product Defect Correction	Class I	Hospital
14/05/2024	Randox Analysers. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
13/05/2024	BD Multitest 6-Color TBNK CE-IVD. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
13/05/2024	MEGADYNE MEGA SOFT Paediatric Patient Return Electrode	Medical Device	Recall	Class I	Hospital
10/05/2024	BD SARS-CoV-2 Reagents for BD MAX Systems. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
10/05/2024	CLEARCUT Dual Bevel Angled Sideport Knives and MVR+ Blade V-Lance Ophthalmic knives , either as sterile standalone knives or within an Alcon Custom Pak	Medical Device	Product Defect Correction	Class II	Hospital
9/05/2024	Corneal tissue - pre-cut	Biological	Hazard Alert	Class II	Hospital
9/05/2024	InstaClear Sheath	Medical Device	Product Defect Correction	Class II	Hospital
9/05/2024	Optetrak Three Peg Patella 26mm - 41mm	Medical Device	Recall	Class II	Hospital
8/05/2024	AlignRT Plus	Medical Device	Product Defect Correction	Class III	Hospital
8/05/2024	Arrow FiberOptix Intra-Aortic Balloon Catheter Kit and Arrow UltraFlex Intra-Aortic Balloon Catheter Kits	Medical Device	Product Defect Alert	Class I	Hospital
8/05/2024	BALLARD* Closed Suction System for Neonates/Pediatrics, 5 Fr, Elbow	Medical Device	Recall	Class III	Hospital
8/05/2024	GlideScope Core 15 and GlideScope Core 15 FHD Monitors	Medical Device	Product Defect Correction	Class II	Hospital
8/05/2024	Zenition 70 systems	Medical Device	Product Defect Correction	Class III	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
7/05/2024	Batteries Supplied by CSB and Used with Plum Infusion Systems	Medical Device	Product Defect Correction	Class II	Hospital
7/05/2024	OXINIUM FEMORAL HEAD 12/14 32MM +4	Medical Device	Recall	Class II	Hospital
7/05/2024	Sevoflurane vaporizers for Flow Family Anesthesia systems	Medical Device	Product Defect Alert	Class II	Hospital
6/05/2024	CliniMACS Prodigy TS 310	Medical Device	Product Defect Correction	Class II	Hospital
3/05/2024	D-Dimer Calibration set. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
3/05/2024	Haines Air Assisted Transfer Mattress	Medical Device	Recall	Class II	Hospital
3/05/2024	Various Mapleson F Anaesthetic Breathing Systems	Medical Device	Product Defect Correction	Class II	Hospital
2/05/2024	AirSense 11 devices	Medical Device	Product Defect Correction	Class III	Consumer
2/05/2024	Fluodeoxyglucose	MEDICINE	Recall	Class III	Hospital
2/05/2024	IMMULITE 2000 and IMMULITE 2000 XPi Anti-TG Ab. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
30/04/2024	Alphamaxx Operating Tables	Medical Device	Product Defect Correction	Class II	Hospital
30/04/2024	Butterfly iQ/ iQ+/ iQ3 diagnostic ultrasound imaging system	Medical Device	Product Defect Correction	Class II	Retail
30/04/2024	Paragon Stem Standard Collared Size 7 / Paragon Stem High Offset Size 8	Medical Device	Recall	Class II	Hospital
30/04/2024	Philips IQon, iCT, Ingenuity, and Brilliance CT 64 systems	Medical Device	Product Defect Correction	Class II	Hospital
29/04/2024	Multiple infectious organism IVDs/ Viruses IVD	Medical Device	Recall	Class II	Hospital
26/04/2024	Hyperparallel Optical Coherence Tomograph	Medical Device	Product Defect Correction	Class III	Retail
26/04/2024	MiniMed 780G	Medical Device	Product Defect Correction	Class II	Consumer
26/04/2024	RYALTRIS olopatadine 600mcg and mometasone furoate 25mcg/actuation nasal spray bottle	Medicine	Product Defect Correction	Class III	Retail
26/04/2024	Stemsys cemented Femoral Stems - coated femoral stem prosthesis modular.	Medical Device	Product Defect Correction	Class II	Hospital
24/04/2024	Circle CBD 200 Full Spectrum Oil - 30ml	Medicine	Recall	Class II	Retail
24/04/2024	Esoflip Dilation Catheter 30mm	Medical Device	Recall	Class I	Hospital

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24/04/2024	PANADOL CHILDREN 1 MONTH - 1 YEAR paracetamol 100 mg/mL oral liquid bottle	Medicine	Product Defect Correction	Class II	Consumer
24/04/2024	Primary microtubes (0.8 mL / 1.0 mL) on STA R EVOLUTION, STA R MAX and STA COMPACT MAX. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
24/04/2024	Vercise Genus IPG KITs	Medical Device	Product Defect Correction	Class II	Hospital
22/04/2024	Patient Information Center (PIC) iX	Medical Device	Product Defect Correction	Class II	Hospital
22/04/2024	Rad-G Device and Rad-G Device with temp	Medical Device	Recall	Class I	Consumer
22/04/2024	X Series Power System Double Trigger Handpiece	Medical Device	Product Defect Correction	Class II	Hospital
19/04/2024	Cobalt XT HF Cardiac Resynchronization Therapy Defibrillator Evera XT DR Defibrillator	Medical Device	Recall	Class II	Hospital
19/04/2024	DxI 9000 Access Immunoassay Analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
19/04/2024	DxI 9000 Access Immunoassay Analyzer. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
19/04/2024	LEUNIG-GREVERS LASER Application	Medical Device	Recall	Class II	Hospital
19/04/2024	SECOV150 / SECOV105	Medical Device	Product Defect Correction	Class II	Hospital
18/04/2024	Dako CoverStainer Devices. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
18/04/2024	Medartis APTUS TriLock Screw	Medical Device	Recall	Class II	Hospital
17/04/2024	NEOMED* Pharmacy Syringes - Nonsterile (Non ENFit)	Medical Device	Recall	Class III	Retail
16/04/2024	HistoCore Pegasus Devices. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
16/04/2024	Philips Spectral CT7500	Medical Device	Product Defect Correction	Class II	Hospital
16/04/2024	Voyant Electrosurgical Generator	Medical Device	Recall	Class III	Hospital
15/04/2024	Human Assayed Multi-Sera Level 3. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
15/04/2024	Rejuran Dermal tissue reconstructive material animal-derived	Medical Device	Recall	Class II	Hospital

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15/04/2024	Tri-Staple 2.0 Black Reinforced Intelligent Reload	Medical Device	Recall	Class II	Hospital
12/04/2024	Endosure Hypochlor 1%	Medical Device	Recall	Class II	Wholesale
12/04/2024	High Flow Insufflation Unit UHI-4	Medical Device	Product Defect Correction	Class I	Hospital
11/04/2024	Surdial X	Medical Device	Product Defect Correction	Class III	Hospital
11/04/2024	Syntel Silicone Thrombectomy Catheter	Medical Device	Recall	Class II	Hospital
10/04/2024	5000 Compact Series Ultrasound Systems	Medical Device	Product Defect Correction	Class II	Hospital
10/04/2024	Airview 4.44	Medical Device	Product Defect Correction	Class III	Retail
10/04/2024	StealthStation S8 Application	Medical Device	Product Defect Correction	Class II	Hospital
10/04/2024	Synapse PACS	Medical Device	Product Defect Correction	Class II	Hospital
9/04/2024	CARDIOHELP-i System	Medical Device	Product Defect Correction	Class II	Hospital
9/04/2024	Merlin.net Web Application and Database	Medical Device	Product Defect Correction	Class III	Consumer
9/04/2024	Motec Wrist Arthrodesis System	Medical Device	Hazard Alert	Class II	Hospital
9/04/2024	myMerlin Application software versions v.1.0.6000, v.1.0.6001, or v.1.0.6002	Medical Device	Product Defect Correction	Class III	Consumer
9/04/2024	myMerlin Mobile Application (iOS) version 1.0.1003	Medical Device	Product Defect Correction	Class III	Consumer
9/04/2024	myMerlinPulse Patient Application	Medical Device	Product Defect Correction	Class III	Consumer
8/04/2024	Airvo 2 devices	Medical Device	Recall	Class II	Retail
8/04/2024	Cellife AMPK Fatburst	Medicine	Recall	Class II	Retail
8/04/2024	DR-XD1000 (FDR Nano)	Medical Device	Product Defect Alert	Class II	Hospital
8/04/2024	SuperLUX, SuperLUX Pro, UltraLUX and UltraLUX Pro	Medical Device	Product Defect Correction	Class II	Retail
5/04/2024	PSR	Medicine	Product Defect Correction	Class III	Hospital
5/04/2024	RayStation RayPlan 7 through 2024A including some service packs	Medical Device	Product Defect Correction	Class II	Hospital
5/04/2024	Weislander Self Retaining Retractor 14cm BL	Medical Device	Product Defect Correction	Class II	Hospital
4/04/2024	Affinis Inverse Drill-bit Devices	Medical Device	Recall	Class II	Hospital

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4/04/2024	iQ200 Series Analyzers and DxU 850m and 840m Iris Analyzers. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
4/04/2024	Respiratory Pathogens (16-well) Step 1 Tubes. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
3/04/2024	Bedside clean kit enzymatic imbibed sponge and container	Medical Device	Recall	Class II	Hospital
3/04/2024	Compounded Medicines	Medicine	Recall	Class II	Hospital
3/04/2024	NexGen CR-Flex Femoral Component, Porous, Size E, Right	Medical Device	Hazard Alert	Class II	Hospital
2/04/2024	HeartWare Ventricular Assist Device (HVAD) System	Medical Device	Product Defect Correction	Class I	Hospital
2/04/2024	OmniLab Advanced + (OLA+) devices	Medical Device	Product Defect Alert	Class I	Hospital
2/04/2024	Rheo Knee and Rheo Knee XC	Medical Device	Product Defect Correction	Class II	Hospital
30/03/2024	BiPAP Devices	Medical Device	Product Defect Alert	Class I	Consumer
27/03/2024	AIRFLOW PROPHYLAXIS MASTER or AIRFLOW One	Medical Device	Recall	Class II	Retail
27/03/2024	Hintermann Series H3 Total Ankle Replacement (TAR) system	Medical Device	Hazard Alert	Class II	Consumer
27/03/2024	K-Citra 10 Tablets Potassium Citrate 1080mg	Medicine	Recall	Class III	Retail
27/03/2024	KLARO In Vivo Surgical Lighting	Medical Device	Recall	Class II	Hospital
26/03/2024	Alinity m System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
26/03/2024	Endosee Advance Cannula Device (REF: CS ESPX5)	Medical Device	Recall	Class III	Hospital
26/03/2024	Ingenia Ambition X	Medical Device	Product Defect Correction	Class II	Hospital
26/03/2024	Mobile Diagnostic wDR 2.x Systems	Medical Device	Product Defect Correction	Class II	Hospital
26/03/2024	NF02L ENFit Double Lumen Replogle Tube 10FR	Medical Device	Recall	Class I	Hospital
25/03/2024	Alcon Custom Pak containing Oasis Medical 27G Chang Hydrodissection Cannulas	Medical Device	Product Defect Correction	Class II	Hospital
25/03/2024	POWERSEAL Sealer and Divider	Medical Device	Recall	Class II	Hospital
22/03/2024	Fresenius Medical Care Haemodialysis Machines Series 4008/5008/6008	Medical Device	Product Defect Alert	Class II	Hospital

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22/03/2024	Surgical procedure kit, cardiothoracic, non-medicated, single-use: Custom Tubing Pack	Medical Device	Recall	Class II	Hospital
21/03/2024	Hugo Robotic-Assisted Surgery (RAS) System	Medical Device	Product Defect Correction	Class II	Hospital
21/03/2024	Hugo Robotic-Assisted Surgery (RAS) System	Medical Device	Product Defect Correction	Class II	Hospital
21/03/2024	PERLA TL 25D SCREW device	Medical Device	Recall	Class II	Wholesale
20/03/2024	Fludeoxyglucose [18F] Injection BP [18F] FDG	Medicine	Product Defect Correction	Class II	Hospital
20/03/2024	HeartMate 3 LVAS Kits	Medical Device	Product Defect Correction	Class I	Hospital
20/03/2024	Panocell – 10 Reagent Red Blood Cells. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
20/03/2024	Shimadzu CVS System - Trinias units	Medical Device	Product Defect Correction	Class II	Hospital
20/03/2024	Zimmer Periarticular Locking Plate System, Distal Lateral Fibula Locking Plate	Medical Device	Hazard Alert	Class II	Hospital
19/03/2024	Evidence MultiSTAT. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
19/03/2024	Impella Devices	Medical Device	Product Defect Correction	Class II	Hospital
18/03/2024	Atlan Anaesthesia workstation	Medical Device	Product Defect Correction	Class II	Hospital
18/03/2024	Clear the Skin Formula a.k.a. Liang Xue Xiao Feng San	Medicine	Recall	Class II	Consumer
15/03/2024	Atellica CH analysers. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
15/03/2024	Cannulae Devices	Medical Device	Recall	Class II	Hospital
15/03/2024	Equinnox Shoulder reverse total shoulder (rTSA) UHMWPE and anatomic total shoulder (aTSA) UHMWPE devices	Medical Device	Hazard Alert	Class II	Hospital
15/03/2024	Fludeoxyglucose (18F) Injection ([18F]FDG)	Medicine	Recall	Class II	Hospital
15/03/2024	Medartis APTUS Wrist Plates	Medical Device	Recall	Class II	Hospital
14/03/2024	Fanttest COVID-19/Influenza A&B Antigen Test Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Consumer
14/03/2024	ID-DiaCell I-II-III, ID-DiaCell I-II-III Asia, LISS/Coombs, Coombs Anti-IgG. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital

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14/03/2024	LABType SSO Typing Tests and LABType XR/CWD DNA Typing Kits. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class III	Hospital
14/03/2024	ResScan 7.0 on AirSense 11 AutoSet device	Medical Device	Product Defect Correction	Class II	Retail
13/03/2024	Astral 100 and Astral 150 ventilators	Medical Device	Product Defect Correction	Class II	Consumer
13/03/2024	Calibration Serum Level 3. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
13/03/2024	MAGNETOM Biograph mMR	Medical Device	Product Defect Correction	Class II	Hospital
13/03/2024	Unimax Medical Systems – Detachable Endo Pouch	Medical Device	Recall	Class II	Hospital
12/03/2024	DIVA 24 Inch Widescreen LCD Touch Display	Medical Device	Product Defect Correction	Class II	Hospital
12/03/2024	NordBed Kid (Paediatric Bed)	Medical Device	Product Defect Correction	Class II	Hospital
8/03/2024	Philips CareEvent & Patient Information Center iX (PIC iX)	Medical Device	Product Defect Correction	Class II	Hospital
8/03/2024	Philips Incisive CT	Medical Device	Product Defect Correction	Class II	Hospital
7/03/2024	DX-D100 Mobile	Medical Device	Product Defect Correction	Class II	Hospital
7/03/2024	Fludeoxyglucose (18F) Injection	Medicine	Recall	Class II	Hospital
6/03/2024	2-[18F]Fluoro-2-deoxy-D-glucose Stabilised Injection BP	Medicine	Product Defect Correction	Class III	Hospital
6/03/2024	HeartSine samaritan PAD 500P	Medical Device	Recall	Class I	Consumer
6/03/2024	Microalbumin and Urine Liquid Controls – Level 3, An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
5/03/2024	Allura Xper, Allura Centron, and Azurion Systems	Medical Device	Product Defect Correction	Class I	Hospital
5/03/2024	Disposable Biopsy Needle Kit	Medical Device	Recall	Class II	Hospital
5/03/2024	Dxl 9000 Access Immunoassay Analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
5/03/2024	MAC VU360 V1.02 SP05 12 Lead ECG Post Acquisition Preview Screen	Medical Device	Product Defect Correction	Class III	Hospital
4/03/2024	ACUSON Redwood 1.0 ultrasound system (product version 1.0), ACUSON Juniper and ACUSON Juniper Select Ultrasound Systems	Medical Device	Product Defect Correction	Class II	Hospital
4/03/2024	Trilogy Evo, Trilogy Evo O2, Trilogy EV300	Medical Device	Product Defect Correction	Class II	Consumer

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1/03/2024	BD BodyGuard MicroSets	Medical Device	Recall	Class I	Hospital
1/03/2024	CADD-Solis Ambulatory Infusion Pumps	Medical Device	Product Defect Correction	Class II	Hospital
1/03/2024	CADD-Solis Ambulatory Infusion Pumps	Medical Device	Product Defect Correction	Class II	Hospital
1/03/2024	Olympus Soltive Premium SuperPulsed Laser System	Medical Device	Product Defect Correction	Class II	Hospital
1/03/2024	Wrench Devices	Medical Device	Recall	Class II	Hospital
29/02/2024	Covidien Auto Suture Structural Balloon Trocar & Auto Suture Blunt Tip Trocar	Medical Device	Product Defect Correction	Class II	Hospital
29/02/2024	EZ2 Connect MDx instrument. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
28/02/2024	BIOFIRE FILMARRAY Pneumonia (PNplus) Panel plus "An in vitro diagnostic medical device (IVD)"	Medical Device	Product Defect Alert	Class II	Hospital
28/02/2024	Chiba Biopsy Needle	Medical Device	Recall	Class I	Hospital
28/02/2024	Low RNA Reagent Cassette. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
28/02/2024	VisuMax, VISUMAX 600 & VISUMAX 800 - Preventive laser source replacement	Medical Device	Product Defect Correction	Class III	Hospital
27/02/2024	Heartmate 3 LVAS Kits with Heartmate 3 Outflow Grafts & Heartmate II LVAS Kits with Heartmate II Outflow Grafts	Medical Device	Product Defect Correction	Class I	Hospital
27/02/2024	HV Sterile Screws	Medical Device	Recall	Class II	Hospital
27/02/2024	therascreen MGMT Pyro Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
26/02/2024	Elecsys Troponin T hs Elecsys Troponin T hs STAT. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
26/02/2024	Irrigation Handle (20/SP)	Medical Device	Product Defect Correction	Class III	Hospital
23/02/2024	3M Tube Securement Device	Medical Device	Recall	Class II	Hospital
22/02/2024	Access Substrate 4 x 130ml. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
22/02/2024	Anti-k. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital

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22/02/2024	CYSTATIN C CALIBRATOR and CONTROL LEVEL 2 and 3 "An in vitro diagnostic medical device (IVD)"	Medical Device	Product Defect Correction	Class II	Hospital
22/02/2024	GAN MAI DA ZAO TANG	Medicine	Recall	Class II	Retail
22/02/2024	Stay Safe Catheter Extension Luer-Lock 25cm, 32cm & 40cm	Medical Device	Product Defect Alert	Class II	Hospital
21/02/2024	Blooms The Chemist Mometasone Nasal Allergy Relief Mometasone Furoate 50 Micrograms / Actuation Aqueous Nasal Spray Bottle	Medicine	Recall	Class II	Retail
21/02/2024	QXDx BCR-ABL %IS Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
20/02/2024	Fantest COVID-19/Influenza A&B Antigen Test Kit. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class III	Consumer
20/02/2024	Neonatal ArcticGel Pads	Medical Device	Recall	Class I	Hospital
20/02/2024	ProxiDiagnost N90 1.1	Medical Device	Product Defect Correction	Class II	Hospital
19/02/2024	ADT BOOSTER diphtheria and tetanus vaccine adsorbed suspension for injection syringe	Medicine	Product Defect Correction	Class III	Retail
16/02/2024	Abre Venous Self-expanding Stent System	Medical Device	Recall	Class II	Hospital
16/02/2024	Fludeoxyglucose	Medicine	Product Defect Correction	Class II	Hospital
16/02/2024	Fludeoxyglucose (18F) Injection	Medicine	Recall	Class II	Hospital
16/02/2024	iSLEEVE 14F Expandable Introducer Set	Medical Device	Recall	Class II	Hospital
16/02/2024	Oxford Classic Floor Lifter	Medical Device	Product Defect Correction	Class I	Hospital
15/02/2024	BIOFIRE FILMARRAY Gastrointestinal (GI) Panel. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Alert	Class II	Hospital
15/02/2024	MESALZ mesalazine 1.2 g gastro-resistant prolonged release tablet bottle	Medicine	Recall	Class II	Retail
15/02/2024	Spry KAFO, Spry Vector Custom, SpryStep Original Custom and Spry Flex Custom	Medical Device	Recall	Class II	Consumer
15/02/2024	SunSeal SPF 50+	Medicine	Recall	Class II	Consumer
14/02/2024	paraPAC plus Ventilator	Medical Device	Product Defect Alert	Class I	Hospital
14/02/2024	Ultra Nature Selancy Women's 100 Blister Pack	Medicine	Recall	Class II	Retail
14/02/2024	Xray Screening table handle	Medical Device	Product Defect Correction	Class II	Hospital

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13/02/2024	Femoral Head	Biological	Hazard Alert	Class II	Hospital
13/02/2024	FLUOXETINE SANDOZ fluoxetine (as hydrochloride) 20mg capsule blister pack	Medicine	Recall	Class II	Wholesale
13/02/2024	Grays Osteotome Cup Cutting Tips	Medical Device	Recall	Class II	Hospital
13/02/2024	VA-LCP Clavicle Plate 2.7, shaft, CS1, right	Medical Device	Recall	Class II	Hospital
12/02/2024	All Care Plus, Care Plus & Lullaby Incubator	Medical Device	Product Defect Correction	Class II	Hospital
12/02/2024	Technetium-99m HDP	Medicine	Product Defect Alert	Class I	Hospital
9/02/2024	BIOFIRE Blood Culture Identification 2 (BCID2) Panel with BD BACTEC Blood Culture Vials	Medical Device	Product Defect Alert	Class II	Hospital
9/02/2024	CooperSurgical SupraSperm 100 Gradient Medium	Medical Device	Recall	Class III	Retail
9/02/2024	Phadia 200 and Phadia 200 Software 1.6.12. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class III	Hospital
8/02/2024	Disposable Analgesia Breathing Circuit 3.0m EXPANDABLE 22mmID Tubing, Filter, Hand piece with One-way Valve and Mouthpiece	Medical Device	Recall	Class II	Hospital
7/02/2024	Knotless TensionTight Button Implant System	Medical Device	Recall	Class II	Hospital
7/02/2024	MR systems with 60cm wide bore	Medical Device	Product Defect Correction	Class II	Hospital
7/02/2024	Slishman Traction Splint (Gen 2)	Medical Device	Recall	Class II	Hospital
6/02/2024	Ionostar Plus REF 2540, 2543, 2546	Medical Device	Recall	Class II	Retail
5/02/2024	Arrow QuickFlash Radial Artery Catheterisation Set	Medical Device	Recall	Class II	Hospital
5/02/2024	Epix Universal Clip Applier	Medical Device	Recall	Class II	Hospital
1/02/2024	3M Surgical Clipper Blade Assembly, 3M Specialty Blade Assembly, 3M Surgical Clipper	Medical Device	Product Defect Correction	Class II	Hospital
31/01/2024	Duracon AP Tibial Insert	Medical Device	Hazard Alert	Class II	Hospital
30/01/2024	Atellica UAS 800 Urine Sediment Analyser & Atellica 1500 Automated Urinalysis System. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
30/01/2024	BrightView systems – BrightView, BrightView X and BrightView XCT	Medical Device	Product Defect Correction	Class II	Wholesale

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
30/01/2024	BrightView systems – BrightView, BrightView X and BrightView XCT	Medical Device	Product Defect Correction	Class II	Hospital
29/01/2024	Aspire FLX Bed	Medical Device	Product Defect Correction	Class II	Consumer
29/01/2024	DX FiberTak Suture Anchor, ST & NDLs	Medical Device	Recall	Class III	Hospital
29/01/2024	Philips Azurion System R1.0, R1.1, R1.2, R2.0, R2.1, and R2.2	Medical Device	Product Defect Correction	Class II	Hospital
29/01/2024	Philips EPIQ Series Ultrasound Systems	Medical Device	Product Defect Correction	Class III	Hospital
29/01/2024	RSR LEM25 RiaRSR VGCC Ab Kit - Anti-human IgG. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
29/01/2024	SPIRIVA RESPIMAT tiotropium 2.5 micrograms/actuation solution for inhalation cartridge (with dose indicator)	Medicine	Product Defect Correction	Class II	Consumer
25/01/2024	Dental Surgical Handpiece S-12 without light	Medical Device	Recall	Class II	Retail
25/01/2024	EQUASHIELD® Closed System Transfer Device, Spike Tubing	Medical Device	Product Defect Alert	Class II	Hospital
24/01/2024	18F-DCFPyL (PSR)	Medicine	Product Defect Correction	Class III	Hospital
24/01/2024	DORC Directional Laser Probe	Medical Device	Recall	Class II	Hospital
24/01/2024	Technopath Multichem IA Plus, Multichem S Plus Level 1, Multichem S Plus Level 2, Multichem S Plus Level 3 and Multichem P. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
23/01/2024	Servo-n HFOV	Medical Device	Product Defect Correction	Class I	Hospital
23/01/2024	Spectral CT 7500	Medical Device	Product Defect Correction	Class II	Hospital
23/01/2024	Teen Mood + Anxiety	Medicine	Recall	Class II	Wholesale
23/01/2024	The Alinity s System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
22/01/2024	Henry Blooms Herb-a-lax Powder 200g	Medicine	Recall	Class II	Consumer
22/01/2024	The Duet External Drainage and Monitoring System (EDMS)	Medical Device	Recall	Class II	Hospital
19/01/2024	SMR MB L1 Liner	Medical Device	Hazard Alert	Class II	Consumer
19/01/2024	The Alinity s System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
17/01/2024	ACTRAPID PENFILL 3ML 5X3ML	Medicine	Product Defect Alert	Class II	Retail

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17/01/2024	BEYER Antrum Punch, Antrum Punch, 65°, 11 cm, Sphenoid Punch, 30°, 11 cm, Sphenoid Punch, 3.2 x 4 mm, Sphenoid Punch, 30°, 1.6 x 2 mm, Galea Spring Hook, 31 cm, Uvula Retractor, Optical Biopsy and Grasping Forceps, Grasping Forceps, flexible, 1 mm, Working Insert, with steering lever, Optical Scissor	Medical Device	Recall	Class II	Hospital
17/01/2024	IC9-RS intracavitary probes	Medical Device	Product Defect Correction	Class II	Hospital
17/01/2024	Metformin Sandoz 1000 mg Tablet 90s Blister	Medicine	Recall	Class II	Retail
16/01/2024	Azurion 7 M20 FlexArm system with Maquet Magnus Table	Medical Device	Product Defect Correction	Class I	Hospital
15/01/2024	CARMUSTINE-JUNO carmustine 100 mg powder for injection vial with diluent vial	Medicine	Recall	Class II	Hospital
15/01/2024	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
15/01/2024	Spectral CT 7500 with software version 5.0.0.X	Medical Device	Product Defect Correction	Class II	Hospital
15/01/2024	Urea. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class III	Hospital
12/01/2024	Optima Coil System	Medical Device	Recall	Class II	Hospital
11/01/2024	CellAED 2.2	Medical Device	Recall	Class I	Consumer
11/01/2024	Disposable Cup Impactors (ICJ) packaged with NOVAE STICK 47 cemented dual mobility cups	Medical Device	Recall	Class II	Wholesale
11/01/2024	EVair and EVair 03 (Jun-Air) Compressors	Medical Device	Product Defect Correction	Class II	Hospital
11/01/2024	Hookup Accessories for AER	Medical Device	Recall	Class III	Hospital
10/01/2024	RF-32#Centrifugal Pump with FLOWPROBE	Medical Device	Recall	Class I	Hospital
9/01/2024	Philips Ingenuity CT and Brilliance CT 64	Medical Device	Product Defect Correction	Class III	Hospital
9/01/2024	PM7100 INVOS Reusable Sensor Cables	Medical Device	Recall	Class II	Hospital
9/01/2024	Syramed µSP6000 Chroma HYP with battery and Volumed µVP7000 Chroma HYP with battery	Medical Device	Product Defect Correction	Class III	Hospital
8/01/2024	Atellica CH Immunoglobulin M_2 (IgM_2). An invitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
8/01/2024	Surefuser+	Medical Device	Recall	Class II	Hospital

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5/01/2024	Equinoxe Reverse Shoulder Constrained Humeral Liner	Medical Device	Hazard Alert	Class II	Hospital
4/01/2024	AntiBac San	Medical Device	Product Defect Correction	Class II	Retail
4/01/2024	HeartMate Touch Communication System	Medical Device	Product Defect Correction	Class II	Hospital
4/01/2024	HLS Set	Medical Device	Product Defect Correction	Class II	Hospital
4/01/2024	Icotec Torque Wrench	Medical Device	Recall	Class II	Hospital
3/01/2024	Cordis OPTeASE Retrievable Vena Cava Filter and OPTeASE Retrieval Catheter	Medical Device	Product Defect Correction	Class III	Hospital
3/01/2024	Fludeoxyglucose FDG	Medicine	Recall	Class III	Hospital
2/01/2024	BD BBL Sensi-Disc. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
2/01/2024	Dxl 9000 Access Immunoassay Analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
22/12/2023	Philips Azurion Systems with software release R2.2.0, R2.2.1, R2.2.3, R2.2.5 and R2.2.6	Medical Device	Product Defect Correction	Class III	Hospital
21/12/2023	Alissa Interpret	Medical Device	Product Defect Correction	Class II	Hospital
21/12/2023	Fresh Frozen Plasma		Recall	Class II	Hospital
21/12/2023	Stericlin Flat Roll 150mmx200m - 800304	Medical Device	Recall	Class I	Hospital
20/12/2023	bkActiv 2300 Ultrasound Systems 2300-56 and 2300-66	Medical Device	Product Defect Correction	Class II	Hospital
20/12/2023	DCA-70 / DCI-70 Drying Cabinets	Medical Device	Product Defect Correction	Class III	Hospital
20/12/2023	Liu Wei Di Huang Wan (Rehmannia Six Formula) BP015	Medicine	Recall	Class II	Consumer
20/12/2023	SECUFILL patient lines X50	Medical Device	Recall	Class II	Hospital
20/12/2023	Sof silk Braided Silk Suture and Ti-Cron Coated Braided Polyester Sutures.	Medical Device	Recall	Class II	Hospital
20/12/2023	Swisse Ultiboost Relax & Sleep	Medicine	Recall	Class III	Wholesale
19/12/2023	iQ200 Series Analysers and DxU 850m and 840m Iris Analysers. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
19/12/2023	MANUJET III With Jet Vent Cath	Medical Device	Recall	Class II	Hospital
19/12/2023	OXALIPLATIN 130MG & 125MG IN 5% GLUCOSE IN POLYOLEFIN BAG (FREEFLEX) FOR INTRAVENOUS INFUSION	Medicine	Recall	Class II	Hospital

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19/12/2023	Panther Fusion SARS-CoV-2/Flu A/B/RSV Assay. An in vitro diagnostic medical device	Medical Device	Product Defect Correction	Class III	Hospital
19/12/2023	XVIVO Disposable Lung Circuit	Medical Device	Product Defect Correction	Class II	Hospital
18/12/2023	BD/CME BodyGuard Infusion Pumps	Medical Device	Product Defect Correction	Class II	Hospital
18/12/2023	Bondi Sands Mineral Zinc Sunscreen SPF50+ Lotion 60ml & 120ml	Medicine	Recall	Class II	Consumer
18/12/2023	Irradiated Femoral Head (L)	Biological	Hazard Alert	Class II	Hospital
18/12/2023	Space Saver Shower Stool	Medical Device	Recall	Class II	Consumer
16/12/2023	Normothermic cornea (R)	Biological	Hazard Alert	Class II	Hospital
15/12/2023	Flow Family Anaesthesia systems	Medical Device	Product Defect Correction	Class II	Hospital
15/12/2023	LOGIWASH Sodium Chloride for Irrigation 0.9%	Medical Device	Recall	Class I	Consumer
15/12/2023	Single Use Distal Cover MAJ-2315	Medical Device	Product Defect Alert	Class I	Hospital
15/12/2023	Sterile Water Syringe supplied with Atrium Express Dry Suction Dry Seal Chest Drain	Medical Device	Recall	Class II	Hospital
14/12/2023	Alinity i HBsAg Reagent Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
14/12/2023	ImmunoCAP Rare Allergen k220, Allergen component rHev b 6.02 Latex. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
14/12/2023	Low RNA Reagent Cassette; 40331. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
14/12/2023	MEGADYNE MEGA SOFT Universal and Universal Plus Reusable Patient Return Electrodes	Medical Device	Product Defect Correction	Class I	Hospital
14/12/2023	Sculptral Poly L Lactic Acid Vials 150mg Powder for Injection	Medical Device	Product Defect Correction	Class III	Retail
14/12/2023	SynchroMed II	Medical Device	Product Defect Correction	Class II	Hospital
13/12/2023	NeoBaseTM 2 Non-derivatized MSMS kit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
13/12/2023	ProclaimXR, ProclaimPlus, ProclaimDRG, and Infinity IPGs	Medical Device	Product Defect Correction	Class II	Hospital
13/12/2023	Q-Stress and X-Scribe Cardiac Stress Testing Systems	Medical Device	Product Defect Correction	Class I	Hospital

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11/12/2023	AEROWASH Eyewash and Wound Irrigation (15 mL & 30 mL). Supplied both individually and as part of some Aero branded and custom made first aid kits.	Medical Device	Recall	Class I	Consumer
11/12/2023	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
11/12/2023	Monolisa HCV Ag/Ab ULTRA V2?. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
11/12/2023	Paparella-Type Vent Tube - 240044	Medical Device	Recall	Class III	Hospital
7/12/2023	The Prenatal, 60s	Medicine	Recall	Class III	Consumer
7/12/2023	Tuohy-Borst Adapter	Medical Device	Recall	Class II	Hospital
6/12/2023	SOLTIVE Laser System	Medical Device	Product Defect Correction	Class II	Hospital
5/12/2023	Impella Introducer Kits	Medical Device	Recall	Class I	Hospital
5/12/2023	Sterile Percutaneous Reference Pin	Medical Device	Recall	Class II	Hospital
4/12/2023	INGENIO, VITALIO, and ADVANTIO dual chamber (DR) extended life (EL) pacemakers and INLIVEN, and INVIVE cardiac resynchronization therapy pacemakers (CRT-Ps)	Medical Device	Hazard Alert	Class I	Hospital
4/12/2023	ProbioSpore	Medicine	Recall	Class II	Retail
1/12/2023	COPPER (Cu). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
1/12/2023	Ocular tissue - Sclera, Cornea	Biological	Hazard Alert	Class III	Hospital
1/12/2023	PIC iX Version 4.X and CareEvent Version C.03.X	Medical Device	Product Defect Correction	Class I	Hospital
1/12/2023	T3030 - LEGENCY REMEDIES SODIUM CHLORIDE 0.9% IRRIGATION (AMPOULES) / 30ML / BOX OF 30	Medical Device	Recall	Class I	Consumer
1/12/2023	Zoom Programming System	Medical Device	Product Defect Correction	Class II	Hospital
30/11/2023	E-Scribe	Medical Device	Product Defect Alert	Class II	Hospital
30/11/2023	Sodium Chloride 0.9% 30ml plastic ampoules	Medical Device	Recall	Class I	Consumer
29/11/2023	Fluoroethyl-L-Tyrosine [18F] (FET)	Medicine	Product Defect Correction	Class III	Hospital
29/11/2023	Luminos Fusion	Medical Device	Product Defect Correction	Class II	Hospital
29/11/2023	MINC+ Benchtop Incubator	Medical Device	Product Defect Correction	Class II	Hospital

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28/11/2023	Dispenser DP30 - Bedside infusion pump, single-channel	Medical Device	Product Defect Correction	Class II	Hospital
28/11/2023	PI-2620 (2-(2-([18F] fluoro) pyridin-4-yl)-9H-pyrrolo[2,3-b:4,5-c'] dipyridine)	Medicine	Product Defect Correction	Class II	Hospital
28/11/2023	PROM and Partus products. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
27/11/2023	Comfort Marker 2.0 Safety Needle used with the Medical Precision Comfort Marker 2.0 Patient Marking System	Medical Device	Product Defect Correction	Class III	Hospital
27/11/2023	da Vinci X/Xi SureForm 45	Medical Device	Product Defect Alert	Class II	Hospital
27/11/2023	Defiguard Touch-7	Medical Device	Product Defect Correction	Class I	Hospital
24/11/2023	Atlantis Abutment in Ti - Straumann Bone Level 3.3 NC	Medical Device	Recall	Class III	Retail
24/11/2023	Low Profile Primary Guide	Medical Device	Recall	Class II	Hospital
24/11/2023	Philips Allura and Azurion systems	Medical Device	Product Defect Correction	Class II	Hospital
23/11/2023	Intravenous Cannula Insertion Pack	Medical Device	Recall	Class II	Hospital
23/11/2023	ZACTIN TABS fluoxetine 20 mg (as hydrochloride) dispersible tablet	Medicine	Recall	Class II	Wholesale
22/11/2023	Achieva 1.5T MRI System	Medical Device	Product Defect Correction	Class I	Hospital
22/11/2023	BIOFIRE TORCH Base Systems. An invitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
22/11/2023	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Product Defect Alert	Class I	Hospital
22/11/2023	Valleylab FT10 FT Series Energy Platform	Medical Device	Product Defect Correction	Class II	Hospital
21/11/2023	Ambu aView 2 Advance	Medical Device	Product Defect Correction	Class II	Hospital
21/11/2023	RX Daytona Plus (with ISE & without ISE). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
20/11/2023	BD BACTEC Micro MGIT Calibration Vial.	Medical Device	Recall	Class II	Hospital
20/11/2023	ResMed Masks with Magnets	Medical Device	Product Defect Correction	Class II	Consumer
20/11/2023	UTAK Validity Control 2 and 3	Medical Device	Product Defect Correction	Class III	Hospital
17/11/2023	Calibration Serum Level 3 and Human Assayed Multi-Sera Level 2 and Level 3. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital

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17/11/2023	METRAN JPAP Travel CPAP Machines	Medical Device	Recall	Class II	Retail
16/11/2023	Balanced 25:25 Oral Liquid 30ml	Medicine	Product Defect Correction	Class III	Retail
15/11/2023	CARDIOHELP System	Medical Device	Product Defect Correction	Class I	Hospital
15/11/2023	DreamStation Auto CPAP - Care Orchestrator	Medical Device	Product Defect Correction	Class II	Hospital
15/11/2023	Kangaroo Enteral Feeding Pump Sets	Medical Device	Product Defect Correction	Class II	Hospital
14/11/2023	Bard Mission Disposable Core Biopsy Instrument and Kit	Medical Device	Recall	Class II	Hospital
14/11/2023	C2 Airwave Oscillometry System	Medical Device	Product Defect Correction	Class III	Hospital
13/11/2023	BIOFIRE BCID2 Panel. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
13/11/2023	CamAPS FX and mylife CamAPS	Medical Device	Product Defect Correction	Class II	Consumer
13/11/2023	HeartStart Intrepid Monitor/Defibrillator	Medical Device	Product Defect Correction	Class II	Hospital
13/11/2023	ID NOW Instrument. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Retail
13/11/2023	IPS CaseDesigner Software	Medical Device	Product Defect Correction	Class II	Retail
13/11/2023	RAPIDPoint 500 and 500e Systems Measurement Cartridges (with lactate). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
10/11/2023	epoc NXS Host. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
10/11/2023	Serology ToRCH IgM Positive Control. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
9/11/2023	ARTIS icono biplane, ARTIS icono floor and Artis pheno with Large Display	Medical Device	Product Defect Correction	Class II	Hospital
8/11/2023	BioCeuticals Zinc Drops	Medicine	Recall	Class II	Consumer
8/11/2023	LISINOPRIL SANDOZ lisinopril dihydrate 20mg tablet blister pack	Medicine	Recall	Class II	Retail
7/11/2023	ACROBAT-i Vacuum Positioner System	Medical Device	Recall	Class II	Hospital
7/11/2023	Merit Maestro Microcatheter	Medical Device	Recall	Class II	Hospital
7/11/2023	oneFIT TOTAL KNEE PSI	Medical Device	Recall	Class II	Hospital
6/11/2023	EZDilate Fixed Wire Balloon	Medical Device	Recall	Class I	Hospital

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6/11/2023	NIM TRIVANTAGE EMG Endotracheal tube	Medical Device	Recall	Class I	Hospital
6/11/2023	The CARDIOHELP-i System	Medical Device	Product Defect Correction	Class III	Hospital
3/11/2023	ENDOEYE HD II	Medical Device	Product Defect Alert	Class II	Hospital
3/11/2023	Quantum TTC Biliary Balloon Dilators	Medical Device	Recall	Class I	Hospital
2/11/2023	Cytocell 20pter Subtelomere Specific Probe. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
1/11/2023	HeartWare Ventricular Assist Device (HVAD) System	Medical Device	Product Defect Correction	Class II	Hospital
30/10/2023	ASSY,USM,IS4000, da Vinci Xi Surgical System and da Vinci X Surgical System	Medical Device	Product Defect Correction	Class II	Hospital
30/10/2023	The Insides Driver (a component of The Insides System PS006 and The Insides System Patient Education Model (Part number: MK-1R001))	Medical Device	Recall	Class II	Hospital
27/10/2023	LINQ II Insertable Cardiac Monitoring Systems (LNQ22)	Medical Device	Hazard Alert	Class II	Hospital
26/10/2023	The CereLink ICP Extension Cable	Medical Device	Recall	Class II	Hospital
25/10/2023	DASATINIB DR. REDDY'S dasatinib 70 mg film coated tablet blister pack	Medicine	Recall	Class II	Consumer
25/10/2023	Irradiated Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
25/10/2023	Neuromedex/Dispomedica Medistrip Vein Stripper	Medical Device	Recall	Class II	Hospital
25/10/2023	Versicon irrigation pump	Medical Device	Product Defect Correction	Class III	Hospital
24/10/2023	ARTIS icono ceiling	Medical Device	Product Defect Correction	Class II	Hospital
24/10/2023	Bondi Sands Everyday Protection Face SPF 50+ Sunscreen Mist	Medicine	Product Defect Correction	Class II	Consumer
23/10/2023	B Braun 0.9% Sodium Chloride Intravenous Infusion BP 100mL Bottle	Medicine	Product Defect Alert	Class III	Hospital
23/10/2023	Integra Cranial Access Kit (without Prep Solutions) Bit and Guard	Medical Device	Recall	Class II	Hospital
20/10/2023	PowerPICC 5Fr SL IR 135cm, PowerPICC 6Fr TL IR 135cm, PowerPICC SV 4F DL Sherlock, PowerPICC SOLO 5Fr DL IR 70cm and Groshong PICC 4F SL Bas	Medical Device	Product Defect Correction	Class II	Hospital

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19/10/2023	BIPAP A40 Pro, BIPAP A40 EFL and the System One Humidifier	Medical Device	Product Defect Correction	Class II	Consumer
19/10/2023	Elekta Medical Linear Accelerator – Accelerator system linear	Medical Device	Product Defect Correction	Class II	Hospital
19/10/2023	Nova Biomedical Stat Profile Prime Plus Analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class I	Hospital
19/10/2023	Sterile Light Handle Cover	Medical Device	Recall	Class II	Hospital
19/10/2023	Thermo Scientific Gram Negative IVD AST Sensititre Plate. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
18/10/2023	Multiple BD Alaris Extension Sets	Medical Device	Product Defect Correction	Class II	Hospital
18/10/2023	VariSoft Infusion Sets	Medical Device	Recall	Class I	Consumer
17/10/2023	Mazor X robotic guidance system	Medical Device	Product Defect Correction	Class II	Hospital
16/10/2023	Philips Ingenia Elition S and MR 7700 Systems with SW version R5.9	Medical Device	Product Defect Correction	Class III	Hospital
13/10/2023	Alinity s System - An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
13/10/2023	Cios Spin, Cios Alpha, Cios Flow with VA30	Medical Device	Product Defect Correction	Class II	Hospital
13/10/2023	EVO IQ Syringe Pump (EVO IQ SYR ANZ)	Medical Device	Product Defect Correction	Class I	Hospital
12/10/2023	2 unit doses of Tc99m Nanoscan	Medical Device	Product Defect Alert	Class II	Hospital
12/10/2023	Carestream DRX-Revolution Mobile X-ray System and Communication & Power Industries, Inc (CPI) generator	Medical Device	Product Defect Correction	Class II	Hospital
12/10/2023	DRX-Revolution Mobile X-ray System(s) Carestream Health Inc. generator	Medical Device	Product Defect Correction	Class II	Hospital
12/10/2023	Irradiated femoral head	Biological	Hazard Alert	Class II	Hospital
12/10/2023	Irradiated femoral head	Biological	Hazard Alert	Class II	Hospital
12/10/2023	TruWave Disposable Pressure Transducer	Medical Device	Product Defect Alert	Class III	Hospital
11/10/2023	Atellica DCA Analyser & Atellica DCA HbA1c Dx Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
11/10/2023	Deluxe Knee Walker	Medical Device	Recall	Class II	Consumer

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11/10/2023	MK014- VaccZyme Diphtheria Toxoid IgG Enzyme Immunoassay kit. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class III	Hospital
11/10/2023	NZ Emergency Chest Re-opening Pack and ANZ Emergency Chest Re-opening Pack	Medical Device	Recall	Class I	Hospital
11/10/2023	RAPIDPoint 500 Blood Gas System and RAPIDPoint 500e Blood Gas System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
11/10/2023	Sodium Chloride 0.9% Freeflex 100mL injection bag	Medicine	Recall	Class II	Hospital
11/10/2023	Teosyal Puresense Redensity I	Medical Device	Product Defect Alert	Class III	Retail
11/10/2023	TN300 Babyroo Radiant Warmer mattress tray	Medical Device	Product Defect Correction	Class II	Hospital
10/10/2023	CARDIOHELP Emergency Drive and CH Emergency Drive	Medical Device	Product Defect Correction	Class II	Hospital
10/10/2023	FETALtrol control	Medical Device	Product Defect Alert	Class III	Hospital
9/10/2023	ETHICAL NUTRIENTS MEGA MAGNESIUM RASPBERRY	Medicine	Recall	Class II	Consumer
6/10/2023	CardioMEMS HF System	Medical Device	Product Defect Correction	Class II	Hospital
6/10/2023	High Flow Insufflation Unit	Medical Device	Product Defect Correction	Class I	Hospital
6/10/2023	In2Flow Nasal cannula	Medical Device	Product Defect Alert	Class II	Hospital
6/10/2023	KETOROLAC-BAXTER ketorolac trometamol 30 mg/1 mL solution for injection ampoule	Medicine	Recall	Class I	Hospital
6/10/2023	MiSeqDx instrument and NextSeq 550Dx instrument. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
6/10/2023	StealthStation S8 and FlexENT	Medical Device	Product Defect Correction	Class II	Hospital
6/10/2023	Trushot 2.0 Hospital Cleaner & Disinfectant, Trushot 2.0 Multi-Hard Surface, Restroom Cleaner & Disinfectant	Medical Device	Product Defect Alert	Class II	Hospital
5/10/2023	Advanced Cement Mixer (ACM) System devices	Medical Device	Recall	Class II	Hospital
5/10/2023	EVIS X1 VIDEO SYSTEM CENTER OLYMPUS	Medical Device	Product Defect Correction	Class I	Hospital
5/10/2023	ID-DiaPanel Plus 6. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class III	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
4/10/2023	ARCHITECT and Alinity c Iron Reagent Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
3/10/2023	FiberLink 0, Blue	Medical Device	Product Defect Alert	Class III	Hospital
3/10/2023	StaySafe Peritoneal Dialysis Disinfection Cap to close patient's peritoneal catheter	Medical Device	Product Defect Alert	Class I	Hospital
29/09/2023	EMBLEM S-ICD and EMBLEM MRI S-ICD enrolled in LATITUDE	Medical Device	Product Defect Correction	Class II	Consumer
29/09/2023	HeartMate Apical Coring Knife	Medical Device	Product Defect Alert	Class II	Hospital
29/09/2023	Tempus Pro Monitor	Medical Device	Product Defect Correction	Class II	Hospital
28/09/2023	EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS	Medical Device	Product Defect Correction	Class I	Hospital
28/09/2023	Kangaroo Connect Enteral Feeding Set, 1000 mL bag, Feed Only, Non-Sterile	Medical Device	Product Defect Correction	Class II	Hospital
27/09/2023	EXALT Model D Single-Use Duodenoscope	Medical Device	Recall	Class II	Hospital
27/09/2023	INOMED C3 CRYOPROBE 2, 1mm SHARP	Medical Device	Recall	Class II	Hospital
26/09/2023	Pilling LOWSLEY PROSTATIC TRACTOR CVD and STR	Medical Device	Product Defect Correction	Class I	Hospital
25/09/2023	Glucose-6-Phosphate Dehydrogenase (G-6-PDH). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
25/09/2023	Impella 5.5 with SmartAssist heart pumps	Medical Device	Product Defect Correction	Class I	Hospital
25/09/2023	MIDAZOLAM 50mg/ 10mL solution for injection	Medicine	Product Defect Correction	Class I	Retail
24/09/2023	Ad-Tech Epidural Spinal Electrodes	Medical Device	Recall	Class II	Hospital
23/09/2023	AMCAL URICALM EFFERVESCENT granules oral powder sachet	Medicine	Recall	Class III	Retail
22/09/2023	The Atrium Ocean, Oasis and Express chest drains: Drain, Oasis Single, Drain, Oasis Paediatric, Drain, Express, Single, Drain, Ocean Single and Drain, Ocean, Paediatric	Medical Device	Product Defect Correction	Class II	Hospital
20/09/2023	Access hsTnI Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
20/09/2023	Hybrid Guidewire (HYBRID12D300)	Medical Device	Product Defect Alert	Class III	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
19/09/2023	18F-Fludeoxyglucose (FDG)	Medicine	Product Defect Correction	Class II	Hospital
19/09/2023	Triathlon Fixation Peg 2 Per Pack	Medical Device	Recall	Class III	Hospital
19/09/2023	Whole Lamellar	Biological	Hazard Alert	Class II	Hospital
18/09/2023	Juno 200 Ventilators	Medical Device	Recall	Class II	Hospital
18/09/2023	Luminos Agile Max, Axiom Luminos dRF, Luminos dRF Max, Ysio, Ysio Max, Ysio X.pree with BABIX holder on the Bucky wall stand	Medical Device	Product Defect Correction	Class II	Hospital
15/09/2023	da Vinci Xi/X Instrument Arm Drapes	Medical Device	Product Defect Correction	Class II	Hospital
15/09/2023	PROVEO 8, M530 OHX and PROvido surgical operating microscopes	Medical Device	Product Defect Correction	Class II	Hospital
14/09/2023	DNCG iso (cromoglicic acid disodium salt) 20 mg/2 mL Solution (Pack of 50 x 2 mL)	Medicine	Recall	Class II	Hospital
13/09/2023	Eligard leuporelin acetate 7.5 mg modified release injection syringe	Medicine	Recall	Class II	Retail
13/09/2023	Lyphochek Hemoglobin A2 Control. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
13/09/2023	RX series analysers. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
12/09/2023	Astral 100 and Astral 150 ventilators	Medical Device	Product Defect Correction	Class II	Consumer
12/09/2023	CARDIOHELP-i	Medical Device	Product Defect Correction	Class I	Hospital
12/09/2023	Technopath Multichem IA Plus, Multichem IA Plus, Multichem S Plus Level 1, Multichem S Plus Level 2, Multichem S Plus Level 3 and Multichem P. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Alert	Class II	Hospital
12/09/2023	Zimmer Dermatome Blades	Medical Device	Recall	Class II	Hospital
11/09/2023	Accu-Chek Solo Cann&P-hold 6mm 10+3, Accu-Chek Solo Cann&P-hold 9mm 10+3, Accu-Chek Solo insertion device ROW, Accu-Chek Solo reservoir Po8, Accu-Chek Solo system G mol AU/en and Accu-Chek Solo system A mol AU/en	Medical Device	Product Defect Correction	Class II	Consumer
11/09/2023	Allergenic Extract – Pecan Nut (Food)	Medical Device	Recall	Class I	Retail
11/09/2023	F-18 Fludeoxyglucose	Medicine	Recall	Class III	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
11/09/2023	Microscalpel Plastic Handle, Incision Knife	Medical Device	Recall	Class II	Hospital
8/09/2023	AU/DxC AU Chemistry Transferrin. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
8/09/2023	Thermo Clone VPS Fast Set, Heavy Body 50mL 2pk Kit	Medical Device	Recall	Class III	Retail
8/09/2023	Venue Go Standard Carts	Medical Device	Product Defect Correction	Class II	Hospital
7/09/2023	CellAED	Medical Device	Recall	Class I	Consumer
7/09/2023	CryoMini	Medical Device	Product Defect Correction	Class II	Retail
7/09/2023	Dispenser DP 30 Pump	Medical Device	Product Defect Correction	Class II	Hospital
7/09/2023	EnSite X EP System with software version 3.0	Medical Device	Product Defect Correction	Class III	Hospital
7/09/2023	Euky Bear Warm Steam Vaporiser - Humidifier	Medical Device	Recall	Class II	Consumer
7/09/2023	VENTANA anti-ALK (D5F3) Rabbit Monoclonal Primary Antibody. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
6/09/2023	F2-01 Frame and CARESCAPE ONE and CARESCAPE Canvas 1000 patient monitors	Medical Device	Product Defect Correction	Class II	Hospital
6/09/2023	Motec Wrist ArthrodesisSystem –Metacarpal Taper	Medical Device	Hazard Alert	Class II	Hospital
6/09/2023	Motec Wrist ArthrodesisSystem –Metacarpal Taper	Medical Device	Hazard Alert	Class II	Hospital
5/09/2023	MD Eleva systems	Medical Device	Product Defect Correction	Class II	Hospital
5/09/2023	Over-ear headphones	Medical Device	Product Defect Correction	Class II	Hospital
4/09/2023	3M Attest Super Rapid 5 Steam-Plus Challenge Pack	Medical Device	Recall	Class III	Hospital
4/09/2023	Allura Xper, Allura Centron, and Azurion systems	Medical Device	Product Defect Correction	Class II	Hospital
4/09/2023	VITROS Chemistry Products ALKP Slides and VITROS XT Chemistry Products TBIL-ALKP Slides. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
1/09/2023	HeartWare Ventricular Assist Device (HVAD) System	Medical Device	Product Defect Correction	Class I	Hospital
1/09/2023	Philips Essenta DR Compact	Medical Device	Product Defect Correction	Class II	Hospital
31/08/2023	GMK Efficiency - Sphere CR Insert Instrument Set Size 1	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
31/08/2023	RevoLock Align Kit and Threaded Inserts	Medical Device	Recall	Class II	Consumer
30/08/2023	Scandinavian Total Ankle Replacement (STAR Ankle)	Medical Device	Hazard Alert	Class II	Consumer
30/08/2023	SV600/800 Mindray Ventilator	Medical Device	Product Defect Correction	Class I	Hospital
29/08/2023	Allura Xper, Allura Centron, Azurion and MultiDiagnost-Eleva systems	Medical Device	Product Defect Correction	Class II	Hospital
29/08/2023	Fludeoxyglucose	Medicine	Recall	Class II	Hospital
29/08/2023	ON-Q Pain Relief System QUIKBLOC Over-the-Needle Catheter Set (Original, Stimulating and NRFit Connector)	Medical Device	Recall	Class III	Hospital
28/08/2023	Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pumps	Medical Device	Product Defect Correction	Class I	Hospital
28/08/2023	MEERA Operating Tables	Medical Device	Product Defect Correction	Class II	Hospital
28/08/2023	Tc99m Mag 3 and Tc99m Cardiolite	Medicine	Recall	Class II	Hospital
25/08/2023	Attune Cementless CR Femur	Medical Device	Hazard Alert	Class II	Hospital
25/08/2023	Minisart HY SRP Syringe	Medical Device	Product Defect Correction	Class II	Hospital
25/08/2023	Sophysa SM1	Medical Device	Recall	Class III	Hospital
24/08/2023	Aquilex Fluid Control System Pump	Medical Device	Product Defect Correction	Class II	Hospital
24/08/2023	EXCOR Cannulae	Medical Device	Hazard Alert	Class I	Hospital
24/08/2023	HeartWare Ventricular Assist Device (HVAD) System	Medical Device	Hazard Alert	Class I	Hospital
23/08/2023	K (Potassium) electrode	Medical Device	Recall	Class II	Hospital
22/08/2023	Centricity Enterprise Archive V2.X, V3.X, V4.X and Enterprise Archive Version 8	Medical Device	Product Defect Correction	Class II	Hospital
22/08/2023	The EasyScreen Respiratory Pathogen Detection Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Alert	Class II	Hospital
21/08/2023	Infusomat Space Infusion Pump	Medical Device	Recall	Class II	Hospital
21/08/2023	Invivoscribe LymphoTrack Dx IGH FR3 Assay Panel - MiSeq and Invivoscribe LymphoTrack Dx IGH FR1/2/3 Panel - MiSeq. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
21/08/2023	Ocular Sciera	Biological	Hazard Alert	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
21/08/2023	Space Plus Infusomat Infusion Pump	Medical Device	Recall	Class II	Hospital
21/08/2023	TC-I Reusable Tip Clip Sensors	Medical Device	Recall	Class II	Hospital
18/08/2023	Genex DS 2.5cc and GeneX DS 5cc	Medical Device	Product Defect Correction	Class II	Hospital
18/08/2023	Philips Incisive CT and CT 3500 systems	Medical Device	Product Defect Correction	Class II	Hospital
18/08/2023	Philips Spectral CT7500	Medical Device	Product Defect Correction	Class II	Hospital
18/08/2023	Radixact Treatment Delivery System	Medical Device	Product Defect Correction	Class II	Hospital
17/08/2023	ORTHO Sera Anti-Lea Murine Monoclonal IgM. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
17/08/2023	The Gallant, Entrant, and Neutrino NxT HV devices	Medical Device	Product Defect Correction	Class II	Hospital
17/08/2023	ZEISS OPMI LUMERA 300 - Suspension Arm	Medical Device	Product Defect Correction	Class II	Hospital
16/08/2023	18F-Fludeoxyglucose (FDG)	Medicine	Product Defect Correction	Class II	Hospital
16/08/2023	Arjo medical beds Enterprise 5000x, Enterprise 8000X, Enterprise 9000X, Citadel assembled with IndiGo module	Medical Device	Product Defect Correction	Class II	Consumer
16/08/2023	One-Way Valve, 22F x 22M	Medical Device	Recall	Class I	Hospital
15/08/2023	Bard Marquee Disposable Core Biopsy Instrument Kit	Medical Device	Recall	Class II	Hospital
15/08/2023	Technetium-99m NanoScan	Medicine	Recall	Class II	Hospital
14/08/2023	BD Alaris Gateway Workstation	Medical Device	Product Defect Correction	Class II	Hospital
14/08/2023	HeartSine Samaritan Public Access Defibrillator Pak (PAD-PAK)	Medical Device	Product Defect Correction	Class I	Consumer
14/08/2023	myLife CamAPS FX app for automated insulin delivery	Medical Device	Product Defect Correction	Class II	Consumer
14/08/2023	Pentacam AXL (Type 70100) and Pentacam AXL Wave (Type 70020)	Medical Device	Product Defect Correction	Class II	Hospital
11/08/2023	HemosIL Liquid Anti-Xa. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
11/08/2023	OCULUS Myopia Master	Medical Device	Product Defect Correction	Class II	Hospital
10/08/2023	aView 2 Advance	Medical Device	Product Defect Correction	Class II	Hospital
10/08/2023	Thermo Scientific MAS Omni CORE Control. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital

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9/08/2023	BritePro Solo Evo Single-Use Fiber Optic Laryngoscope Handle	Medical Device	Product Defect Correction	Class I	Hospital
9/08/2023	FDR Visionary Suite	Medical Device	Product Defect Correction	Class II	Hospital
9/08/2023	Iron_2 reagent wedge pairs. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
8/08/2023	Medfusion Model 3500 and Model 4000 Syringe Infusion Pumps	Medical Device	Product Defect Correction	Class I	Hospital
7/08/2023	Anti-Fya. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
7/08/2023	FDG	Medicine	Recall	Class III	Hospital
7/08/2023	HAMILTON-C1/T1/MR1 Ventilators	Medical Device	Product Defect Correction	Class I	Hospital
7/08/2023	LymphoTrack Dx IGH FR3 Assay Panel – MiSeq. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
7/08/2023	McGRATH MAC 2 Disposable Laryngoscope Blade	Medical Device	Recall	Class I	Hospital
4/08/2023	INJEKT 10 ML and INJEKT 10 ML LL	Medical Device	Recall	Class II	Hospital
4/08/2023	Medima infusion Sets used with Large Volume Infusion Pumps	Medical Device	Product Defect Correction	Class II	Hospital
3/08/2023	HeartStart Intrepid Monitor/Defibrillator	Medical Device	Product Defect Correction	Class I	Hospital
3/08/2023	Technetium-99m Nanoscan	Medicine	Recall	Class II	Hospital
2/08/2023	PDS II (polydioxanone) Suture and PDS Plus Antibacterial (polydioxanone) Suture	Medical Device	Recall	Class II	Hospital
1/08/2023	EVO IQ Large Volumetric Pumps (LVP)	Medical Device	Product Defect Correction	Class II	Hospital
1/08/2023	McKesson/Change Healthcare Cardiology Hemo with the Nurse Charting Solution	Medical Device	Product Defect Correction	Class III	Hospital
1/08/2023	SODIUM CHLORIDE INTRAVENOUS INFUSION BP 0.9% 100/50 mL	Medicine	Recall	Class I	Hospital
28/07/2023	Change Healthcare Cardiology, Change Healthcare Cardiology Hemo and Change Healthcare Cardiology ECG Management	Medical Device	Product Defect Correction	Class III	Hospital
27/07/2023	Diacan Flex 14G 2,2x25mm	Medical Device	Recall	Class II	Hospital
27/07/2023	Urinary/Cerebrospinal Fluid Protein. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital

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25/07/2023	Exactech Ultra-High Molecular Weight Polyethylene (UHMWPE) Liners (Optetrak/Optetrak Logic Knee & Vantage Ankle)	Medical Device	Hazard Alert	Class II	Hospital
25/07/2023	IView GT - Linear Accelerator	Medical Device	Product Defect Correction	Class III	Hospital
25/07/2023	Philips Spectral CT7500	Medical Device	Product Defect Correction	Class II	Hospital
24/07/2023	Alinity m Sample Prep Kit 1. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
24/07/2023	Irradiated Femoral Head (R)	Biological	Hazard Alert	Class II	Hospital
24/07/2023	Restoris MCK Tibial Baseplate Trial STD RM/LL Sizes 5 and 6	Medical Device	Recall	Class II	Hospital
24/07/2023	Restoris RIO Straight Cup Reamer Handle	Medical Device	Recall	Class III	Hospital
21/07/2023	DexaHEXAL 4 mg / ml Injection Solution	Medicine	Recall	Class II	Hospital
21/07/2023	Immunoglobulin A (IgA). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
21/07/2023	MetaVision version 6.x	Medical Device	Product Defect Correction	Class II	Hospital
21/07/2023	Sirdalud (Tizanidin) MR 6 mg capsules	Medicine	Recall	Class II	Retail
21/07/2023	Specific Protein Calibrator. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
20/07/2023	3D9-3v Transducer (Accessory to Philips Ultrasound Systems : EPIQ Elite, Affiniti 30, 50, and 70, ClearVue 850, HD15, iU22, Compact 5000)	Medical Device	Product Defect Correction	Class II	Hospital
20/07/2023	ACUSON Redwood 2.0 ultrasound systems - 18L6 transducer	Medical Device	Product Defect Correction	Class II	Hospital
20/07/2023	Disposable EMR Kit and Distal Attachment	Medical Device	Recall	Class II	Hospital
20/07/2023	Immunoassay Speciality I Level 1. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
20/07/2023	MAS Omni-Infectious BSI Positive Control Panel. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
20/07/2023	Surgical face Mask - Earloop Level 3 Barrier	Medical Device	Product Defect Alert	Class II	Hospital
19/07/2023	Bilirubin Total (DCA). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital

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19/07/2023	Liquichek Pediatric Control. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
18/07/2023	Sternal Retractor contained within ANZ Emergency Chest Re-Opening Packs	Medical Device	Recall	Class I	Hospital
17/07/2023	Australia Top 1 Health Management Pty Ltd - ARTG: 338200	Medical Device	Product Defect Alert	Class II	Hospital
17/07/2023	CKT Group Australia Pty Ltd - Mask, surgical, single use	Medical Device	Product Defect Alert	Class II	Retail
17/07/2023	Hasky Aus Distributors Pty Ltd - Airway protection face mask	Medical Device	Product Defect Alert	Class II	Retail
17/07/2023	Lead Extraction Lead Clippers	Medical Device	Recall	Class I	Hospital
17/07/2023	Medispec Australia Pty Ltd - ARTG: 335721	Medical Device	Product Defect Alert	Class II	Hospital
14/07/2023	SABRIL 500mg tablet blister pack 100 tablet pack	Medicine	Recall	Class I	Retail
14/07/2023	SOZO Bilateral Arm L-Dex Software	Medical Device	Product Defect Correction	Class II	Retail
14/07/2023	Symbia Pro.specta	Medical Device	Product Defect Correction	Class II	Hospital
12/07/2023	Access Thyroglobulin Calibrator. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
12/07/2023	DANA-i Insulin Pump	Medical Device	Recall	Class II	Consumer
12/07/2023	FIVE S 5.3 x 65, sterile, for single use (Pc.) and FIVE S 5.3 x 65, sterile, for single use (Pack.)	Medical Device	Recall	Class II	Hospital
12/07/2023	Incubator - Babyleo TN500 IncuWarmer	Medical Device	Product Defect Correction	Class II	Hospital
12/07/2023	Swan-Ganz Double Lumen Monitoring Catheter	Medical Device	Product Defect Correction	Class II	Hospital
11/07/2023	18F – Fluorodeoxyglucose Injection	Medicine	Product Defect Correction	Class III	Hospital
10/07/2023	Air/Water Valve MAJ-1444	Medical Device	Product Defect Correction	Class I	Hospital
10/07/2023	Skeletal Dynamics Protean Radial Head Plate (Left and Right designs)	Medical Device	Product Defect Correction	Class III	Hospital
7/07/2023	18F – Fluorodeoxyglucose Injection	Medicine	Product Defect Correction	Class III	Hospital
7/07/2023	ACL TOP SW 6.4.0. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
7/07/2023	Bronchoscopes, tracheal intubation scopes and airway moileoscopes	Medical Device	Product Defect Correction	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
7/07/2023	CADD Infusion System Disposables (also known as Veletri Consumables kit)	Medical Device	Product Defect Alert	Class I	Hospital
7/07/2023	Fusion Lithotripsy Extraction Baskets	Medical Device	Recall	Class I	Hospital
7/07/2023	MINOP trocar, outer diameter 6 mm	Medical Device	Recall	Class III	Hospital
7/07/2023	MRI system Vantage Titan 3T MRT-3010	Medical Device	Product Defect Correction	Class II	Hospital
7/07/2023	Musculoskeletal tissue: Bone, Morsellised, Irradiated, Frozen-L, Bone, Segmented, Irradiated, Frozen-L, Tendon (non-irradiated)	Biological	Hazard Alert	Class II	Hospital
7/07/2023	O&M Halyard Surgical and Procedural Facemasks	Medical Device	Product Defect Alert	Class II	Hospital
6/07/2023	Access Folate and Access TSH Reagent Packs when used on Dxl 9000 Access Immunoassay Analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
6/07/2023	Carina Ventilator, Adult	Medical Device	Product Defect Correction	Class II	Hospital
6/07/2023	IntelliVue MX40 Patient Monitor	Medical Device	Product Defect Correction	Class I	Hospital
6/07/2023	Multiple Smiths Medical Devices	Medical Device	Recall	Class II	Hospital
6/07/2023	Plum 360 Infusion System	Medical Device	Product Defect Correction	Class I	Hospital
5/07/2023	500 XLE treatment chairs	Medical Device	Product Defect Correction	Class II	Retail
5/07/2023	Alcon Phaco Tips and packs or kits containing	Medical Device	Product Defect Correction	Class II	Hospital
5/07/2023	APO Frusemide 40mg	Medicine	Product Defect Correction	Class III	Retail
5/07/2023	Rotaflow II Drive	Medical Device	Product Defect Correction	Class I	Hospital
4/07/2023	Britepro Solo Single-Use Fiber Optic Laryngoscope Handle	Medical Device	Recall	Class I	Hospital
4/07/2023	CADD Infusion System Disposables	Medical Device	Recall	Class I	Hospital
4/07/2023	ID-DiaPanel and ID-Panel P. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
4/07/2023	Natural Instinct Kids SPF50+ Clean Sunscreen	Medicine	Recall	Class II	Consumer
3/07/2023	Allura Xper and Azurion systems	Medical Device	Product Defect Correction	Class II	Hospital
30/06/2023	EVOLUTIS Reusable Instruments	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
30/06/2023	Full Vision Treadmill and QStress System (with Treadmill)	Medical Device	Product Defect Correction	Class II	Hospital
30/06/2023	Hamilton C1, T1, MR1 Ventilators	Medical Device	Product Defect Correction	Class II	Hospital
30/06/2023	HAMILTON-C1/T1/C3 Ventilators with Neonatal Option	Medical Device	Product Defect Alert	Class II	Hospital
30/06/2023	Oxford Advance Patient Hoist	Medical Device	Product Defect Correction	Class II	Consumer
30/06/2023	TruSignal SpO2 Sensors	Medical Device	Product Defect Correction	Class II	Hospital
29/06/2023	Cholesterol, Direct HDL-Cholesterol, Direct Bilirubin and Liquid CO2-2. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
29/06/2023	INTESTINAL VIDEOSCOPE OLYMPUS PSF-1, SINGLE USE POWERSPIRAL TUBE DPST-1 and POWERSPIRAL CONTROL UNIT PCSU	Medical Device	Recall	Class I	Hospital
29/06/2023	Sterile compounded infusion bags containing carboplatin or carmustine diluted in 5% glucose	Medicine	Recall	Class II	Hospital
29/06/2023	Treatment chairs 500 XLE	Medical Device	Product Defect Correction	Class II	Hospital
28/06/2023	Macroplastique	Medical Device	Hazard Alert	Class II	Hospital
28/06/2023	MEGADYNE Suction Coagulators Handswitching, 10Fr, 8Fr and 12Fr (6 inch).	Medical Device	Recall	Class II	Hospital
28/06/2023	Philips Spectral CT 7500	Medical Device	Product Defect Correction	Class III	Hospital
28/06/2023	Stephan Applicator EasyFlow nCPAP with magnet and sealing cap for pressure measuring connection	Medical Device	Product Defect Correction	Class II	Hospital
23/06/2023	Abtectcell III 0.8% Reagent Red Blood Cells. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class I	Hospital
22/06/2023	ARTIS pheno, ARTIS icono biplane, ARTIS icono floor	Medical Device	Product Defect Correction	Class II	Hospital
22/06/2023	Fluphenazine deconate (Neuraxpharm) 25mg/1mL soln for IM inj amp (1mLx5)	Medicine	Recall	Class I	Retail
22/06/2023	OEC Flexiview 8800 systems, OEC 9800 systems, OEC 9900 systems and OEC Elite systems all with 9-inch Image Intensifier.	Medical Device	Product Defect Correction	Class II	Hospital
22/06/2023	ultraView Universal AP Red Detection Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
22/06/2023	Vivid S60 / Vivid S70 / Vivid S60N / Vivid S70N Ultrasound Systems	Medical Device	Product Defect Correction	Class II	Hospital
21/06/2023	46923 Haematological concentrate system kits, platelet concentration: A-CP-Kit-3, RegenACR-C Plus, RegenACR-C Extra, RegenKit-BCT-1, RegenKit-BCT-2 Plus, RegenKit-BCT-3 and RegenKit-BCT-T	Medical Device	Recall	Class II	Hospital
21/06/2023	Disposable Yankauer Sucker - rose tip, non-vented, double wrapped	Medical Device	Product Defect Correction	Class II	Hospital
21/06/2023	Phenocell C 3% and Phenocell C 0.8% An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
21/06/2023	Philips MR room cage installations	Medical Device	Product Defect Correction	Class II	Hospital
21/06/2023	TC-I Reusable Tip Clip Sensor	Medical Device	Recall	Class II	Hospital
21/06/2023	TheraSleeve	Medical Device	Product Defect Correction	Class II	Hospital
20/06/2023	Adjustable Gastric Band	Medical Device	Recall	Class I	Hospital
20/06/2023	Umbilical cord clamp remover	Medical Device	Product Defect Alert	Class III	Hospital
19/06/2023	Philips Big Bore RT, Brilliance CT Big Bore and Brilliance CT Big Bore Oncology (software version 4.8.0)	Medical Device	Product Defect Correction	Class II	Hospital
19/06/2023	Philips PageWriter TC30/50/70 Cardiographs	Medical Device	Product Defect Correction	Class III	Hospital
19/06/2023	Reliance Vision Multi-Chamber Washer	Medical Device	Product Defect Correction	Class II	Hospital
16/06/2023	BIONEKTOR OCTOPUS DBL LUMEN 2ARV	Medical Device	Recall	Class III	Hospital
16/06/2023	Bronchofiberscope and Bronchovideoscope	Medical Device	Product Defect Correction	Class I	Hospital
16/06/2023	Cytokine and Growth factors Array	Medical Device	Product Defect Correction	Class III	Hospital
16/06/2023	Exactech Ergo Impactor Handle	Medical Device	Recall	Class II	Hospital
16/06/2023	Single use, surgical, mask	Medical Device	Product Defect Alert	Class II	Hospital
15/06/2023	18F – Fluorodeoxyglucose Injection	Medicine	Product Defect Correction	Class III	Hospital
15/06/2023	da Vinci X/Xi Tip-Up Fenestrated Grasper (Version 12)	Medical Device	Recall	Class I	Hospital
14/06/2023	BD Synapsys. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
14/06/2023	FLUOROURACIL 3,675MG IN 0.9% SODIUM CHLORIDE IN SUREFUSER + (5ML/HR) FOR INTRAVENOUS INFUSION.	Medicine	Recall	Class III	Hospital
14/06/2023	Philips Spectral CT 7500	Medical Device	Product Defect Correction	Class II	Hospital
13/06/2023	Datascope Sensation Plus/MEGA IAB CATHETERS	Medical Device	Product Defect Correction	Class I	Hospital
13/06/2023	Durepair Dura Regeneration Matrix	Medical Device	Recall	Class I	Hospital
13/06/2023	DxA 5000 Automation System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
13/06/2023	Fludeoxyglucose (18F) Injection ([18F]FDG)	Medicine	Recall	Class II	Hospital
13/06/2023	The Alinity ci-series. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
9/06/2023	Endotracheal Tube Connector	Medical Device	Recall	Class I	Hospital
9/06/2023	NeuroLogica OmniTom Elite Computed Tomography systems	Medical Device	Product Defect Correction	Class II	Hospital
9/06/2023	Olympus HF-Resection Electrode	Medical Device	Product Defect Correction	Class I	Hospital
8/06/2023	Fludeoxyglucose (18F) Injection FDG - 10mL Vial	Medicine	Recall	Class II	Hospital
8/06/2023	Vanta Implantable Neurostimulator (INS)	Medical Device	Product Defect Correction	Class II	Consumer
7/06/2023	Azurion and Allura Xper series	Medical Device	Product Defect Correction	Class II	Hospital
7/06/2023	Cardiac Ultra-Low Control. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Alert	Class II	Hospital
7/06/2023	DreamStation GO (DSGO) sleep therapy device	Medical Device	Product Defect Correction	Class II	Consumer
7/06/2023	Giraffe OmniBeds and Giraffe OmniBed Carestation	Medical Device	Product Defect Correction	Class II	Hospital
7/06/2023	Technetium-99m & Technetium-99m labelled radiopharmaceuticals: Tc99m DTPA, Tc99m DTPA Pulmonary Ventilation, Tc99m Neurolite and Tc99m Mebrofenin	Medicine	Recall	Class II	Hospital
7/06/2023	Tiger Snake Antivenom 3000 Units Injection Vial	Medicine	Recall	Class II	Retail

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
5/06/2023	Accu-Chek Solo diabetes manager included in Accu-Chek Solo system kits and Accu-Chek Solo replacement kits: DM Guide Solo mol, DM Aviva Solo mol, Accu-Chek Solo System G mol AU/en, Accu-Chek Solo system A mol AU/en, Accu-Chek Guide Solo Repl mol and Accu-Chek Aviva Solo Repl mol	Medical Device	Product Defect Correction	Class II	Consumer
5/06/2023	Besmed Health Business Corp, Paediatric Size 2, Cushioned Disposable Face Mask, packaged with the LifeVac Airway Clearance Device	Medical Device	Recall	Class II	Consumer
5/06/2023	EBV R-GENE and BK Virus R-GENE. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Alert	Class II	Hospital
5/06/2023	Superset Fixed Elbow Catheter Mount 22F-22M/15F = 70mm-150mm	Medical Device	Recall	Class I	Hospital
5/06/2023	VERITAS Advanced Infusion and Fluidics Packs	Medical Device	Recall	Class II	Hospital
2/06/2023	4.0 Mm Cannulated Cancellous Screw, Full Thread, T15, 24mm	Medical Device	Recall	Class III	Hospital
2/06/2023	Afinion 2 and Alere Afinion 2. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Retail
2/06/2023	Anti-Adenovirus ELISA (IgM). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
2/06/2023	BD Alaris Pump Module Model 8100 – All devices	Medical Device	Product Defect Correction	Class I	Hospital
2/06/2023	Oxylog 3000 plus	Medical Device	Product Defect Correction	Class II	Hospital
2/06/2023	PocketECG PC Client software	Medical Device	Product Defect Correction	Class II	Hospital
2/06/2023	PushTracker E2 and E3 component utilised with the SmartDrive MX2+ Power Assist Device	Medical Device	Product Defect Correction	Class II	Consumer
1/06/2023	Calibration Serum Level 3, Human Precision Control Levels 2 & 3 and Human Assayed Multi-Sera Levels 2 & 3. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
1/06/2023	HeartWare Ventricular Assist Device (HVAD) System	Medical Device	Recall	Class I	Hospital
1/06/2023	Infinity Centralstation	Medical Device	Product Defect Correction	Class I	Hospital
1/06/2023	T2100-ST Treadmill	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
31/05/2023	Thermo Scientific MAS Omni CORE Controls. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Alert	Class III	Wholesale
30/05/2023	Betta Link SR Reusable Guide Pronged BSM, Betta Link SR Guide Fishmouth BSM, Betta Link Implant Kit Shoulder BSM, Betta Link LG Reusable Guide Pronged BSM, Betta Link LG Guide Fishmouth BSM and Betta Link Implant Kit Hip BSM	Medical Device	Recall	Class II	Hospital
30/05/2023	Corpuls3 Software	Medical Device	Product Defect Alert	Class II	Hospital
26/05/2023	Lorazepam Injection, USP 2 mg/ml	Medicine	Recall	Class II	Hospital
26/05/2023	MobileDiagnost wDR	Medical Device	Product Defect Correction	Class II	Hospital
26/05/2023	Philips IQon, iCT, Ingenuity and Brilliance CT 64 systems	Medical Device	Product Defect Correction	Class III	Hospital
26/05/2023	Tempus LS	Medical Device	Product Defect Correction	Class I	Retail
26/05/2023	Treadmill TMX428 110V, Treadmill TMX428 220V, Treadmill TMX428CP 110V and Treadmill TMX428CP 220V	Medical Device	Product Defect Correction	Class II	Hospital
25/05/2023	Tunneling Instrument 600MM	Medical Device	Recall	Class II	Hospital
24/05/2023	Allen Advance Chest Support with pad	Medical Device	Recall	Class II	Hospital
24/05/2023	EliA GBM Wells. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Alert	Class II	Hospital
24/05/2023	Fabian HFO, fabian +nCPAP evolution and fabian Therapy evolution	Medical Device	Product Defect Correction	Class II	Hospital
24/05/2023	Medifab Carrot III XL Car Seat	Medical Device	Product Defect Correction	Class II	Consumer
24/05/2023	VITROS XT 7600 Integrated System and VITROS 5600 Integrated System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
22/05/2023	BioComposite Labral SwiveLock 3.5 mm X 15.8mm	Medical Device	Hazard Alert	Class III	Hospital
22/05/2023	Philips Incisive CT System	Medical Device	Product Defect Correction	Class II	Hospital
19/05/2023	Shengquan FFP2 Particle Filtering Half Mask	Medical Device	Product Defect Alert	Class II	Retail
19/05/2023	StealthStation S7 Cranial Software v3.1.4	Medical Device	Product Defect Correction	Class I	Hospital
18/05/2023	Aptio Automation Storage and Retrieval Module (SRM). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
18/05/2023	CARTO OCTARAY Mapping Catheter with TRUEref Technology	Medical Device	Product Defect Correction	Class II	Hospital
18/05/2023	Lipoprotein(a). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
18/05/2023	Nano-Tech T4 Respirator - All Batches - ARTG 335981	Medical Device	Product Defect Alert	Class II	Hospital
18/05/2023	Phenobarbital. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Alert	Class III	Hospital
18/05/2023	Resuscitaire Infant Radiant Warmer with the Optional Scale	Medical Device	Product Defect Correction	Class II	Hospital
18/05/2023	Sodium Chloride 5% Ophthalmic Solution, 15ml [1] Eye drop (US)	Medicine	Recall	Class III	Retail
18/05/2023	Sufentanil citrate injection, USP 50 mcg/ml	Medicine	Recall	Class III	Retail
17/05/2023	Access Hybritech p2PSA assay. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
17/05/2023	BioFire FilmArray Gastrointestinal (GI) Panel. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
16/05/2023	UroPass Ureteral Access Sheath	Medical Device	Recall	Class I	Hospital
15/05/2023	Access 2 Immunoassay Analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
15/05/2023	AQUIOS IMMUNO-TROL Cells. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
15/05/2023	Technetium-99m and Technetium-99m Macrosalb	Medicine	Recall	Class II	Hospital
15/05/2023	VersaLyse Lysing Solution. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
12/05/2023	Cobalt XT/Cobalt /Crome, ICDs and CRT-Ds	Medical Device	Product Defect Correction	Class I	Hospital
11/05/2023	Cornea (Normothermic) R	Biological	Hazard Alert	Class II	Hospital
11/05/2023	VITROS Chemistry Products Calibrator Kit 20. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
10/05/2023	Tearaway Introducer Kit	Medical Device	Recall	Class II	Hospital
9/05/2023	3M Ophthalmic Drape	Medical Device	Recall	Class II	Hospital
9/05/2023	SYQUET 25 mg quetiapine (as fumarate) tablet blister pack	Medicine	Recall	Class II	Retail
8/05/2023	BEPOD Percutaneous Chevron Burr / MIS II D3.0x20mm and BEPOD Percutaneous Chevron Burr / MIS II D2.0x20mm	Medical Device	Recall	Class II	Wholesale

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
8/05/2023	LIFECODES HLA-DQA1/B1 SSO Typing Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
8/05/2023	LISS4122 - Laparoscopic Irrigation/Suction Set - Double Spike with detached 5mm probe	Medical Device	Product Defect Correction	Class II	Hospital
5/05/2023	Dispomedica Medistrip Vein Stripper	Medical Device	Recall	Class II	Hospital
5/05/2023	HORIZON Microclip Titanium Ligating Clips w/tape	Medical Device	Recall	Class II	Hospital
5/05/2023	Philips Incisive CT & CT 3500 System	Medical Device	Product Defect Correction	Class I	Hospital
4/05/2023	18F – Fluorodeoxyglucose Injection	Medicine	Product Defect Correction	Class III	Hospital
4/05/2023	Bicarbonate Reagent OSR6x90. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
4/05/2023	IntelliVue G7m Anesthesia Gas Modules	Medical Device	Product Defect Correction	Class II	Hospital
3/05/2023	ExacTrac Dynamic Radiation Therapy Patient Positioning System	Medical Device	Product Defect Correction	Class I	Hospital
3/05/2023	P044701 - Polyclonal Goat Anti-Mouse Immunoglobulins/HRP. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
1/05/2023	Diathermy Suction Devices	Medical Device	Recall	Class III	Hospital
1/05/2023	Oxygen Therapy Flowmeter	Medical Device	Recall	Class II	Hospital
28/04/2023	Icelock 125 Ratchet, Icelock 600 XM Ratchet, Icelock 621 Ratchet, Icelock 621 Ratchet Adaption Kit and Ratchet Lock Body	Medical Device	Recall	Class II	Retail
28/04/2023	P044701 - Polyclonal Goat Anti-Mouse Immunoglobulins/HRP	Medical Device	Product Defect Correction	Class III	Wholesale
27/04/2023	AMSCO 600 Sterilizer	Medical Device	Product Defect Correction	Class II	Hospital
27/04/2023	mask, surgical, single use	Medical Device	Product Defect Alert	Class II	Hospital
26/04/2023	EliA GliadinDP IgG Well, Phadia 2500E and Operating Software Phadia Prime version 2.6.11. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
26/04/2023	F18 Fludeoxyglucose	Medicine	Recall	Class I	Hospital
26/04/2023	iQ200 Series, DxU 850m and 840m Iris Analyzers. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Alert	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
26/04/2023	Midstream Collection Pack	Medical Device	Recall	Class II	Hospital
26/04/2023	Trilogy Evo, Trilogy Evo O2, Trilogy EV300	Medical Device	Product Defect Correction	Class I	Consumer
24/04/2023	Single Fiber Optical DVI Extender Receiver	Medical Device	Product Defect Correction	Class II	Hospital
24/04/2023	Surgical/medical respirator, single-use	Medical Device	Product Defect Alert	Class II	Hospital
21/04/2023	Femoral Head (L)	Biological	Hazard Alert	Class II	Hospital
21/04/2023	Milled Bone Coarse 18g	Biological	Hazard Alert	Class II	Hospital
21/04/2023	Milled Bone Coarse 18g	Biological	Hazard Alert	Class II	Hospital
21/04/2023	Milled Bone Coarse 8g	Biological	Hazard Alert	Class II	Hospital
21/04/2023	Multiple biological allograft components. Milled Bone Coarse 18g, Femoral Head (R), Femur (L) Portion, Milled Bone 18g, Tendon EHL (L), Tendon EHL (R), Tendon Tibialis Posterior (L)	Biological	Recall	Class II	Hospital
21/04/2023	Tendon Achilles (R)	Biological	Hazard Alert	Class II	Hospital
21/04/2023	Tendon Tibialis Posterior (R)	Biological	Hazard Alert	Class II	Hospital
20/04/2023	Long Depth Gauge	Medical Device	Recall	Class III	Hospital
19/04/2023	Biofil Level 3 Surgical Mask	Medical Device	Product Defect Alert	Class II	Retail
19/04/2023	Fluoroethyl-L-Tyrosine [18F] Injection	Medicine	Product Defect Correction	Class III	Hospital
18/04/2023	Airo TruCT Mobile CT Scanner	Medical Device	Product Defect Correction	Class II	Hospital
17/04/2023	Allplex RV Essential Assay. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Alert	Class II	Hospital
17/04/2023	Atrium Pneumostat Chest Drain Valve	Medical Device	Product Defect Correction	Class II	Hospital
17/04/2023	Attest Steam Chemical Integrators	Medical Device	Recall	Class III	Hospital
17/04/2023	BRAF Mutation Assay. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Alert	Class II	Hospital
17/04/2023	Shimadzu X-Ray system - X-Ray tube support, ceiling mounted CH-200/CH-200M	Medical Device	Product Defect Correction	Class II	Hospital
17/04/2023	Single Use Distal Cover	Medical Device	Recall	Class I	Hospital
17/04/2023	TEAM3A & TEAM3I	Medical Device	Product Defect Correction	Class III	Hospital
14/04/2023	18F DCFPyL	Medicine	Recall	Class I	Hospital
14/04/2023	Codman Cranial Hand Drill	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
14/04/2023	Dofetilide Capsules 125 mcg	Medicine	Recall	Class II	Retail
14/04/2023	Florbetapir [18F] Injection	Medicine	Product Defect Correction	Class III	Hospital
14/04/2023	Fluoroethyl-L-Tyrosine [18F] Injection	Medicine	Recall	Class II	Hospital
14/04/2023	Gastrointestinal Anchor Set, SAF-T-PEXY T-Fasteners	Medical Device	Recall	Class III	Hospital
14/04/2023	Lateral Lumbar Ti-Life Plate - Small and Large	Medical Device	Recall	Class II	Hospital
14/04/2023	Sani Cloth 70, Sani Cloth Active, Sani Cloth Chlorine Wipes - 50, 125 and 200 count	Medical Device	Product Defect Alert	Class III	Hospital
14/04/2023	Tc99m Cardiolite	Medicine	Recall	Class II	Hospital
13/04/2023	Atellica CH Toxicology Calibrator (TOX CAL). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
13/04/2023	DR-XD1000 (FDR Nano)	Medical Device	Product Defect Correction	Class II	Hospital
13/04/2023	Mission Kit 20G x 10CM	Medical Device	Recall	Class II	Hospital
13/04/2023	Water for Injection (WFI) ampoules co-packed with Simulect 20mg vials	Medicine	Product Defect Correction	Class II	Hospital
12/04/2023	A1AT Controls. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
12/04/2023	HOYA Vivinex iSert Toric IOLs	Medical Device	Recall	Class II	Hospital
12/04/2023	Input Output Module (IOM), Storage and Retrieval Module (SRM), Vesmatic Cube 80 Interface Module (VMC) and Alinity h Interface Module (HSQ). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
12/04/2023	NUVAXOVID (SARS-CoV-2 rS [NVX-CoV2373]) COVID-19 VACCINE	Medicine	Recall	Class II	Wholesale
11/04/2023	18F DCFPyL	Medicine	Recall	Class I	Hospital
11/04/2023	Arthrex Quickset Kit - 5CC, 8CC + 16CC	Medical Device	Recall	Class II	Hospital
11/04/2023	Cardiosave Intra-Aortic Balloon Pumps (IABP) Safety Disk	Medical Device	Product Defect Correction	Class I	Hospital
11/04/2023	F18 Fludeoxyglucose	Medicine	Product Defect Correction	Class III	Hospital
11/04/2023	mask, single use, surgical	Medical Device	Product Defect Alert	Class II	Hospital
11/04/2023	mask, single use, surgical	Medical Device	Product Defect Alert	Class II	Hospital
11/04/2023	Medihealth Guard Facemask Pty Ltd	Medical Device	Product Defect Alert	Class II	Retail

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
11/04/2023	Moosh (Australia) Pty Ltd	Medical Device	Product Defect Alert	Class II	Retail
11/04/2023	Public respirator, single use	Medical Device	Recall	Class II	Hospital
11/04/2023	Public Respirator, Single use	Medical Device	Product Defect Alert	Class II	Hospital
11/04/2023	Redon Bottle	Medical Device	Recall	Class II	Hospital
11/04/2023	RX Monaco. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
11/04/2023	Sunry Health Management Pty Ltd	Medical Device	Product Defect Alert	Class II	Hospital
6/04/2023	Jelco Optiva IV Catheter 24G	Medical Device	Recall	Class II	Hospital
6/04/2023	Philips Azurion System	Medical Device	Product Defect Correction	Class II	Hospital
6/04/2023	Surgipack Clear Tip Digital Thermometer	Medical Device	Recall	Class II	Retail
5/04/2023	(18F) DCFPyL	Medicine	Recall	Class I	Hospital
5/04/2023	CC300	Medical Device	Product Defect Correction	Class II	Hospital
5/04/2023	Elekta Unity Systems	Medical Device	Product Defect Correction	Class II	Hospital
5/04/2023	QUADROX-I Pediatric Microporous Membrane Oxygenator with SOFTLINE Coating and QUADROX_iD Pediatric with Bioline Coating	Medical Device	Recall	Class II	Hospital
5/04/2023	TEAM3A & TEAM3I Fetal Monitor	Medical Device	Product Defect Correction	Class III	Wholesale
4/04/2023	Arya Mobility Pty Ltd	Medical Device	Product Defect Alert	Class II	Retail
4/04/2023	Shiley Adult Flexible Tracheostomy Tube with TaperGuard Cuff and Cuffless: Disposable Inner Cannula or Reusable Inner Cannula	Medical Device	Recall	Class I	Hospital
4/04/2023	Vectibix (panitumumab) 100mg/5mL vial	Medicine	Recall	Class II	Hospital
4/04/2023	VentStar Anesthesia (N) 180, VentStar Basic (P)180, Seattle PAP plus, Ventstar Coax, Ventstar Coax 180, Ventstar Coax 230	Medical Device	Recall	Class II	Hospital
4/04/2023	WATCHDOG Hemostasis Valve Kit	Medical Device	Recall	Class III	Hospital
3/04/2023	Fiasp, Saxenda and Ozempic	Medicine	Product Defect Alert	Class II	Retail
3/04/2023	Hugo Robotic-Assisted Surgery (RAS) System	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
3/04/2023	Orbital Retractor - Left and Right	Medical Device	Recall	Class I	Hospital
3/04/2023	PSR 18 F DCFPyL	Medicine	Recall	Class I	Hospital
31/03/2023	ADHEAR Configuration Software 1.0 and ADHEAR Configuration Software 1.0 Service Release 1	Medical Device	Product Defect Correction	Class III	Retail
31/03/2023	ANGIOGUARD RX Emboli Capture Guidewire System	Medical Device	Recall	Class I	Hospital
31/03/2023	BioCeuticals Ultra Potent-C Chewable (60s)	Medicine	Recall	Class II	Consumer
31/03/2023	public respirator, single use	Medical Device	Recall	Class II	Hospital
30/03/2023	Artis One with Hybrid Cable	Medical Device	Product Defect Correction	Class II	Hospital
29/03/2023	18F- Fluoroestradiol Injection	Medicine	Product Defect Correction	Class III	Hospital
29/03/2023	da Vinci X and Xi system	Medical Device	Product Defect Correction	Class I	Hospital
29/03/2023	Samsung Digital Diagnostic Mobile X-ray System GM85	Medical Device	Product Defect Correction	Class III	Hospital
29/03/2023	Starrsred Control Level N. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class III	Hospital
28/03/2023	ambIT cassette filter, male connector	Medical Device	Recall	Class I	Hospital
28/03/2023	Cornea (Normothermic) R	Biological	Hazard Alert	Class II	Hospital
28/03/2023	INTELLANAV STABLEPOINT Ablation Catheter	Medical Device	Recall	Class II	Hospital
28/03/2023	Maxi Kidney Care - Wealthy Health, 2VNR Goodlife and Goodlife Nutrition	Medicine	Recall	Class III	Retail
28/03/2023	Philips Incisive CT	Medical Device	Product Defect Correction	Class II	Hospital
28/03/2023	Philips Spectral CT 7500	Medical Device	Product Defect Correction	Class II	Hospital
28/03/2023	Thermo Clone VPS Regular Set, Heavy Body 50mL 2pk Kit, Thermo Clone VPS Fast Set, Heavy Body 50mL 2pk Kit and Thermo Clone VPS Fast Set, Heavy Body 50mL Cartridge 10pk Econo Kit	Medical Device	Recall	Class III	Retail
27/03/2023	Assayed Urine Control Levels 2 & 3. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
27/03/2023	Atellica IM Cortisol 50T, Atellica IM Cortisol 250T, ADVIA Centaur Cortisol 50T and ADVIA Centaur Cortisol 250T. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
27/03/2023	BD Alaris System PC Unit Model 8015	Medical Device	Product Defect Correction	Class II	Hospital
27/03/2023	Philips DigitalDiagnost C50 System	Medical Device	Product Defect Correction	Class II	Hospital
27/03/2023	Technetium-99m Macrosalb	Medicine	Recall	Class II	Hospital
24/03/2023	Glofitamab SC 80mg/2mL vials	Medicine	Recall	Class II	Hospital
23/03/2023	AMPEQ Pty Ltd - Public face mask, reusable	Medical Device	Product Defect Alert	Class II	Hospital
23/03/2023	Big Start	Medical Device	Product Defect Alert	Class II	Retail
23/03/2023	Estitch Australia Pty Ltd	Medical Device	Product Defect Alert	Class II	Retail
23/03/2023	Life Biotech Pty Ltd	Medical Device	Product Defect Alert	Class II	Retail
23/03/2023	Mask, surgical, single use	Medical Device	Product Defect Alert	Class II	Hospital
23/03/2023	Mask, surgical, single-use	Medical Device	Product Defect Alert	Class II	Sponsor
23/03/2023	MiSeqDx instrument and NextSeq 550Dx instrument. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
22/03/2023	Plum 360 Infusion System and Plum A+ & Plum A+3 Infusion Systems	Medical Device	Product Defect Correction	Class II	Hospital
21/03/2023	Express Mini 500 Chest Drain	Medical Device	Product Defect Correction	Class II	Hospital
20/03/2023	a3600 Storage and Retrieval Module 15K (SRM), a3600 Storage and Retrieval Module 9K (SRM), and FlexLab Storage and Retrieval Module 12K(SRM). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
20/03/2023	Evolut PRO+ 34 mm Transcatheter Aortic Valve (TAV)	Medical Device	Hazard Alert	Class I	Hospital
17/03/2023	Atellica DCA and Atellica DCA ACR Reagent Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
17/03/2023	MyLife App	Medical Device	Product Defect Correction	Class II	Consumer
16/03/2023	150cm Straight Extension/Injector Line for CT & MRI	Medical Device	Recall	Class II	Hospital
16/03/2023	18F Fludeoxyglucose	Medicine	Recall	Class I	Hospital
16/03/2023	Heater Cooler Unit HCU 40, High Voltage	Medical Device	Product Defect Correction	Class I	Hospital
16/03/2023	Integre Pro/Proscan lasers - Integre Pro Yellow and Spare Optics Bench Yellow	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
16/03/2023	STA R MAX / STA-R EVOLUTION, STA COMPACT MAX and STA COMPACT. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
16/03/2023	Vscan Air CL	Medical Device	Product Defect Correction	Class II	Hospital
16/03/2023	Zenith Branch Endovascular Graft - Iliac Bifurcation (ZBIS)	Medical Device	Recall	Class II	Hospital
15/03/2023	18F DCFPyL PSR	Medicine	Recall	Class I	Hospital
15/03/2023	Ambulatory insulin infusion pump software patent	Medical Device	Product Defect Correction	Class II	Consumer
15/03/2023	VITROS Chemistry Products ALTV Slides. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
14/03/2023	Trilogy Evo O2 and Trilogy EV300	Medical Device	Product Defect Correction	Class II	Hospital
10/03/2023	Infinity CentralStation (ICS)	Medical Device	Product Defect Correction	Class II	Hospital
10/03/2023	mask, single use, surgical	Medical Device	Product Defect Alert	Class II	Hospital
10/03/2023	Mednow Pty Ltd mask, surgical, single use	Medical Device	Product Defect Alert	Class II	Hospital
10/03/2023	Safelight Cable Clear 5mm x 3.05m	Medical Device	Recall	Class II	Hospital
10/03/2023	SmartPerfusion	Medical Device	Product Defect Correction	Class II	Hospital
9/03/2023	Change Healthcare Cardiology	Medical Device	Product Defect Correction	Class II	Hospital
8/03/2023	Habib EndoHPB Bipolar Radiofrequency Catheter	Medical Device	Product Defect Correction	Class II	Hospital
8/03/2023	Mission Kit 16G x 10CM and Mission Kit 18G x 16CM	Medical Device	Recall	Class II	Hospital
8/03/2023	Philips DigitalDiagnost, ProxiDiagnost, and CombiDiagnost systems	Medical Device	Product Defect Correction	Class III	Hospital
8/03/2023	RBX TOPIRAMATE 200 mg tablets	Medicine	Recall	Class III	Wholesale
8/03/2023	The EasyScreen Sample Processing Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
7/03/2023	AMCAL DRY COUGH FORTE 4mg/mL and AMCAL DRY COUGH MIXTURE 1mg/mL	Medicine	Recall	Class II	Retail
7/03/2023	APOHEALTH DRY TICKLY COUGH RELIEF pholcodine 1 mg/mL oral liquid bottle and APOHEALTH DRY TICKLY COUGH RELIEF FORTE pholcodine 4 mg/mL oral liquid bottle	Medicine	Recall	Class II	Retail

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7/03/2023	BENADRYL DRY, TICKLY COUGH FORTE pholcodine 4mg/mL oral liquid bottle and CODRAL DRY COUGH FORTE STRENGTH pholcodine 4mg/mL oral liquid bottle	Medicine	Recall	Class II	Retail
7/03/2023	CHEMISTS' OWN DRY TICKLY COUGH FORTE pholcodine 4 mg/mL oral liquid bottle (new formulation)	Medicine	Recall	Class II	Retail
7/03/2023	DURO-TUSS liquids and lozenges and DIFFLAM lozenges containing pholcodine	Medicine	Recall	Class II	Retail
7/03/2023	Hamilton C6 Ventilators	Medical Device	Product Defect Alert	Class II	Hospital
7/03/2023	Pharmacy Health Dry Cough Relief Forte Pholcodine 4mg/mL oral liquid bottle and Priceline Pharmacy Dry Cough Relief Forte Pholcodine 4mg/mL oral liquid	Medicine	Recall	Class II	Retail
7/03/2023	Pharmacy Health Dry Tickly Cough Mixture 200mL	Medicine	Recall	Class II	Retail
7/03/2023	Tempus Pro Patient Monitor	Medical Device	Product Defect Correction	Class II	Hospital
6/03/2023	Eagle Health Holdings Ltd mask, surgical, single use	Medical Device	Product Defect Alert	Class II	Hospital
3/03/2023	F18 Fludeoxyglucose (FDG)	Medicine	Product Defect Alert	Class III	Hospital
3/03/2023	HB Access Pty Ltd mask, surgical, single use	Medical Device	Product Defect Alert	Class II	Hospital
1/03/2023	ATIVAN lorazepam 2.5mg tablet bottle	Medicine	Recall	Class II	Retail
1/03/2023	Attune REV LPS INSERT XSM 12MM	Medical Device	Hazard Alert	Class II	Hospital
1/03/2023	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
1/03/2023	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Product Defect Alert	Class III	Hospital
1/03/2023	Trifecta Valve and Trifecta Valve with Glide Technology	Medical Device	Hazard Alert	Class II	Consumer
28/02/2023	1 mL CLEAR Oral Syringe, Pharmacy Pack, non-sterile	Medical Device	Recall	Class III	Hospital
28/02/2023	Dofetilide Capsules 125mcg, 250 mcg and 500 mcg	Medicine	Recall	Class II	Retail
28/02/2023	Doxazosin Tablets USP 1 mg,	Medicine	Recall	Class II	Retail
28/02/2023	PerFix Plug, PerFix Light Plug, Ventralex Hernia Patch and Bard Mesh	Medical Device	Product Defect Correction	Class III	Hospital
27/02/2023	Fludeoxyglucose (18F)	Medicine	Product Defect Alert	Class III	Hospital

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27/02/2023	Zenith Branch Endovascular Graft - Iliac Bifurcation (ZBIS)	Medical Device	Product Defect Alert	Class II	Hospital
24/02/2023	CgA kits. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
24/02/2023	HeartSine SAM 360P	Medical Device	Product Defect Correction	Class II	Wholesale
22/02/2023	Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pump (IABP)	Medical Device	Product Defect Correction	Class I	Hospital
22/02/2023	Monaco Treatment Planning System	Medical Device	Product Defect Correction	Class II	Hospital
22/02/2023	NovaStar TS and NovaStar plus masks	Medical Device	Product Defect Correction	Class II	Consumer
21/02/2023	CardioMEMS HF Systems	Medical Device	Product Defect Correction	Class II	Hospital
21/02/2023	CardioMEMSTM Electronics Systems Radiofrequency (RF) Emissions	Medical Device	Product Defect Correction	Class II	Consumer
20/02/2023	CombiDiagnost R90 1.0 and 1.1, ProxiDiagnost N90 1.0	Medical Device	Product Defect Correction	Class III	Hospital
17/02/2023	Luminos Agile (VC10), Luminos Agile Max (VE10, VF10, VF11), Luminos dRF (VD10), Luminos dRF Max (VE10, VF10, VF11), Luminos Lotus Max (VF11), Urooskop Omnia (VD10) and Urooskop Omnia Max (VE10, VF10, VF11)	Medical Device	Product Defect Correction	Class II	Hospital
17/02/2023	Sample Diluent. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
16/02/2023	AtmosAir Velaris & AtmosAir Velaris Plus	Medical Device	Product Defect Correction	Class III	Hospital
16/02/2023	Efficia External Paddles	Medical Device	Product Defect Correction	Class I	Hospital
16/02/2023	FDG	Medicine	Recall	Class II	Hospital
16/02/2023	Freestyle LibreLink Android app and Android 13	Medical Device	Product Defect Correction	Class II	Consumer
16/02/2023	Frozen Femoral head	Biological	Hazard Alert	Class II	Hospital
16/02/2023	injeTAK Adjustable Tip Needle	Medical Device	Recall	Class II	Hospital
16/02/2023	MicroVue C1-Inhibitor Plus EIA. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
16/02/2023	MobileDiagnost wDR 2.2 and MobileDiagnost wDR with Windows 10 Upgrade	Medical Device	Product Defect Correction	Class III	Hospital
16/02/2023	Monnal T60 Ventilator	Medical Device	Product Defect Correction	Class II	Hospital
15/02/2023	Curash Nappy Rash Cream	Medicine	Recall	Class II	Consumer

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15/02/2023	Philips Incisive CT system	Medical Device	Product Defect Correction	Class II	Hospital
15/02/2023	Thermo Scientific MAS Omni CARDIO	Medical Device	Product Defect Correction	Class II	Hospital
15/02/2023	Tracoe Experc Set Vario, Tracoe Experc Set Twist and Tracoe Experc Set Twist Plus	Medical Device	Product Defect Correction	Class II	Hospital
14/02/2023	18F-DCFPyL	Medicine	Product Defect Correction	Class III	Hospital
14/02/2023	Oxygenator and Cardiotomy/Venous Reservoir with Balance Biosurface, Oxygenator with Cortiva BioActive Surface, Oxygenator with Cortiva BioActive Surface, Cardiotomy/Venous Reservoir with Balance Biosurface and Any Tubing Pack containing any of the 3 product numbers listed	Medical Device	Product Defect Alert	Class I	Hospital
14/02/2023	PM4-306 - PRIMAGARD PROCEDURE MASK, EAR LOOPS, BLUE	Medical Device	Product Defect Alert	Class II	Hospital
13/02/2023	Celestone Chronodose Injection Ampoule	Medicine	Recall	Class II	Retail
13/02/2023	Select 1 day (somofilcon A) soft contact lenses	Medical Device	Recall	Class III	Consumer
9/02/2023	Infusomat Space Transfusion Lines	Medical Device	Product Defect Alert	Class II	Hospital
8/02/2023	ARTIS pheno systems with software version VE10B in combination with a Siemens Healthineers table or a Trumpf/MAQUET table	Medical Device	Product Defect Correction	Class II	Hospital
8/02/2023	EVO IQ Large Volumetric Pump (LVP)	Medical Device	Product Defect Correction	Class I	Hospital
8/02/2023	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Recall	Class II	Hospital
8/02/2023	Health One Surgical Face Mask with Eye Shield Anti-fog, Anti-splash	Medical Device	Product Defect Alert	Class II	Hospital
8/02/2023	Lyphochek Coagulation Control. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
7/02/2023	Anaconda Custom Stent Grafts System (Anaconda Custom)	Medical Device	Hazard Alert	Class I	Hospital
7/02/2023	Atellica DCA HbA1c Dx Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
7/02/2023	Clariti 1 day toric contact lenses	Medical Device	Recall	Class III	Retail

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6/02/2023	Atellica CH LDL Cholesterol Direct, CH Total Protein II, CH Triglycerides (concentrated) & CH Triglycerides_2.	Medical Device	Product Defect Correction	Class II	Hospital
6/02/2023	Grafton DBM products:	Biological	Recall	Class II	Hospital
6/02/2023	MINC+ Benchtop Incubator	Medical Device	Product Defect Correction	Class II	Hospital
6/02/2023	MYLA AST Filters with VITEK MS. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
2/02/2023	Cytokine Control Kit	Medical Device	Product Defect Correction	Class II	Hospital
2/02/2023	Femoral Head - Fresh Frozen - Non-irradiated	Biological	Hazard Alert	Class II	Hospital
2/02/2023	IH-1000	Medical Device	Product Defect Correction	Class III	Hospital
2/02/2023	Perfusor Original Line	Medical Device	Recall	Class II	Hospital
2/02/2023	SmartPill SmartBar	Medical Device	Recall	Class II	Hospital
2/02/2023	Superlite Electric Foldable Wheelchair	Medical Device	Product Defect Correction	Class II	Consumer
2/02/2023	The DRX-Compass/DR-FIT X-ray System	Medical Device	Product Defect Correction	Class II	Hospital
1/02/2023	HLS Set Advanced and the PLS Set	Medical Device	Product Defect Alert	Class I	Hospital
1/02/2023	HR Trace Elements. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
1/02/2023	Irradiated Milled Bone	Biological	Hazard Alert	Class II	Hospital
1/02/2023	Mini TightRope FT	Medical Device	Recall	Class III	Hospital
31/01/2023	MedChart v8.3.1.3, v9.0, v10.1, v11, v12	Medical Device	Product Defect Correction	Class II	Hospital
31/01/2023	Medicinal cannabis vape cartridges: Releaf Critical Kush 0.5g cart & Releaf White Lemon 0.5g cart	Medicine	Product Defect Correction	Class III	Consumer
30/01/2023	Efficia Pads Adapter Cable	Medical Device	Product Defect Correction	Class I	Hospital
30/01/2023	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Recall	Class II	Hospital
30/01/2023	Multiple Elecsys Troponin devices. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Alert	Class II	Hospital
30/01/2023	Technetium-99m	Medicine	Recall	Class II	Hospital
30/01/2023	Tri-Staple 2.0 Black Intelligent Reload and Lap Bariatric Sleeve-With Energy Procedure Kit	Medical Device	Recall	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
26/01/2023	Biofinity XR toric (comfilcon A) soft contact lenses	Medical Device	Recall	Class III	Retail
25/01/2023	Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pump (IABP)	Medical Device	Product Defect Correction	Class I	Hospital
25/01/2023	Disability vehicle, cycle, tricycle, foot-propelled	Medical Device	Product Defect Correction	Class II	Consumer
25/01/2023	Philips Respironics V680 Ventilator	Medical Device	Recall	Class I	Hospital
24/01/2023	Thermodilution Catheter And Kits	Medical Device	Product Defect Correction	Class II	Hospital
24/01/2023	XP-100 Automated Hematology Analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
23/01/2023	BISOLVON PHOLCODINE DRY FORTE 4mg/mL oral liquid bottle	Medicine	Recall	Class II	Retail
23/01/2023	myNeedle Guide 2D license, myNeedle Guide 2D AWP only Workflow license	Medical Device	Product Defect Correction	Class II	Hospital
23/01/2023	PET Gantry Locking Mechanism – Biograph Mobile and Seismic Installations	Medical Device	Product Defect Correction	Class III	Hospital
20/01/2023	Sedecal Statif Stum X-Ray System	Medical Device	Product Defect Correction	Class II	Hospital
20/01/2023	Vancomycin Viatrix 1000mg vials	Medicine	Product Defect Alert	Class II	Hospital
19/01/2023	FB 112k-1005-1, IIFT Mosaic: Glutamate Receptor (type AMPA1) / Glutamate Receptor (type AMPA2). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
19/01/2023	Multicath 2 Catheter - Vygon GmbH	Medical Device	Recall	Class II	Hospital
19/01/2023	Plus Medical Disposable Face Mask - EN Type II	Medical Device	Product Defect Alert	Class II	Retail
19/01/2023	TCM Prostate Support	Medicine	Recall	Class II	Retail
18/01/2023	Cardiosave Hybrid IABP and Cardiosave Rescue IABP	Medical Device	Product Defect Correction	Class I	Hospital
17/01/2023	Atellica IM & ADVIA Centaur Folate. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
17/01/2023	Covera and Covera Plus Vascular Covered Stent	Medical Device	Recall	Class II	Hospital
17/01/2023	Selenia Dimensions / 3Dimensions mammography system	Medical Device	Product Defect Correction	Class II	Hospital
17/01/2023	Univera Firm Ureteral Stent Sets	Medical Device	Product Defect Correction	Class II	Hospital
17/01/2023	Venovo 9F 14/160/800mm OUS	Medical Device	Recall	Class I	Hospital

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16/01/2023	Alfacalcidol Hexal 1 µg 50 and 100 soft capsules	Medicine	Recall	Class III	Hospital
16/01/2023	Broviac CVC Comp Rep 4.2Fr and 6.6Fr SL	Medical Device	Recall	Class II	Hospital
16/01/2023	MR View&Go or syngo.via.	Medical Device	Product Defect Correction	Class II	Hospital
13/01/2023	AU/DxC AU Chemistry Lactate. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
13/01/2023	HBA/MacConkey agar without added salt (HBA/Mac no salt). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
13/01/2023	Horse Blood Agar (HBA). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
13/01/2023	Horse Blood Agar with colistin and nalidixic acid (HBA+CNA). An in vitro medical device (IVD).	Medical Device	Recall	Class II	Hospital
12/01/2023	Airo TruCT Mobile CT Scanner	Medical Device	Product Defect Correction	Class II	Hospital
12/01/2023	Hypodermic needle, single-use, sterile (59230)	Medical Device	Recall	Class II	Retail
12/01/2023	Iodine-131 capsule	Medicine	Recall	Class II	Hospital
11/01/2023	ATOM IncuArch Infant Transport Incubator	Medical Device	Product Defect Correction	Class III	Hospital
11/01/2023	QUATTROCONE30 implant	Medical Device	Recall	Class II	Retail
10/01/2023	M5071A Adult and M5072A Infant/child pads cartridges for use with HS1/OnSite/Home AEDs	Medical Device	Product Defect Correction	Class II	Retail
10/01/2023	MUTARS HD coupling C-O-M 12.5mm TiN	Medical Device	Hazard Alert	Class II	Hospital
9/01/2023	CADD Infusion System Disposables as part of the Veletri Consumables kit (Electric infusion pump administration set)	Medical Device	Product Defect Alert	Class I	Hospital
9/01/2023	Fast Cath Swartz 10F Guiding Introducer	Medical Device	Product Defect Correction	Class III	Hospital
6/01/2023	Flow Anesthesia System - Flow-c, Flow-e and Flow-i	Medical Device	Product Defect Correction	Class I	Hospital
6/01/2023	PP2420 HBA+CNA/Brilliance UTI Clarity. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
6/01/2023	Technetium-99m and Technetium-99m Macrosalb	Medicine	Recall	Class II	Hospital
6/01/2023	Yongli Face Mask	Medical Device	Product Defect Alert	Class II	Hospital
5/01/2023	All Defigard Touch 7 devices	Medical Device	Product Defect Correction	Class II	Hospital

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5/01/2023	Dako CoverStainer CS10030. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Wholesale
5/01/2023	Peanut (Arachis hypogaea)	Medical Device	Recall	Class II	Hospital
5/01/2023	Polyclonal Rabbit Anti-Human IgG/FITC Rabbit F(ab') ₂ . An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
4/01/2023	Medical Surgical Mask	Medical Device	Product Defect Alert	Class II	Hospital
4/01/2023	Shred Maxx, Shred Maxx Male, Shred Maxx Super Strength, Glow Maxx, Cli Maxx, X Maxx and GMax	Medicine	Recall	Class II	Consumer
3/01/2023	Canon Aquilion Serve CT scanner	Medical Device	Product Defect Correction	Class III	Hospital
3/01/2023	Color Cuff Sterile Disposable Tourniquet Cuffs	Medical Device	Product Defect Correction	Class III	Hospital
3/01/2023	Support Arm for tremoflo C100	Medical Device	Product Defect Correction	Class III	Hospital
3/01/2023	Vadi Expiratory Filter Heater	Medical Device	Product Defect Alert	Class II	Hospital
23/12/2022	ComfortCleanse	Medicine	Recall	Class II	Wholesale
23/12/2022	PHARMACY ACTION DRY COUGH RELIEF pholcodine 1mg/mL oral liquid bottle	Medicine	Recall	Class II	Retail
23/12/2022	SimplyGo Oxygen Concentrator	Medical Device	Product Defect Alert	Class III	Consumer
22/12/2022	CADD Infusion System Disposables	Medical Device	Product Defect Alert	Class I	Hospital
22/12/2022	Fu Gui Ba Wei Tang a.k.a. Rehmannia Eight Vitality Formula & Nuan Gong Cheng Yun Fang a.k.a. Motherhood 1 Formula	Medicine	Recall	Class II	Consumer
22/12/2022	Histology FISH Accessory Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
21/12/2022	REVACLEAR 300 Dialyser and REVACLEAR 400 Dialyser	Medical Device	Recall	Class II	Hospital
20/12/2022	ARTIS icono / pheno system in combination with a Siemens Healthineers VE OR Table	Medical Device	Product Defect Correction	Class II	Hospital
20/12/2022	Artis zee/ Artis Q/ Artis Q.zen systems with software version VD12A	Medical Device	Product Defect Correction	Class II	Hospital
20/12/2022	Fluphenazine deconate (Neuraxpharm) 25mg/1mL soln for IM inj amp (1mLx5)	Medicine	Recall	Class II	Retail

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
20/12/2022	Forearm Crutch - Tall and Adult sizes	Medical Device	Recall	Class II	Consumer
20/12/2022	Immunotrol Infliximab. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
20/12/2022	Nuclear Medicine 600/800 series systems	Medical Device	Product Defect Correction	Class I	Hospital
20/12/2022	Tc99m Sestamibi, Tc99m MAG3 and Tc99m Sulphur Colloid	Medicine	Recall	Class II	Hospital
19/12/2022	Accu-Chek Solo cannula assembly & pump holder (9 mm; 10+3 & 6 mm; 10+3) and Accu-Chek Solo supply kit (9 mm) & (6 mm)	Medical Device	Recall	Class II	Consumer
19/12/2022	KN95 respirators supplied by Ironbark Creek Investments	Medical Device	Recall	Class II	Retail
19/12/2022	Tissue-Tek Polar D and Tissue-Tek Polar DM Cryostat Microtome. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
16/12/2022	All NexGen Complete Knee Solution Stemmed Nonaugmentable Option Tibial Components	Medical Device	Hazard Alert	Class II	Hospital
16/12/2022	Fresh frozen femoral head (Bone) - irradiated	Biological	Hazard Alert	Class II	Hospital
15/12/2022	BIOSTOP G Bioresorbable Cement Restrictor	Medical Device	Recall	Class II	Hospital
15/12/2022	epoc Host 2, epoc Host 2 (Refurbished), epoc Host 2, ROW (MC55X) and epoc NXS Host, ROW. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
14/12/2022	Alinity m System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
14/12/2022	HeartWare Ventricular Assist Device (HVAD) System	Medical Device	Hazard Alert	Class I	Hospital
14/12/2022	IMMULITE 2000 Thyroglobulin. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
14/12/2022	OAPL FACE MASK DISPOSABLE 3PLY EARLOOP	Medical Device	Product Defect Alert	Class II	Retail
13/12/2022	AXIOM Luminos TF, AXIOM Iconos R100 and R200, AXIOM Luminos Agile, Luminos Agile Max, AXIOM Luminos dRF, Luminos dRF Max and LUMINOS Lotus Max systems	Medical Device	Product Defect Correction	Class II	Hospital
13/12/2022	Philips ProxiDiagnost N90 1.1	Medical Device	Product Defect Correction	Class II	Hospital
12/12/2022	Deep Lung Support	Medicine	Recall	Class II	Retail
9/12/2022	Codman Surgical Patties XRAY 1/2X1/2-200	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
9/12/2022	Multiple Quinapril Products	Medicine	Recall	Class II	Retail
9/12/2022	OAPL Protective Face Mask with Earloops KN95 Mask 4PLY EAR LOOP	Medical Device	Recall	Class II	Hospital
9/12/2022	Quinapril 20 mg 30 tablet blister	Medicine	Recall	Class II	Retail
9/12/2022	STATIF STU / STATIF STUM	Medical Device	Product Defect Correction	Class II	Hospital
9/12/2022	Surgipack Digital Thermometers	Medical Device	Product Defect Correction	Class II	Retail
9/12/2022	ThermoBrite Elite. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
7/12/2022	Invisalign System	Medical Device	Recall	Class II	Hospital
7/12/2022	SHOEBOX Audiometry Standard and Pro systems running iPadOS 16.1 or 16.1.1.	Medical Device	Product Defect Correction	Class II	Consumer
7/12/2022	Vanta Clinician Programmer Application A71200	Medical Device	Product Defect Correction	Class II	Hospital
5/12/2022	Enterprise Imaging XERO Viewer	Medical Device	Product Defect Correction	Class II	Hospital
5/12/2022	Floradix Liquid products	Medicine	Recall	Class III	Retail
5/12/2022	Mahurkar Acute Dual Lumen High Flow (13.5 French) Hemodialysis Catheters (Mahurkar QPlus)	Medical Device	Recall	Class II	Hospital
2/12/2022	18F-Fluorodeoxyglucose	Medicine	Product Defect Alert	Class II	Hospital
2/12/2022	VIDAS Anti-HEV IgM (HEVM). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
1/12/2022	Brilliance iCT and IQon Spectral CT X-Ray system	Medical Device	Product Defect Correction	Class II	Hospital
1/12/2022	PrimeOn Artemis Level 2 Procedure Face Mask w/Earloop - Yellow	Medical Device	Product Defect Alert	Class II	Hospital
30/11/2022	Integre Scan Red Yellow, Integre Scan Yellow and Integre Pro Yellow	Medical Device	Product Defect Correction	Class III	Hospital
30/11/2022	Mupirocin nasal ointment	Medicine	Recall	Class III	Hospital
30/11/2022	ORISE Gel Submucosal Lifting Agent	Medical Device	Recall	Class I	Hospital
29/11/2022	HeartStart Intrepid Monitor/Defibrillators	Medical Device	Product Defect Correction	Class II	Hospital
29/11/2022	Philips Ingenia Elition X, Ingenia Elition S and MR 7700	Medical Device	Product Defect Correction	Class II	Hospital
28/11/2022	Philips Fetal Spiral Electrode	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
28/11/2022	Proshield Level 2 & 3 Surgical Masks and Proshield N95 Respirators	Medical Device	Product Defect Alert	Class II	Hospital
28/11/2022	Y Type Blood/Solution Infusion Set	Medical Device	Recall	Class II	Hospital
25/11/2022	B105P/B125P (B1x5P) and B105M/B125M/B155M (B1x5M) patient monitors	Medical Device	Product Defect Correction	Class II	Hospital
25/11/2022	ENT CDS MATER HEALTH SERVICE	Medical Device	Product Defect Correction	Class II	Hospital
25/11/2022	Oncentra Brachy	Medical Device	Product Defect Correction	Class II	Hospital
25/11/2022	Specific Protein Control Levels 1-3. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
25/11/2022	VITROS Immunodiagnostic Products Intact PTH Reagent Pack. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
24/11/2022	Alinity m Resp-4-Plex AMP Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
24/11/2022	Examination Table Top	Medical Device	Product Defect Correction	Class II	Hospital
24/11/2022	ID-DiaPanel (1-11). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
24/11/2022	INJ198 PRENOXAD 1mg/mL Solution for Injection in a pre-filled syringe (naloxone hydrochloride)	Medicine	Product Defect Alert	Class II	Wholesale
24/11/2022	Sensis, Sensis Vibe Hemo, Sensis Vibe Combo with VD12A software	Medical Device	Product Defect Correction	Class II	Hospital
24/11/2022	V.A.C. Ulta Therapy Unit	Medical Device	Product Defect Correction	Class III	Hospital
24/11/2022	V.A.C. Ulta Therapy Unit	Medical Device	Product Defect Correction	Class III	Hospital
23/11/2022	Aspire Superlite Adjustable Seat Walker	Medical Device	Product Defect Correction	Class II	Consumer
23/11/2022	da Vinci X/Xi SureForm 45 and SureForm 60 Staplers	Medical Device	Product Defect Alert	Class II	Hospital
23/11/2022	VENTANA PD-L1 (SP142) Assay. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
22/11/2022	Philips 12-Lead Chest Lead-set (AAMI/IEC)	Medical Device	Product Defect Correction	Class II	Hospital
22/11/2022	Vliwaktiv Absorbent activated charcoal dressing 10cm x 20cm	Medical Device	Recall	Class II	Hospital
21/11/2022	18F-Fuoroethyl-L-Tyrosine Injection	Medicine	Product Defect Correction	Class III	Hospital

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21/11/2022	Brilliance iCT, CT5000 Ingenuity Plus, CT5000 Ingenuity Pro and Brilliance CT 64 Channel	Medical Device	Product Defect Correction	Class II	Hospital
21/11/2022	Disposable cuffs for tourniquet application	Medical Device	Recall	Class II	Hospital
21/11/2022	M530 OHX, PROvido and Proveo 8 Surgical Microscopes	Medical Device	Product Defect Correction	Class II	Hospital
18/11/2022	Dermalon Monofilament Nylon sutures, Novafil Monofilament Polybutester Suture, Surgilon Braided Nylon suture, Surgipro Monofilament Polypropylene Sutures, Ti-Cron Coated Braided Polyester Suture, Monosof Monofilament Nylon sutures, Sofsilk Coated Braided Silk Suture, Surgidac Uncoated Braided Polyester suture and Surgipro II Monofilament Polypropylene Sutures	Medical Device	Recall	Class II	Hospital
18/11/2022	Endoeye Flex 3d Deflectable Videoscope, LTF-190-10-3D	Medical Device	Product Defect Correction	Class II	Hospital
18/11/2022	Suction Coagulator, foot-controlled (25/case)	Medical Device	Recall	Class II	Hospital
17/11/2022	PDS II (polydioxanone) Suture	Medical Device	Recall	Class II	Hospital
17/11/2022	Power Backup Batteries Flow Family	Medical Device	Recall	Class II	Hospital
17/11/2022	X-CORE 2, Ti Core, Static	Medical Device	Product Defect Correction	Class II	Hospital
16/11/2022	Automated External Defibrillator	Medical Device	Recall	Class I	Retail
16/11/2022	Irradiated femoral head	Biological	Hazard Alert	Class II	Hospital
16/11/2022	The 3M Ranger Blood/Fluid Warming System	Medical Device	Recall	Class II	Hospital
16/11/2022	Vivid Ultrasound Systems with batteries - Vivid S5, Vivid S5 N, Vivid S6, Vivid S6 N, Vivid i, Vivid i N, Vivid q, Vivid q N	Medical Device	Product Defect Correction	Class II	Hospital
15/11/2022	ED-Flow AER & ED-Flow SD AER	Medical Device	Product Defect Correction	Class II	Hospital
15/11/2022	LinkSeq HLA Typing Kits. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
15/11/2022	Vicks VapoRub Xtra Strong 100g	Medicine	Recall	Class II	Consumer
14/11/2022	Syngo.via with VB20, VB30, VB40, VB60 and VB70 software	Medical Device	Product Defect Correction	Class II	Hospital
11/11/2022	Fludeoxyglucose [18F] FDG for injection supplied in a multidose vial	Medicine	Recall	Class I	Hospital

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11/11/2022	TRACOE vario P-Tracheostomy Tube with minimally traumatic insertion system, TRACOE expirc Set vario, TRACOE twist plus P-Tracheostomy Tube with minimally traumatic insertion system and TRACOE expirc Set twist plus	Medical Device	Product Defect Alert	Class II	Hospital
10/11/2022	AQUIOS CL Flow Cytometry System, AQUIOS IMMUNO-TROL, and AQUIOS IMMUNO-TROL Low Cells, AQUIOS IMMUNO-TROL Cells (PLG/Tetra) and AQUIOS IMMUNO-TROL Low Cells (PLG/Tetra). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
10/11/2022	BD Connecta Stopcock with extension tube - 100 cm	Medical Device	Recall	Class II	Hospital
10/11/2022	Philips Incisive CT PIM	Medical Device	Product Defect Correction	Class II	Hospital
9/11/2022	3gAllergy Specific IgE Universal Assay Kit (600T). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
9/11/2022	CAPILLARYS 3 TERA and OCTA. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
9/11/2022	Sanjin Watermelon Frost Insufflation	Medicine	Product Defect Alert	Class II	Consumer
8/11/2022	Human Cornea	Biological	Hazard Alert	Class II	Hospital
8/11/2022	MO-INS-0552 Posterior Lumbar Interbody Fusion (PLIF) T-Handle Cage Inserter	Medical Device	Product Defect Correction	Class III	Hospital
8/11/2022	ReelPass Suture Lasso, 45 CRV Left, ReelPass Suture Lasso, 45 CRV Right and ReelPass Suture Lasso, 90 CRV Straight	Medical Device	Recall	Class II	Hospital
8/11/2022	Straight cup positioner and Curved cup positioner	Medical Device	Recall	Class II	Hospital
8/11/2022	Trilogy 100 portable ventilator devices	Medical Device	Recall	Class II	Hospital
7/11/2022	DBL Vancomycin (vancomycin hydrochloride) 500 mg vial	Medicine	Recall	Class II	Retail
7/11/2022	Exactech Shoulder GPS Impactor Handle	Medical Device	Recall	Class II	Hospital
7/11/2022	Kiwi Vacuum assisted delivery (VAC-6000M and VAC-6000ME)	Medical Device	Product Defect Correction	Class II	Hospital
4/11/2022	GEHC T2100-ST Treadmill	Medical Device	Product Defect Correction	Class II	Hospital
3/11/2022	Aero Chrome Breathable High Performance Surgical Gown with Blue Huck Towel, L	Medical Device	Recall	Class II	Hospital
3/11/2022	FDG	Medicine	Recall	Class II	Hospital

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3/11/2022	Numerous antibiotic and oncology compounded medicines	Medicine	Product Defect Alert	Class II	Hospital
3/11/2022	PLS Set, PLS Set Plus and HIT Set PLS Plus	Medical Device	Product Defect Correction	Class I	Hospital
2/11/2022	Anti-HSV-1/2 Pool ELISA (IgM). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
2/11/2022	Detox + Deloat	Medicine	Recall	Class II	Consumer
1/11/2022	Alcon Custom PAK	Medical Device	Product Defect Correction	Class II	Hospital
31/10/2022	da Vinci X/Xi Fenestrated Bipolar Forceps	Medical Device	Recall	Class II	Hospital
31/10/2022	Omnipod DASH Personal Diabetes Manager (PDM)	Medical Device	Product Defect Alert	Class II	Consumer
31/10/2022	Polaris 600 (MedView) Operating Light	Medical Device	Product Defect Correction	Class III	Hospital
31/10/2022	ReSolve Locking Drainage Catheter	Medical Device	Product Defect Correction	Class II	Hospital
28/10/2022	FLOCARE INFINITY ENTERAL FEEDING PUMP	Medical Device	Product Defect Correction	Class II	Hospital
28/10/2022	Philips Respironics – Sleep & Respiratory Care Devices	Medical Device	Product Defect Correction	Class III	Consumer
27/10/2022	DreamWear Full Face Mask, DreamWisp Nasal Mask, Wisp and Wisp Youth Nasal Mask and Amara View Full Face Mask	Medical Device	Product Defect Correction	Class II	Consumer
26/10/2022	NEO-fit device	Medical Device	Recall	Class II	Hospital
26/10/2022	StandTall Sheath Extender	Medical Device	Recall	Class III	Wholesale
25/10/2022	3M Steri-Drape Surgical Drapes	Medical Device	Recall	Class II	Hospital
25/10/2022	Coseal Surgical Sealant 2ml, 4ml and 8ml.	Medical Device	Product Defect Correction	Class III	Hospital
21/10/2022	HeartWare (HVAD) System	Medical Device	Hazard Alert	Class I	Hospital
21/10/2022	VITROS XT 3400 and VITROS XT 7600 Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
20/10/2022	Alinity m System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
19/10/2022	T19 Beersheba. Dried medicinal cannabis flower	Medicine	Recall	Class III	Consumer
18/10/2022	Technetium-99m HDP	Medicine	Recall	Class II	Hospital
13/10/2022	MIM Encore software	Medical Device	Product Defect Correction	Class II	Hospital

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13/10/2022	Thermo Scientific AcroMetrix HCVRNA+. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Wholesale
12/10/2022	VITROS Immunodiagnostic Products HIV Combo Reagent Pack and VITROS Immunodiagnostic Products HIV Combo Calibrators. An in vitro medical device (IVD)	Medical Device	Recall	Class II	Hospital
11/10/2022	Amplitude Platform with the TaqPath COVID-19 HT Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
11/10/2022	BD Trucount Tubes for Flow Cytometry, BD Leucocount Kit for Flow Cytometry/cell counts, BD Multitest 6-Color TBNK Reagent for Flow cytometry/cell counts and BD Stem Cell Enumeration Kit in Flow Cytometry. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
11/10/2022	BME SPEED Implant Kit 15X12mm	Medical Device	Recall	Class II	Hospital
10/10/2022	ARTIS pheno systems	Medical Device	Product Defect Correction	Class II	Hospital
7/10/2022	DASATINIB DR. REDDY'S dasatinib 50 mg film coated tablet blister pack	Medicine	Recall	Class II	Consumer
7/10/2022	Ransel. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
7/10/2022	Surdial X	Medical Device	Product Defect Correction	Class II	Hospital
7/10/2022	Synapse PACS Version 5.x	Medical Device	Product Defect Correction	Class II	Hospital
7/10/2022	Teledyne Oxygen sensor R-22A	Medical Device	Recall	Class II	Hospital
5/10/2022	Chloradet 5L and Chloradet 20L	Medical Device	Recall	Class II	Retail
5/10/2022	Endo Stitch V-Loc 180 Absorbable Reload and Endo Stitch V-Loc PBT Non-Absorbable Reload	Medical Device	Recall	Class II	Hospital
5/10/2022	Insertion Kit for use with SENSATION PLUS 8Fr. 50cc IABC and SENSATION PLUS 8Fr. 50cc IAB Catheter	Medical Device	Product Defect Alert	Class II	Hospital
5/10/2022	Novation Crown Cup GXL Liner	Medical Device	Hazard Alert	Class II	Hospital
4/10/2022	ImmunoCAP Allergen f76. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
30/09/2022	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Recall	Class II	Hospital

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30/09/2022	Susi Eves Tonsil Snare	Medical Device	Recall	Class II	Hospital
30/09/2022	TM80 & N-Series & BeneVision Central Monitoring System	Medical Device	Product Defect Correction	Class II	Hospital
29/09/2022	IH-500. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
28/09/2022	MicroVenton Inc WEB Detachment Controller	Medical Device	Recall	Class II	Hospital
28/09/2022	Tc99m MAA	Medicine	Product Defect Alert	Class II	Hospital
27/09/2022	Atellica CH 930 Analyzer - Lithium and Lithium 2. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
27/09/2022	PROVIVE MCT-LCT INJ. 1% 20ML GV	Medicine	Recall	Class III	Retail
26/09/2022	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Recall	Class II	Hospital
26/09/2022	KH600 Mobile Shower Trolley	Medical Device	Product Defect Correction	Class II	Hospital
26/09/2022	Li-ion Battery Model 100 (AutoPulse brand) used with ZOLL's AutoPulse Resuscitation System	Medical Device	Recall	Class II	Hospital
26/09/2022	TurmeriX Powder 360gm	Medicine	Recall	Class III	Wholesale
23/09/2022	Floradix Liquid Magnesium 250 mL	Medicine	Recall	Class III	Retail
23/09/2022	FuturePAD Tablet USB Power Adapter used with the Philips Lumify Ultrasound System	Medical Device	Product Defect Correction	Class III	Hospital
21/09/2022	MR Patient Care Portal 5000	Medical Device	Product Defect Correction	Class II	Hospital
20/09/2022	F18-DCFPyL Injection	Medicine	Product Defect Alert	Class II	Hospital
20/09/2022	IH-QC8. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
20/09/2022	Xpert EV. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
16/09/2022	DOXORUBICIN 46MG IN SYRINGE (TERUMO) FOR INTRAVENOUS USE	Medicine	Recall	Class II	Hospital
15/09/2022	AMSORB PLUS PREFILLED G-CAN 1.0L — CO2 Absorbers	Medical Device	Product Defect Correction	Class I	Hospital
15/09/2022	PE-Conjugated Goat Anti-Human IgG. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
15/09/2022	Philips IntelliVue Monitors with Nellcor SpO2 Boards	Medical Device	Product Defect Correction	Class II	Hospital
15/09/2022	Syntel Silicone Over the Wire Embolectomy Catheter	Medical Device	Recall	Class II	Wholesale

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14/09/2022	Alinity hq Analyzer and Alinity hs Slide Maker Stainer Module. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
14/09/2022	Anti-GM1 Autoantibodies ELISA. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
14/09/2022	HeartWare Ventricular Assist Device (HVAD) system Power Sources and Monitor Data Cables for Controller Port Bent Pins	Medical Device	Product Defect Correction	Class II	Hospital
14/09/2022	PRIMOVISt disodium gadoxetate 181.43 mg/mL (0.25M) 10mL injection pre-filled syringe	Medicine	Product Defect Alert	Class II	Hospital
13/09/2022	Pinnacle3 Radiation Therapy Planning System	Medical Device	Product Defect Correction	Class II	Hospital
8/09/2022	Alinity m System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
7/09/2022	ISO-GARD FILTER	Medical Device	Recall	Class II	Hospital
7/09/2022	VERITAS Advanced Infusion Packs	Medical Device	Recall	Class II	Hospital
5/09/2022	KM8020 III Karma Eagle Wheelchair	Medical Device	Product Defect Correction	Class II	Consumer
5/09/2022	Micro-X Rover Mobile X-Ray Unit	Medical Device	Product Defect Correction	Class II	Hospital
2/09/2022	N Antiserum to Human IgG 2mL & 5mL. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
1/09/2022	Codman CereLink ICP Monitor (ICP Monitor)	Medical Device	Recall	Class II	Hospital
1/09/2022	IMMAGE Immunochemistry Systems - Rheumatoid Factor. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
31/08/2022	Catheter Pack, Eye Toilet Dressing Pack, Single Swab Stick Orange 8 and Syringe 50 mL Bulb Irrigation Mini Pack	Medical Device	Product Defect Correction	Class III	Hospital
31/08/2022	EVOLVE Stem 7.5mm +2 and EVOLVE Stem 9.5mm +4	Medical Device	Recall	Class II	Hospital
31/08/2022	TRIKAFTA elexacaftor / tezacaftor / ivacaftor and ivacaftor 100mg/50mg/75mg and 150mg film-coated tablet blister pack	Medicine	Product Defect Alert	Class III	Consumer
30/08/2022	ARveo8, ARveo, M530 OHX and PROvido Surgical Microscopes	Medical Device	Product Defect Correction	Class II	Hospital
29/08/2022	Rapid-Guard Immune Boost	Medicine	Recall	Class II	Retail

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24/08/2022	Bio-Tenodesis Screw, Bio-Interference Screw w/disp shth, Bio-Tenodesis Screw 5.5 mm	Medical Device	Recall	Class III	Hospital
24/08/2022	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Recall	Class II	Hospital
24/08/2022	Puritan Bennett 500 series ventilators	Medical Device	Product Defect Correction	Class II	Hospital
23/08/2022	Artis system	Medical Device	Product Defect Correction	Class II	Hospital
23/08/2022	Dimension Magnesium (MG) Flex reagent cartridge. An in vitro diagnostic device	Medical Device	Recall	Class II	Hospital
23/08/2022	Haemonetics Platelet Storage Bags	Medical Device	Recall	Class II	Hospital
23/08/2022	VIDAS 3 system. An in vitro diagnostic device	Medical Device	Product Defect Correction	Class II	Hospital
22/08/2022	Catheter Kit	Medical Device	Recall	Class II	Hospital
22/08/2022	GSS TERMINAL UNITS	Medical Device	Recall	Class II	Hospital
22/08/2022	STERRAD 100NX Sterilization System	Medical Device	Product Defect Correction	Class III	Hospital
19/08/2022	IMMULITE 2000 and IMMULITE 2000 XPI Thyroid Stimulating Immunoglobulins (TSI). An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
18/08/2022	Everest MI XT Inner and Outer Dilators	Medical Device	Recall	Class II	Hospital
18/08/2022	Zoledronic Acid SUN zoledronic acid 5 mg / 100 mL injection solution vial	Medicine	Recall	Class II	Retail
17/08/2022	Philips SmartPath to dStream and Ingenia systems	Medical Device	Product Defect Correction	Class II	Hospital
17/08/2022	QMS Tacrolimus Calibrator. An in vitro medical diagnostic device.	Medical Device	Product Defect Correction	Class II	Hospital
16/08/2022	BiPAP A40	Medical Device	Recall	Class I	Consumer
16/08/2022	D-Touch Disposable Medical Facemasks	Medical Device	Product Defect Alert	Class II	Retail
16/08/2022	Hikma Lorazepam Injection, USP 2mg/ml	Medicine	Recall	Class III	Hospital
15/08/2022	Anti-FITC-AP CISH Accessory Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
15/08/2022	Fixed Core Wire Guide and Roadrunner Hydrophilic Wire Guide	Medical Device	Recall	Class II	Hospital
12/08/2022	CoughAssist E70 International (CoughAssist 2)	Medical Device	Product Defect Alert	Class III	Consumer

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12/08/2022	Regulator Click Style Medical Oxygen 25 L/min 2 Self Seal SIS, 1 Hose Barb	Medical Device	Product Defect Correction	Class III	Wholesale
11/08/2022	F18-Fludeoxyglycose Injection (FDG)	Medicine	Product Defect Correction	Class II	Hospital
10/08/2022	iChemVELOCITY Strips. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
9/08/2022	18F-Fludeoxyglucose (FDG)	Medicine	Recall	Class I	Hospital
9/08/2022	Philips EPIQ Ultrasound System	Medical Device	Product Defect Correction	Class II	Hospital
9/08/2022	TIP CAPS, SELF-RIGHTING LUER SLIP, (DISCPAC, 25 Pack) YELLOW, STERILE	Medical Device	Recall	Class II	Hospital
8/08/2022	Elm dosing pipette	Medical Device	Product Defect Correction	Class III	Hospital
5/08/2022	GELITA-SPON Product Range	Medical Device	Recall	Class II	Hospital
4/08/2022	Corvocet Biopsy System	Medical Device	Recall	Class II	Hospital
4/08/2022	Nexxis encoders	Medical Device	Product Defect Correction	Class I	Wholesale
3/08/2022	Centricity systems	Medical Device	Product Defect Correction	Class I	Hospital
3/08/2022	XYLOCAINE 2% with ADRENALINE 1:200000 Multi Dose VIAL (with Preservative) pack of 10x20ml	Medicine	Recall	Class II	Hospital
2/08/2022	Remel RapID NF Plus System. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
1/08/2022	ORIGIO Sequential Cleave	Medical Device	Recall	Class I	Hospital
29/07/2022	ENT sinus suction tubes	Medical Device	Recall	Class II	Hospital
29/07/2022	EverFlex Self-Expanding Peripheral Stent with Entrust Delivery System	Medical Device	Product Defect Correction	Class II	Hospital
29/07/2022	Giraffe Bedded Warmers and Panda iRes Warmers.	Medical Device	Product Defect Correction	Class I	Hospital
27/07/2022	Getinge ED-Flow AER and the Getinge ED Flow SD AER	Medical Device	Product Defect Correction	Class II	Hospital
26/07/2022	AMSORB PLUS PREFILLED G-CAN 1.0L (GE part# 2105489-003)	Medical Device	Recall	Class II	Hospital
26/07/2022	NUCLISENS Magnetic Silica. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
26/07/2022	Technetium-99m HDP	Medicine	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
26/07/2022	Zenex, Assurity, and Endurity pacemakers with SBP PMH Pre-Molded Header (SBP PMH)	Medical Device	Hazard Alert	Class I	Hospital
22/07/2022	Femoral Head Allograft (R) Irradiated	Biological	Hazard Alert	Class II	Hospital
22/07/2022	Roadrunner PC Hydrophilic Wire Guide and RoadRunner UniGlide Hydrophilic Wire Guide	Medical Device	Recall	Class I	Hospital
21/07/2022	BD PhaSeal Y-Site Connector C80	Medical Device	Recall	Class III	Hospital
21/07/2022	DigitalDiagnost C50 and DigitalDiagnost C50 1.1	Medical Device	Product Defect Correction	Class II	Hospital
21/07/2022	Vanta Implantable Neurostimulator (INS) and Vanta Clinician Programmer Application (CP App)	Medical Device	Product Defect Correction	Class II	Hospital
20/07/2022	D-100 HbA1c Elution Buffer A. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Alert	Class III	Hospital
20/07/2022	EVOLVE TRIAD Plate Cutter	Medical Device	Recall	Class II	Hospital
20/07/2022	Pregnosis Digital 1 test. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class III	Retail
20/07/2022	Servo-u, Servo-n and Servo-air ventilator systems	Medical Device	Product Defect Correction	Class I	Hospital
20/07/2022	The BD Veritor Plus Analyser. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Retail
20/07/2022	Urine Collector Bag	Medical Device	Recall	Class III	Consumer
19/07/2022	ChemoLock Port	Medical Device	Recall	Class II	Hospital
19/07/2022	TaperFit Stem Size 0 38mm Offset 12/14 TAPER	Medical Device	Hazard Alert	Class II	Hospital
18/07/2022	Atellica CH 930 Analyser - Iron_2 Assay. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
18/07/2022	cobas pure e 402 analytical unit and cobas e 801 analytical unit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
18/07/2022	da Vinci EndoWrist Clip Applier Instruments	Medical Device	Product Defect Correction	Class II	Hospital
15/07/2022	3M Clarity Aligners and Clarity Retainers	Medical Device	Product Defect Correction	Class II	Hospital
14/07/2022	HAMILTON-C6 ventilator	Medical Device	Product Defect Correction	Class II	Hospital
14/07/2022	Unima Evolution Screw	Medical Device	Recall	Class III	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
13/07/2022	AXIOM Sensis XP, Sensis / Sensis Lite or Sensis Vibe Combo	Medical Device	Product Defect Correction	Class II	Hospital
13/07/2022	Centricity Universal Viewer and Universal Viewer Software	Medical Device	Product Defect Correction	Class II	Hospital
12/07/2022	Canon Ultrasound Stress Echo option (USSE-AI900A)	Medical Device	Product Defect Correction	Class II	Hospital
12/07/2022	HeartWare Ventricular Assist Device (HVAD) Battery	Medical Device	Product Defect Correction	Class I	Hospital
12/07/2022	Philips Efficia CMS200 Central Monitoring Station and the Efficia CM100, CM10, CM120, CM12 and CM150.	Medical Device	Product Defect Correction	Class I	Hospital
12/07/2022	Supple Peri Guard Repair Patch	Medical Device	Product Defect Correction	Class III	Hospital
11/07/2022	AR-1616-L and AR-1616-X Finger Trap – Large and X-Large Sizes	Medical Device	Recall	Class III	Hospital
11/07/2022	Medicina ENfit reusable enteral syringes & Medicina single-use and reusable oral tip syringes	Medical Device	Recall	Class III	Consumer
11/07/2022	Pressure Plates used in Level 1 Fast Fluid Flow Fluid Warmers	Medical Device	Product Defect Alert	Class I	Hospital
11/07/2022	Tibbs Arterial Cannula set of 3 / Tibbs Arterial Cannula Large Cone	Medical Device	Recall	Class I	Hospital
8/07/2022	Boston Scientific Model 3120 ZOOM programmers	Medical Device	Product Defect Correction	Class II	Hospital
8/07/2022	Dochem Face Mask and Dochem Face Mask Type IIR	Medical Device	Product Defect Alert	Class II	Retail
8/07/2022	Slade Health compounded medicines containing one of the following S8 medicines: Fentanyl, Hydromorphone, Ketamine, Morphine, Oxycodone, Pethidine	Medicine	Product Defect Alert	Class III	Hospital
7/07/2022	Covidien Shiley Hi-Contour and Low-Contour Oral/Nasal Tracheal Tubes Cuffed.	Medical Device	Recall	Class II	Hospital
7/07/2022	Revogene. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
6/07/2022	Phadia 2500E, Phadia 2500EE, Phadia 5000E and Phadia 5000E+E. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
6/07/2022	Servo-air with High mobile cart	Medical Device	Product Defect Correction	Class II	Hospital
5/07/2022	ATTUNE Measured Sizing & Rotation Guide Instrument	Medical Device	Recall	Class II	Hospital

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1/07/2022	HLS Set Advanced 7.0 with BIOLINE Coating and HLS Set Advanced 5.0 with BIOLINE Coating	Medical Device	Product Defect Alert	Class I	Hospital
1/07/2022	Lucas' Papaw Ointment	Medicine	Recall	Class II	Consumer
1/07/2022	Minisart syringe filters	Medical Device	Product Defect Correction	Class II	Hospital
29/06/2022	Defigard Touch 7 Defibrillator and Pacemaker	Medical Device	Product Defect Correction	Class I	Hospital
29/06/2022	PHARMACY ACTION Low Dose Aspirin 100mg tablet blister pack	Medicine	Product Defect Alert	Class III	Retail
28/06/2022	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Recall	Class II	Hospital
28/06/2022	ID-DiaPanel Plus 6. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Alert	Class II	Hospital
27/06/2022	Femoral Head Allograft - (R) Irradiated	Biological	Hazard Alert	Class II	Hospital
27/06/2022	PELORIS instruments with the RemoteCare solution installed. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
24/06/2022	ARTIS pheno with Large Display	Medical Device	Product Defect Correction	Class II	Hospital
24/06/2022	Cholesterol (CHOL). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Alert	Class II	Hospital
24/06/2022	CT, PET, or NM table	Medical Device	Product Defect Correction	Class II	Hospital
23/06/2022	Cholestech LDX System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Retail
23/06/2022	Philips V680 Ventilator	Medical Device	Product Defect Correction	Class I	Hospital
23/06/2022	Sample packs (30s)- Bretaris Genuair 1 x 30 dose inhalers	Medicine	Recall	Class III	Hospital
21/06/2022	3Shape Implant Studio software versions from 2.17.3.0 to R1.2.15 (2.17.3.0 and R1.2.15 included)	Medical Device	Product Defect Correction	Class II	Hospital
21/06/2022	Medtronic Cobalt and Crome Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds)	Medical Device	Recall	Class I	Hospital
21/06/2022	Medtronic Cobalt XT, Cobalt and Crome Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds)	Medical Device	Hazard Alert	Class I	Hospital
20/06/2022	Medi-Trace Cadence Defibrillation Electrodes	Medical Device	Product Defect Correction	Class II	Hospital

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20/06/2022	Sensis and Sensis Vibe Combo systems with software version VD12A	Medical Device	Product Defect Correction	Class II	Hospital
20/06/2022	Triathlon Solid CR Tibial Insert Trials	Medical Device	Recall	Class II	Hospital
20/06/2022	VASERlipo System	Medical Device	Product Defect Correction	Class II	Hospital
20/06/2022	VENTANA HE 600 System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
17/06/2022	Alinity c Hemoglobin A1c Reagent Kit (HbA1c) - An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
17/06/2022	Calibration Serum Level 3 (CAL2351). An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
17/06/2022	DURAClone B27 Reagent Kit	Medical Device	Product Defect Correction	Class II	Hospital
17/06/2022	Leica CM1950 and Leica CM3050 S. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
17/06/2022	nordicBrainEx	Medical Device	Product Defect Correction	Class II	Hospital
16/06/2022	Aisys CS2 Anaesthesia Systems: P/N: 1011-9050-000 – GTIN: 00840682102292	Medical Device	Product Defect Correction	Class II	Hospital
16/06/2022	Avance CS2 and Avance CS2 Pro Anaesthesia Systems: P/N:1009-9050-000 - GTIN: 00840682102322	Medical Device	Product Defect Correction	Class II	Hospital
16/06/2022	Merlin Patient Care System (PCS) Software Model 3330 25.3.X or earlier and Merlin.net MN 5000 v11.7 Remote Monitoring Application	Medical Device	Product Defect Correction	Class II	Hospital
14/06/2022	Corflo J tube, MIC-KEY GJ tube and Corflo PEG Kits	Medical Device	Product Defect Correction	Class II	Hospital
9/06/2022	Anti-IA2 ELISA (IgG). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
9/06/2022	Heater Unit HU 35, 230 V	Medical Device	Product Defect Correction	Class II	Hospital
9/06/2022	The Alinity ci-series software versions 3.3.3 and lower. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
8/06/2022	All Carestation 750/750c Anesthesia Delivery Systems	Medical Device	Product Defect Correction	Class II	Hospital
8/06/2022	Centricity Universal Viewer Zero Footprint Client Versions 6.0 SP6 through SP11.4	Medical Device	Product Defect Correction	Class II	Hospital
8/06/2022	Disposable Pedicle Access Needle	Medical Device	Product Defect Correction	Class II	Hospital

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8/06/2022	Iodine 131 Capsule	Medicine	Recall	Class II	Hospital
8/06/2022	Palindrome Precision Chronic Haemodialysis Catheters and Palindrome Chronic Haemodialysis Catheters	Medical Device	Recall	Class II	Hospital
7/06/2022	Ambu VivaSight 2 DLT	Medical Device	Recall	Class II	Hospital
7/06/2022	CoolSculpting-branded parallel plate applicators (CoolCore, CoolCurve, CoolCurve+, CoolMax, and CoolFit)	Medical Device	Recall	Class II	Hospital
6/06/2022	Arjo Citadel Plus Bed Frame with Powerdrive	Medical Device	Product Defect Correction	Class II	Hospital
6/06/2022	Citadel Patient Care System	Medical Device	Product Defect Correction	Class II	Hospital
6/06/2022	Philips ProxiDiagnost N90 and DigitalDiagnost.	Medical Device	Product Defect Correction	Class II	Hospital
6/06/2022	'YelloPort Elite Universal Seal' port access system for use in Minimally Invasive Surgery	Medical Device	Product Defect Correction	Class III	Hospital
3/06/2022	CORTAK 2 Enteral Access System (EAS)	Medical Device	Product Defect Correction	Class I	Hospital
3/06/2022	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Recall	Class II	Hospital
2/06/2022	Alinity m System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
2/06/2022	TeneoTreatment Centre	Medical Device	Product Defect Correction	Class II	Retail
1/06/2022	All MiniMed 640G, 670G, 700, 770G, and 780G Insulin Pumps	Medical Device	Product Defect Correction	Class I	Consumer
1/06/2022	ARTIS icono biplane	Medical Device	Product Defect Correction	Class II	Hospital
1/06/2022	GreenLight HPS EA Laser Fiber	Medical Device	Recall	Class III	Hospital
1/06/2022	Poole Sucker with Green Handle D/P 25CM	Medical Device	Recall	Class II	Hospital
1/06/2022	Vari-Flex Junior	Medical Device	Product Defect Correction	Class II	Consumer
31/05/2022	#1 MAC F/O LARYNGOSCOPE F/O Laryngoscope Set-MAC and F/O Laryngoscope Set-MAC W/LED	Medical Device	Recall	Class III	Hospital
27/05/2022	Artis zeego / Artis Q zeego	Medical Device	Product Defect Correction	Class II	Hospital
27/05/2022	Navbit Sprint - Lateral	Medical Device	Product Defect Correction	Class III	Hospital
27/05/2022	Nucleus 7 Sound Processor (CP1000, CP1001)	Medical Device	Product Defect Correction	Class III	Consumer
27/05/2022	Philips DreamStation BiPAP AVAPS30	Medical Device	Product Defect Correction	Class III	Hospital

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27/05/2022	Philips PageWriter TC30/50/70 Cardiographs	Medical Device	Product Defect Correction	Class III	Hospital
27/05/2022	SP-50 slidemaker-stainer. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
26/05/2022	BiliLux - Spring Arm	Medical Device	Product Defect Correction	Class II	Hospital
25/05/2022	1688 Camera Control Unit (CCU)	Medical Device	Product Defect Correction	Class II	Hospital
25/05/2022	BD Connecta Plus3 stopcocks contained within Multigate Custom Procedure Packs	Medical Device	Recall	Class II	Hospital
23/05/2022	Medtronic NIM CONTACT Reinforced EMG Endotracheal Tube and NIM Standard Reinforced EMG Endotracheal Tube	Medical Device	Product Defect Correction	Class I	Hospital
20/05/2022	18 F-fluoro-ethyl-tyrosine (18F-FET)	Medicine	Product Defect Correction	Class III	Hospital
20/05/2022	Safe-T-Centesis Kit 6FR x 16CM	Medical Device	Recall	Class I	Hospital
19/05/2022	ABL800 Basic and ABL8XX FLEX. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class I	Hospital
19/05/2022	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Product Defect Alert	Class II	Hospital
19/05/2022	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Product Defect Alert	Class II	Hospital
19/05/2022	Molnlycke Procedure Packs – Various containing component Blink Medical Sternal Retractor	Medical Device	Recall	Class I	Hospital
19/05/2022	Mueller-Hinton Broth, cation-adjusted. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
18/05/2022	All CARESCAPE Central Station V2 units	Medical Device	Product Defect Correction	Class II	Hospital
18/05/2022	Volista StandOp SF & DF cupolas	Medical Device	Product Defect Correction	Class II	Hospital
17/05/2022	GORE BIO-A Tissue Reinforcement devices	Medical Device	Recall	Class III	Hospital
17/05/2022	Scarlet AC-T, the Cervical Secured Lordotic Cage - SCA-AC LS 06-S	Medical Device	Recall	Class II	Hospital
17/05/2022	t:slim X2 Insulin Pump	Medical Device	Product Defect Correction	Class II	Consumer
16/05/2022	E.SPINE-Reduction Pedicle Screw-ø6mm-Length 45mm and E.SPINE-Pedicle Screw-ø6mm-Length 45mm	Medical Device	Recall	Class II	Wholesale
16/05/2022	The Alinity s System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital

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16/05/2022	Ultra-High Molecular Weight Polyethylene (UHMWPE) Liners (Optetrak/Optetrak Logic Knee & Vantage Ankle)	Medical Device	Hazard Alert	Class II	Hospital
13/05/2022	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Recall	Class II	Hospital
13/05/2022	HbA1c. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
13/05/2022	N95 Particulate Respirator N95 FT-N058	Medical Device	Product Defect Alert	Class II	Retail
13/05/2022	Philips V60/V60 Plus/V680 Ventilator	Medical Device	Product Defect Alert	Class I	Hospital
13/05/2022	Sentinel Diagnostics Copper and Controls. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
13/05/2022	The Alinity h-series. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
13/05/2022	The BD Connecta products	Medical Device	Recall	Class II	Hospital
12/05/2022	EEA Autosuture Circular Stapler with DST Series Technology, 25mm	Medical Device	Recall	Class II	Hospital
12/05/2022	Nester Embolization Microcoil and Tornado Embolization Microcoil	Medical Device	Recall	Class II	Hospital
12/05/2022	St Knee Procedure Pack containing BD Plastipak 50mL Syringe with Luer-Lok Tip.	Medical Device	Product Defect Correction	Class II	Hospital
12/05/2022	TEG Hemostasis System Functional Fibrinogen Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
12/05/2022	Various procedure packs containing BD Plastipak 50mL Syringe with Luer-Lok Tip	Medical Device	Product Defect Correction	Class II	Hospital
11/05/2022	Medfusion syringe pump	Medical Device	Product Defect Correction	Class I	Hospital
11/05/2022	Swisse Beauty Collagen Glow Gummies	Medicine	Recall	Class II	Consumer
10/05/2022	BiPAP A40 Pro & BiPAP A40 EFL	Medical Device	Product Defect Correction	Class III	Hospital
10/05/2022	Fentanyl GH 100mcg/2mL	Medicine	Product Defect Alert	Class I	Retail
6/05/2022	Amplitude Platform with TagPath COVID-19 HT Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
6/05/2022	PainChek	Medical Device	Product Defect Correction	Class III	Hospital
6/05/2022	Reliance Synergy Washer/Disinfector	Medical Device	Product Defect Correction	Class II	Hospital

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6/05/2022	TruSight Cystic Fibrosis Library Prep. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
5/05/2022	Argyle Fistula Cannulas with Anti-reflux Valve (15G/30mm)	Medical Device	Recall	Class II	Hospital
5/05/2022	Promed Level 1 surgical face masks with ties	Medical Device	Product Defect Alert	Class II	Hospital
4/05/2022	Avance CS2 and Avance CS2 Pro anesthesia devices	Medical Device	Product Defect Correction	Class II	Hospital
4/05/2022	HERZUMA trastuzumab (rch) 440 mg powder for injection for intravenous infusion vial with diluent	Medicine	Product Defect Correction	Class III	Hospital
4/05/2022	The HeartWare HVAD System	Medical Device	Hazard Alert	Class I	Hospital
3/05/2022	2XP SPF50+ BRONZE PROTECT SUNSCREEN LOTION	Medicine	Recall	Class II	Consumer
3/05/2022	Argon Medical Devices Coaxial Introducer Needle	Medical Device	Product Defect Correction	Class III	Hospital
3/05/2022	Medtronic Cobalt and Crome Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds)	Medical Device	Hazard Alert	Class II	Hospital
3/05/2022	Philips Incisive CT	Medical Device	Product Defect Correction	Class II	Hospital
2/05/2022	Cardioblate Gemini-s Irrigated RF Surgical Ablation System	Medical Device	Product Defect Correction	Class II	Hospital
2/05/2022	MONOPLUS SUTURE	Medical Device	Recall	Class II	Hospital
29/04/2022	CM320-Series Washer Disinfector	Medical Device	Product Defect Correction	Class II	Hospital
29/04/2022	Flexible Endoscopes with single channel and attached T Luer	Medical Device	Product Defect Correction	Class II	Hospital
29/04/2022	Purist Australian - Mask, medical single use	Medical Device	Product Defect Alert	Class II	Retail
28/04/2022	9100-Series Washer-Disinfector	Medical Device	Product Defect Correction	Class II	Hospital
28/04/2022	CARESCAPE R860, Engström Carestation and Engström PRO	Medical Device	Product Defect Correction	Class II	Hospital
28/04/2022	Gemini Disposable Surgical Masks	Medical Device	Product Defect Alert	Class II	Hospital
28/04/2022	IntelePACS	Medical Device	Product Defect Correction	Class II	Hospital
28/04/2022	METHOTREXATE 65MG IN SYRINGE (TERUMO) FOR INTRAVENOUS USE	Medicine	Recall	Class II	Hospital
27/04/2022	AST-ST03 TEST KIT and AST-YS08 TEST KIT. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital

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27/04/2022	Control LQ COVID-19 IgG + IgM. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
27/04/2022	Negative Pressure Wound Therapy devices	Medical Device	Product Defect Correction	Class II	Hospital
27/04/2022	VIDAS CMV IgM. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
26/04/2022	Baby Bum Mineral SPF50+ Lotion	Medicine	Recall	Class II	Consumer
26/04/2022	Cancer Council Sensitive Sunscreen SPF50+ 110mL (Tube) and Cancer Council Sensitive Sunscreen SPF50+ 200mL (Pump)	Medicine	Recall	Class II	Consumer
26/04/2022	Humid-Vent Flex Tube	Medical Device	Recall	Class I	Hospital
26/04/2022	PICO50 Arterial Blood Sampler. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
26/04/2022	SPF 50+ Lotion Spray Coconut Beach 200ml	Medicine	Recall	Class II	Consumer
22/04/2022	ACCUPRIL (quinapril hydrochloride) 5/10/20 mg tablets	Medicine	Recall	Class II	Retail
22/04/2022	AXIOM Sensis XP or Sensis/Sensis Lite with VC12M software	Medical Device	Product Defect Correction	Class II	Hospital
22/04/2022	iMRX System	Medical Device	Product Defect Correction	Class II	Hospital
22/04/2022	Philips Ingenia Elition X, Ingenia Elition S	Medical Device	Product Defect Correction	Class II	Hospital
22/04/2022	Sara Plus floor lifts	Medical Device	Product Defect Correction	Class II	Hospital
21/04/2022	EasyScreen Respiratory Pathogen Detection Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
21/04/2022	Nivea Sun Protect and Moisture Lotion SPF 30 200ml	Medicine	Recall	Class II	Consumer
21/04/2022	OOK SNOW ALL	Medical Device	Product Defect Correction	Class II	Hospital
20/04/2022	Getinge Flow-c	Medical Device	Product Defect Correction	Class II	Hospital
20/04/2022	MiSeqDx instrument and NextSeq 550Dx instrument. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
19/04/2022	Molnlycke Procedure Packs – Various containing component Sol-MTM Blunt Fill Needle within Molnlycke Procedure Packs	Medical Device	Product Defect Correction	Class III	Hospital

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19/04/2022	Philips Azurion R2.2 and R2.2.1	Medical Device	Product Defect Correction	Class II	Hospital
19/04/2022	Stress Relief	Medicine	Recall	Class I	Consumer
14/04/2022	18F-Fludeoxyglucose	Medicine	Product Defect Correction	Class II	Hospital
14/04/2022	ARTIS icono biplane and ARTIS icono floor	Medical Device	Product Defect Correction	Class II	Hospital
14/04/2022	DBL VANCOMYCIN vancomycin (as hydrochloride) 500mg powder for injection vial	Medicine	Recall	Class II	Hospital
13/04/2022	ABS6090 AEROBURN PE Burn Sheets, 60 cm x 90 cm	Medical Device	Recall	Class II	Consumer
13/04/2022	Plastipak 50ml Syringes	Medical Device	Product Defect Correction	Class II	Hospital
12/04/2022	ACUSON 9VE4 transducer	Medical Device	Recall	Class II	Hospital
12/04/2022	AV-Set ONLINEPlus 5008-R	Medical Device	Recall	Class II	Hospital
12/04/2022	Easy Grip FLO	Medical Device	Recall	Class II	Hospital
12/04/2022	HeartWare Ventricular Assist Device (HVAD) system	Medical Device	Product Defect Correction	Class II	Hospital
12/04/2022	Medihood McMonty Device and Hood	Medical Device	Product Defect Correction	Class II	Hospital
12/04/2022	Percept PC BrainSense	Medical Device	Product Defect Alert	Class II	Hospital
12/04/2022	Universal Plus Laparoscopic Electrodes	Medical Device	Recall	Class II	Hospital
11/04/2022	Draeger Australia Pty Infinity CentralStation (ICS)	Medical Device	Product Defect Correction	Class II	Hospital
11/04/2022	Melobic 15 (meloxicam 15mg) tablet blister pack	Medicine	Recall	Class II	Retail
11/04/2022	MetaFix Collared Stem Size 7 and MetaFix Collarless Stem Size 3	Medical Device	Recall	Class III	Hospital
8/04/2022	fabian HFOi ventilators with software version older than 5.2.1	Medical Device	Product Defect Correction	Class II	Hospital
8/04/2022	Femoral Head (R) MC Small - Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
8/04/2022	Surgical Face Mask Level 2	Medical Device	Product Defect Alert	Class II	Hospital
6/04/2022	NeoLynx v4.2 IVD, NeoLynx v4.1 IVD and IonLynx v4.2 IVD. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
5/04/2022	Alinity i Homocysteine Reagent Kit, An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Alert	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
5/04/2022	Auralis pump	Medical Device	Product Defect Correction	Class III	Consumer
4/04/2022	EPIQ series and Affiniti series Diagnostic Ultrasound Systems with the Auto Measure licensed option	Medical Device	Product Defect Correction	Class II	Hospital
4/04/2022	MA-KN95-WOO	Medical Device	Recall	Class II	Retail
4/04/2022	Puritan Bennett 980 Series Ventilator	Medical Device	Product Defect Correction	Class I	Hospital
4/04/2022	Schiller Defibrillator - FRED Easyport Plus	Medical Device	Product Defect Correction	Class II	Hospital
4/04/2022	VITEK 2 GP ID Test Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
4/04/2022	VITROS Immunodiagnostic Products FSH Reagent Pack, LH Reagent Pack and Prolactin Reagent Pack. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
1/04/2022	CUSTODIOL 1000 mL perfusion solution, bag	Medical Device	Product Defect Correction	Class III	Hospital
31/03/2022	ABL90 FLEX and ABL90 FLEX PLUS. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
31/03/2022	The MAXONIQ OsseoFrame	Medical Device	Product Defect Correction	Class II	Retail
30/03/2022	HeartStart HS1 AEDs/OnSite/Home AED	Medical Device	Product Defect Correction	Class II	Retail
29/03/2022	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Recall	Class II	Hospital
29/03/2022	FORE-SIGHT ELITE Tissue Oximeter Module and FORE-SIGHT ELITE Absolute Tissue Oximeter Monitor	Medical Device	Product Defect Correction	Class II	Hospital
28/03/2022	Geeef Disposable Medical Mask	Medical Device	Product Defect Alert	Class II	Hospital
28/03/2022	Moosh P2 Respirator Mask	Medical Device	Product Defect Alert	Class II	Hospital
28/03/2022	Tc99m Mebrofenin	Medicine	Product Defect Alert	Class II	Hospital
25/03/2022	PIPR Finger Replacement (Proximal Interphalangeal Replacement)	Medical Device	Product Defect Correction	Class III	Hospital
25/03/2022	PrisMax System	Medical Device	Product Defect Correction	Class II	Hospital
25/03/2022	Saiph Total Knee Replacement	Medical Device	Product Defect Correction	Class III	Hospital
24/03/2022	Philips Azurion systems with R1.x software	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
24/03/2022	SIMPSON SHELF PESSAR VARIOUS SIZES	Medical Device	Recall	Class III	Hospital
23/03/2022	ARIS HiQ. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
23/03/2022	DISPOSABLE GRASPING FORCEPS FG-51D	Medical Device	Recall	Class II	Hospital
23/03/2022	IN.PACT Admiral Paclitaxel-coated PTA Balloon Catheters	Medical Device	Recall	Class II	Hospital
22/03/2022	Anti-Lua (LU1). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
22/03/2022	AQUINARETIC 20/12.5 and 10/12.5 quinapril hydrochloride and hydrochlorothiazide 20/12.5mg and 10/12.5 tablet blister pack and ACCURETIC 10/12.5 and 20/12.5 tablet blister pack	Medicine	Recall	Class II	Retail
22/03/2022	Photopheresis System	Medical Device	Product Defect Correction	Class III	Hospital
22/03/2022	SuperLUX, SuperLUX Pro, UltraLUX and UltraLUX Pro	Medical Device	Product Defect Correction	Class II	Retail
21/03/2022	Magec Device System	Medical Device	Product Defect Correction	Class I	Hospital
21/03/2022	Merlin Patient Care System (PCS)	Medical Device	Product Defect Correction	Class II	Hospital
21/03/2022	ORAc collect DNA, ORAc collect Dx, ORAc collect RNA. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class III	Hospital
18/03/2022	Multi-Modality Touch Screen Module (MM-TSM) a part of the IntraSight Integrated IVUS System	Medical Device	Product Defect Correction	Class II	Hospital
18/03/2022	MUSE NX R1 systems with Web Edit option	Medical Device	Product Defect Correction	Class II	Hospital
18/03/2022	Triathlon Tritanium Tibial Baseplate and Triathlon Primary Tibial Baseplate	Medical Device	Recall	Class III	Hospital
17/03/2022	AutonoMe Pre-loaded Delivery System	Medical Device	Recall	Class II	Hospital
17/03/2022	Fludeoxyglucose F18 Injection (F-18 FDG)	Medicine	Product Defect Alert	Class II	Hospital
17/03/2022	STERRAD Booster Adaptor IV	Medical Device	Recall	Class III	Hospital
16/03/2022	DARATUMUMAB 1,800MG IN SYRINGE (TERUMO)	Medicine	Recall	Class II	Hospital
15/03/2022	20/30 Priority Pack Accessory Kit	Medical Device	Recall	Class II	Hospital
15/03/2022	Alinity m HBV AMP kit and Alinity m HBV. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital

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15/03/2022	Signa & Discovery MR	Medical Device	Product Defect Correction	Class II	Hospital
11/03/2022	Enhanced Estradiol (eE2). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
11/03/2022	Longteng Disposable Surgical Medical Mask	Medical Device	Product Defect Alert	Class II	Retail
11/03/2022	OptiPro FFP2 Mask	Medical Device	Product Defect Alert	Class II	Hospital
11/03/2022	Peripheral/coronary vasculature catheter, infusion	Medical Device	Recall	Class II	Hospital
11/03/2022	Trinity Depth Gauge	Medical Device	Recall	Class II	Hospital
11/03/2022	Well Lead – Adult Oxygen Mask	Medical Device	Recall	Class I	Hospital
10/03/2022	APC-30 Procedure Pack	Medical Device	Recall	Class III	Wholesale
10/03/2022	Esophageal/Rectal/Skin Temperature Probes	Medical Device	Product Defect Correction	Class II	Hospital
9/03/2022	Combination of ANATOMIC femoral component Size 7 or 8 with the cemented inset patellar component diameter 23mm.	Medical Device	Product Defect Correction	Class II	Hospital
9/03/2022	Natural Laxative Senna and Prune	Medicine	Recall	Class III	Wholesale
8/03/2022	2288 Premium Plus disposable masks ear-loop ultra-sensitive with anti-fog shields	Medical Device	Product Defect Alert	Class II	Retail
8/03/2022	Atrium Advanta V12 Covered Stent System	Medical Device	Product Defect Correction	Class II	Hospital
7/03/2022	Beare Medical Face Mask for Single Use - Level 2 Barrier - BMD 2	Medical Device	Product Defect Alert	Class II	Hospital
7/03/2022	Proshield Duckbill Fluid Resistant, Proshield Resistant, Proshield Clearview, Proshield Elite Visor Mask, Proshield Elite Antifog Mask, Proshield Elite Pleated Mask and Proshield Super Resistant Antifog Mask	Medical Device	Product Defect Alert	Class II	Hospital
4/03/2022	Atellica UAS 800 Urine Sediment Analyser and Atellica 1500 Automated Urinalysis System - An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
4/03/2022	OWear Mask with Earloop Fluid Protection IIR-120 mmHg	Medical Device	Product Defect Alert	Class II	Hospital
4/03/2022	OWear Procedure Mask – Earloop OMK001 Level 2	Medical Device	Product Defect Alert	Class II	Retail
4/03/2022	Premium Ear-loop-3 Layers Masks	Medical Device	Product Defect Alert	Class II	Retail

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3/03/2022	Havyco Vy & Tea	Medicine	Recall	Class II	Consumer
3/03/2022	Mask, surgical, single use	Medical Device	Product Defect Alert	Class II	Hospital
3/03/2022	Philips HeartStart Intrepid Monitor/Defibrillator	Medical Device	Product Defect Alert	Class I	Hospital
3/03/2022	Revogene. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
2/03/2022	AEROPLAST Adhesive Bandages	Medical Device	Recall	Class III	Retail
2/03/2022	ARTIS icono biplane, ARTIS icono floor, ARTIS pheno with syngo Application Software	Medical Device	Product Defect Correction	Class II	Hospital
2/03/2022	FAST FISH Prenatal Enumeration Probe kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
1/03/2022	Artis Zee, Zeego, Q, Q.zen Systems	Medical Device	Product Defect Correction	Class II	Hospital
1/03/2022	EXALT Model D Single-Use Duodenoscope	Medical Device	Product Defect Correction	Class II	Hospital
1/03/2022	Infusion administration set, infusion pump	Medical Device	Product Defect Alert	Class II	Hospital
1/03/2022	RayStation 4-11B, and RayPlan 1, 2, 7-11B including some service packs	Medical Device	Product Defect Correction	Class II	Hospital
28/02/2022	ARTIS icono biplane, ARTIS icono floor, ARTIS pheno with software version VE20 to VE21	Medical Device	Product Defect Correction	Class II	Hospital
28/02/2022	Atellica CH 930 Analyzer. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
28/02/2022	Batec Handbikes of the MINI, MINI 2, SCRAMBLER 2, ELECTRIC 2	Medical Device	Product Defect Correction	Class II	Consumer
28/02/2022	Ripe KN95 Nanofiber filtration Anti-Particulate Anti-virus Mask	Medical Device	Recall	Class II	Hospital
28/02/2022	Total Bile Acids. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
25/02/2022	ACL TOP 300 CTS, ACL TOP 350 CTS, ACL TOP 500 CTS, ACL TOP 550 CTS, and ACL TOP 970 CL. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
25/02/2022	MR systems with Twinspeed	Medical Device	Product Defect Correction	Class II	Hospital
25/02/2022	Philips CombiDiagnost R90 and ProxiDiagnost N90 Systems with software version 1.1.1 or higher	Medical Device	Product Defect Correction	Class II	Hospital
24/02/2022	Bovine Chemistry Assay Level 1, 2 and 3. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class III	Hospital

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24/02/2022	Brilliance iCT, IQon Spectral CT, Ingenuity CT, Brilliance CT 64	Medical Device	Product Defect Correction	Class II	Hospital
24/02/2022	Human Chorionic Gonadotropin (HCG). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
24/02/2022	Ripe Doctors KN95	Medical Device	Product Defect Alert	Class II	Hospital
23/02/2022	Access hsTnI Reagent Pack. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
23/02/2022	SpaceOAR System and SpaceOAR Vue System	Medical Device	Product Defect Correction	Class I	Hospital
23/02/2022	ThermoFisher Scientific Infinity Ammonia Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
22/02/2022	Getinge ED-Flow AER (Automated Endoscope Reprocessor); and Getinge ED-Flow SD AER.	Medical Device	Product Defect Correction	Class II	Hospital
21/02/2022	Liquiband Fix8 Open Hernia Mesh Fixation Device	Medical Device	Recall	Class III	Hospital
21/02/2022	Shimadzu Sonialvision G4	Medical Device	Product Defect Correction	Class II	Hospital
21/02/2022	UNIVERSAL TWINBAR 670 QRH (Quick Release Hook)	Medical Device	Product Defect Correction	Class II	Hospital
18/02/2022	Cellife Covid 19 Antigen Test Cassette pack of 5. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class III	Wholesale
18/02/2022	Pendulum Camera Head	Medical Device	Product Defect Alert	Class II	Hospital
18/02/2022	Philips Azurion 7 M20 systems with a software R2.0.x	Medical Device	Product Defect Correction	Class II	Hospital
18/02/2022	Philips Big Bore RT, Brilliance CT Big Bore Oncology, and Brilliance CT Big Bore with software 4.8.x	Medical Device	Product Defect Correction	Class II	Hospital
17/02/2022	3 PLY DISPOSABLE SURGICAL FACE MASK	Medical Device	Product Defect Alert	Class II	Retail
17/02/2022	Halyard Surgical Mask	Medical Device	Product Defect Alert	Class II	Retail
17/02/2022	RESOLVE HALO - STERILE PACKAGING	Medical Device	Product Defect Alert	Class II	Hospital
17/02/2022	Servo-u and Servo-n ventilator systems	Medical Device	Product Defect Correction	Class II	Hospital
15/02/2022	JUGGERLOC 6MM SLOTTED REAMER	Medical Device	Recall	Class II	Hospital
15/02/2022	TFN-ADVANCED Proximal Femoral Nailing System (TFNA)	Medical Device	Product Defect Correction	Class II	Hospital
15/02/2022	Trustcare Outdoor Rollators	Medical Device	Product Defect Correction	Class II	Consumer

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14/02/2022	Alinity m System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
11/02/2022	Acrylic Flowmeter/Flowmeter Manifold Family	Medical Device	Product Defect Correction	Class III	Retail
11/02/2022	Revolution CT, Revolution CT ES, Revolution Apex and Revolution CT with Apex edition	Medical Device	Product Defect Correction	Class II	Hospital
11/02/2022	Veisha KN95 Mask	Medical Device	Recall	Class II	Hospital
10/02/2022	Mask, surgical, single-use	Medical Device	Product Defect Alert	Class II	Sponsor
9/02/2022	HemosIL AcuStar ADAMTS13 Activity. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
9/02/2022	Microvention HydroSoft 3D Endovascular Embolization Coil	Medical Device	Product Defect Correction	Class III	Hospital
9/02/2022	NextSeq 550Dx instrument. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
8/02/2022	Ellura	Medicine	Recall	Class II	Consumer
8/02/2022	PiCCO Monitoring Kit, 150cm line 5/pkg	Medical Device	Recall	Class I	Hospital
7/02/2022	Alinity s System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
7/02/2022	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Recall	Class II	Hospital
7/02/2022	Panther Fusion Extraction Reagent-X. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
7/02/2022	Philips DigitalDiagnost C90 and CombiDiagnost R90	Medical Device	Product Defect Correction	Class II	Hospital
7/02/2022	Sevoflurane Quik-Fil Vaporizer for Flow Family Anaesthesia systems	Medical Device	Product Defect Correction	Class I	Hospital
7/02/2022	Ysio systems with VC10 software	Medical Device	Product Defect Correction	Class II	Hospital
4/02/2022	CARESCAPE Central Station (CSCS) V2.0.x.	Medical Device	Product Defect Correction	Class I	Hospital
4/02/2022	IVD products (red blood cells). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Alert	Class III	Hospital
3/02/2022	BEVACIZUMAB (AVASTIN) 3MG IN SYRINGE (BECTONDICKINSON) FOR OCULAR USE	Medicine	Recall	Class III	Hospital
3/02/2022	e-PTFE Micro-filtration Membrane Mask	Medical Device	Product Defect Alert	Class II	Hospital
3/02/2022	HysteroLux Fluid Management System	Medical Device	Recall	Class II	Hospital

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2/02/2022	Cocoon Respirator Masks	Medical Device	Product Defect Alert	Class II	Retail
2/02/2022	Everest MI XT Inner and Outer Dilators	Medical Device	Recall	Class II	Hospital
2/02/2022	PRIMASOFT SURGICAL MASK, TIE, SOFT, WHITE, PG4-2333	Medical Device	Product Defect Alert	Class II	Hospital
1/02/2022	Actosolv 100,000/600,000 UI powder for powder for solution for injection	Medicine	Recall	Class II	Retail
1/02/2022	cobas z 480 analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
1/02/2022	MedChart - all versions from 8.1.1 onwards	Medical Device	Product Defect Correction	Class II	Hospital
1/02/2022	MS-2 Step composite pack [MIFEPRISTONE LINEPHARMA 200 MG TABLET mifepristone 200 mg tablet blister; GyMiso misoprostol 200 microgram tablet blister]	Medicine	Recall	Class II	Retail
31/01/2022	Philips eCareManager (eCM) using Sentry Score	Medical Device	Product Defect Correction	Class III	Hospital
31/01/2022	Precice Unyte and Precice Freedom trade names	Medical Device	Product Defect Correction	Class II	Hospital
28/01/2022	HeartWare Ventricular Assist Device (HVAD)	Medical Device	Product Defect Correction	Class I	Hospital
28/01/2022	Particulate Respirator FFP2 NR	Medical Device	Product Defect Alert	Class II	Retail
28/01/2022	Philips Volcano SyncVision Systems (400-0100.10, 30000485688x)	Medical Device	Product Defect Correction	Class II	Hospital
27/01/2022	ACUSON Juniper ultrasound system with Juniper 1.0 (VA10D / VA10E / VA10F) software	Medical Device	Product Defect Correction	Class II	Hospital
27/01/2022	Piksters Shield Face Masks Level 3	Medical Device	Product Defect Alert	Class II	Retail
27/01/2022	St John Respirator Mask	Medical Device	Recall	Class II	Hospital
25/01/2022	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
25/01/2022	PowerPICC	Medical Device	Product Defect Correction	Class II	Hospital
25/01/2022	Rocket Copeland Fetal Scalp Electrode.	Medical Device	Product Defect Correction	Class III	Hospital
24/01/2022	BenchMark ULTRA Stainer Module. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
20/01/2022	Transfer Set (MiniCap Extended Life PD Transfer Set)	Medical Device	Product Defect Correction	Class II	Hospital
19/01/2022	5mmx45cmm, Epix Reusable Probe	Medical Device	Recall	Class II	Hospital

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19/01/2022	A Barcs & Co Nominees - Foldable Protective Earloop Mask KN95	Medical Device	Recall	Class II	Retail
19/01/2022	Osteomed Standard Titanium Screw 2.0mm x 5mm	Medical Device	Recall	Class II	Hospital
19/01/2022	Oxford UP - Mobile Patient Stand Assist & Transfer Device	Medical Device	Product Defect Correction	Class II	Consumer
18/01/2022	XScribe System, HScribe System, Diagnostic Cardiology Suite (DCS) and RScribe System	Medical Device	Product Defect Correction	Class II	Hospital
17/01/2022	Implantcast AGILON glenoid cementless	Medical Device	Hazard Alert	Class II	Hospital
17/01/2022	Philips ST80i Stress Test System	Medical Device	Product Defect Correction	Class II	Hospital
14/01/2022	Exeter V40 Cemented Hip Stem	Medical Device	Recall	Class III	Hospital
13/01/2022	Arrow Trerotola 5FR Percutaneous Thrombolytic Device (PTD)	Medical Device	Recall	Class II	Hospital
13/01/2022	CHARLOTTE MTP Hex Screw 2.7mm x 18mm	Medical Device	Recall	Class III	Hospital
13/01/2022	RayStation/RayPlan 6, 7, 8A, 8B, 9A, 9B including some service packs	Medical Device	Product Defect Correction	Class II	Hospital
13/01/2022	Xstrahl Concerto 2.x User Interface Software used with Xstrahl Limited radiotherapy system	Medical Device	Product Defect Correction	Class II	Hospital
12/01/2022	Endurant II/IIIs Stent Graft System	Medical Device	Recall	Class II	Hospital
12/01/2022	NIM Trivantage EMG Endotracheal Tube	Medical Device	Recall	Class I	Hospital
11/01/2022	All GE Healthcare MRI systems with superconducting magnets	Medical Device	Product Defect Correction	Class I	Hospital
11/01/2022	da Vinci Xi and X 12-8mm Cannula Reducer	Medical Device	Recall	Class II	Hospital
11/01/2022	MEDPOR Barrier Surgical Implant	Medical Device	Recall	Class III	Hospital
10/01/2022	NEO-prene CPAP Cap System - Midline Prong version	Medical Device	Recall	Class II	Hospital
7/01/2022	Bio Protect Disposable Surgical Face Mask 3 Ply with Earloop Level 2	Medical Device	Recall	Class II	Retail
7/01/2022	Cryptococcal Antigen Lateral Flow Assay (CrAg LFA). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
7/01/2022	iMRX System	Medical Device	Product Defect Correction	Class II	Hospital
7/01/2022	Infusomat Space Pump - Infusion pump, general-purpose	Medical Device	Recall	Class III	Hospital

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7/01/2022	Mazor X robotic guidance system	Medical Device	Product Defect Correction	Class II	Hospital
6/01/2022	BV Endura, BV Pulsera and Veradius Unity	Medical Device	Product Defect Correction	Class II	Hospital
6/01/2022	Gemini KN95 Protective Medical Masks	Medical Device	Recall	Class II	Hospital
6/01/2022	Hip and Knee Replacement Implants	Medical Device	Recall	Class III	Hospital
6/01/2022	Ultrabiotic Factors for Juniors, Chewable Tablets, (30s and 60s)	Medicine	Recall	Class III	Retail
5/01/2022	Femoral Head Allograft - Coarse Milled Bone	Biological	Hazard Alert	Class II	Hospital
5/01/2022	Inhibin B Gen II ELISA. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
5/01/2022	MobileDiagnost wDR	Medical Device	Product Defect Correction	Class II	Hospital
5/01/2022	Philips Fetal Spiral Electrode	Medical Device	Product Defect Correction	Class II	Hospital
5/01/2022	Philips Zenition 50, Zenition 70, Veradius Unity systems	Medical Device	Product Defect Correction	Class II	Hospital
24/12/2021	Bellavista 1000 and 1000E Ventilators	Medical Device	Product Defect Correction	Class I	Hospital
24/12/2021	EFTIAR Octane, vials and syringes, 5 ml and 7 ml	Medical Device	Product Defect Correction	Class I	Hospital
24/12/2021	Shimadzu Sonialvision G4 and Sonialvision Safire 17	Medical Device	Product Defect Correction	Class II	Hospital
24/12/2021	Trimethoprim Sulfametoxazole 1.25-23.75 µg disk. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
23/12/2021	Airo TruCT Mobile Scanning System	Medical Device	Product Defect Correction	Class II	Hospital
23/12/2021	DELFI Xpress hAFP Kit, DELFI Xpress Free hCGβ kit, DELFI Xpress PAPP-A kit. In vitro diagnostic medical devices (IVDs)	Medical Device	Recall	Class II	Hospital
22/12/2021	AU/DxC AU Magnesium. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
22/12/2021	AU/DxC AU Uric Acid. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class III	Hospital
22/12/2021	Defigard Touch 7	Medical Device	Product Defect Correction	Class I	Hospital
22/12/2021	EliA ANA Positive Control 2500/5000. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
21/12/2021	BD Veritor Plus Analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital

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21/12/2021	ID-DiaPanel Plus 6 (6x4 ml). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
21/12/2021	ImmunoCAP Specific IgG assay, Test Gm23. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Alert	Class III	Hospital
21/12/2021	Lidocaine Hydrochloride Topical Solution USP, 4%, 50mL	Medicine	Recall	Class II	Consumer
20/12/2021	'Banana Boat' Sunscreen Sprays SPF 50+ (aerosol sunscreen)	Medicine	Recall	Class II	Consumer
20/12/2021	30X0.3 mL IKERVIS (Ciclosporin) 1mg/mL eyedrop	Medicine	Recall	Class II	Hospital
20/12/2021	Makrite 9500-N95 Particulate Respirators	Medical Device	Recall	Class II	Retail
20/12/2021	Stryker Twist Drills 5mm	Medical Device	Recall	Class III	Hospital
20/12/2021	Technomed Disposable Subdermal Corkscrew Electrodes	Medical Device	Recall	Class II	Hospital
17/12/2021	Glyceryl trinitrate (GTN) Syringes 1mg/10mL in Sodium Chloride 0.9%	Medicine	Product Defect Alert	Class II	Hospital
17/12/2021	Huo Xiang Zheng Qi Wan a.k.a. Agastache Formula (BP046)	Medicine	Recall	Class II	Retail
17/12/2021	ImmunoCAP Total IgE, ImmunoCAP Specific IgE and ViewAllergy. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
17/12/2021	IntelePACS	Medical Device	Product Defect Correction	Class II	Hospital
17/12/2021	Jagtome RX, Hydratome RX, Dreamtome RX, Cannulating Sphincterotomes and Jagtome Revolution RX	Medical Device	Recall	Class II	Hospital
17/12/2021	MedChart - Information system software, application program, patient record	Medical Device	Product Defect Correction	Class II	Hospital
17/12/2021	RECHARGER KITs InterStim Micro, ACTIVA RC and RestoreUltra & RestoreSensor	Medical Device	Product Defect Correction	Class I	Consumer
16/12/2021	Alinity m System - An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
16/12/2021	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Recall	Class II	Hospital
16/12/2021	GLOBAL UNITE STEMS	Medical Device	Recall	Class II	Hospital
16/12/2021	Perseus A500 Anesthesia workstation ceiling mounted version	Medical Device	Product Defect Correction	Class II	Hospital
14/12/2021	Endeavour KN95 Mask	Medical Device	Recall	Class II	Hospital

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14/12/2021	Multiple Reagent Red Blood Cell IVD's. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
13/12/2021	Babyleo TN500 IncuWarmer	Medical Device	Product Defect Correction	Class II	Hospital
13/12/2021	Invacare Perfecto2 V Oxygen Concentrator	Medical Device	Product Defect Correction	Class II	Consumer
10/12/2021	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Product Defect Alert	Class II	Hospital
9/12/2021	Andatech Pty Ltd - MedSense Medical Face Mask - Mask, surgical, single use	Medical Device	Product Defect Alert	Class II	Retail
9/12/2021	Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pump (IABP)	Medical Device	Product Defect Correction	Class I	Hospital
9/12/2021	Femoral Head-NINP (Non-Irradiated, Non-processed)	Biological	Hazard Alert	Class II	Hospital
8/12/2021	D25 (D2S) Adult Return Electrode	Medical Device	Recall	Class III	Hospital
8/12/2021	Molnlycke Procedure Packs - Donor Pack	Medical Device	Recall	Class II	Hospital
8/12/2021	Ryles Tube x-Ray Line, Rectal Catheter and Infant Feeding tube	Medical Device	Product Defect Correction	Class II	Hospital
7/12/2021	Better Health Pharmacy Pty Ltd - ARTG: 342635	Medical Device	Product Defect Alert	Class II	Hospital
7/12/2021	Calibration Serum Level 3. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
7/12/2021	Dixi Medical Microdeep depth electrodes	Medical Device	Product Defect Correction	Class II	Hospital
7/12/2021	Merchant Star Pty Ltd - ARTG: 340955	Medical Device	Product Defect Alert	Class II	Hospital
7/12/2021	Young Line Trading Company - ARTG: 334729	Medical Device	Product Defect Alert	Class II	Hospital
6/12/2021	GUT BUG	Medicine	Recall	Class II	Retail
6/12/2021	LigaSure Blunt Tip Laparoscopic Sealer/Divider, Nano-Coated	Medical Device	Recall	Class II	Hospital
6/12/2021	Transfusion Set with Needleless Access Site	Medical Device	Recall	Class II	Hospital
3/12/2021	Aquilion ONE, Prime SP, Lightning and Exceed LD CT Systems	Medical Device	Product Defect Correction	Class III	Hospital
3/12/2021	Atellica CH β 2-Microglobulin (B2M). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
2/12/2021	Althea THC18	Medicine	Recall	Class II	Consumer
2/12/2021	GRI Medical Angiography Tray	Medical Device	Product Defect Alert	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
2/12/2021	Perios Pty Ltd - KN95 Particulate Respirator	Medical Device	Recall	Class II	Retail
1/12/2021	Leica M220 F12 Surgical Microscopes	Medical Device	Product Defect Correction	Class II	Hospital
1/12/2021	MedSense Medical Disposable Mask	Medical Device	Product Defect Alert	Class II	Retail
30/11/2021	Disposables Kit, UCL Suture Passing	Medical Device	Product Defect Alert	Class III	Hospital
30/11/2021	Philips MobileDiagnost wDR	Medical Device	Product Defect Correction	Class III	Hospital
30/11/2021	RAPID 20 E. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
30/11/2021	Sensis and Sensis Vibe Combo systems with software version VD12A	Medical Device	Product Defect Correction	Class II	Hospital
30/11/2021	Sensis Vibe Hemo with software VD12A	Medical Device	Product Defect Correction	Class II	Hospital
30/11/2021	TaqPath COVID-19 Combo Kit, 1,000 reactions. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
29/11/2021	Avelle NPWT pump	Medical Device	Recall	Class II	Hospital
26/11/2021	OPRA Axor II	Medical Device	Product Defect Correction	Class II	Hospital
26/11/2021	Technetium-99m HDP and Technetium-99m Sodium Pertechnetate	Medicine	Recall	Class II	Hospital
25/11/2021	Proshield N95 Small Surgical Respirator	Medical Device	Product Defect Alert	Class II	Hospital
25/11/2021	UTAK Validity Control 2. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
24/11/2021	A9 Anaesthesia System	Medical Device	Product Defect Correction	Class II	Hospital
24/11/2021	Brilliance CRE. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
24/11/2021	Daddy's Choice Surgical face mask, disposable	Medical Device	Product Defect Correction	Class II	Hospital
24/11/2021	Digital Angiography System Trinius X-ray Generator	Medical Device	Product Defect Correction	Class II	Hospital
24/11/2021	Evidence Investigator. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Retail
24/11/2021	Malosa Medical Refractive and Cataract Kits	Medical Device	Recall	Class I	Hospital
23/11/2021	Abre venous self-expanding stent system	Medical Device	Product Defect Correction	Class II	Hospital
23/11/2021	All Giraffe Incubator and Giraffe OmniBed Devices	Medical Device	Product Defect Correction	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
23/11/2021	Atellica CH 930 Analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
23/11/2021	Philips Azurion 7 M20 FlexArm SW 2.0	Medical Device	Product Defect Correction	Class III	Hospital
22/11/2021	Intertrade Group Pty Ltd - ARTG: 333630	Medical Device	Product Defect Alert	Class II	Hospital
22/11/2021	MiniMed Remote Controller MMT-503 used with MiniMed 508 insulin pump or Paradigm pumps	Medical Device	Recall	Class II	Consumer
22/11/2021	New Line Sydney Pty Ltd - ARTG: 333829	Medical Device	Product Defect Alert	Class II	Hospital
22/11/2021	OEI Trading - ARTG: 333969	Medical Device	Product Defect Alert	Class II	Hospital
22/11/2021	SOMATOM Confidence, Definition Edge, Definition Edge Plus, Definition AS with syngo.CT VB20A_SP5	Medical Device	Product Defect Correction	Class II	Hospital
22/11/2021	The Product Group Pty Ltd - ARTG: 333861	Medical Device	Product Defect Alert	Class II	Hospital
22/11/2021	YXYS International Pty Ltd - ARTG: 333925	Medical Device	Product Defect Alert	Class II	Hospital
19/11/2021	cobas 4800 HPV Amplification/Detection Kits. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
18/11/2021	CombiDiagnost R90	Medical Device	Product Defect Correction	Class II	Hospital
18/11/2021	StealthStation S7/i7 running Synergy Cranial and StealthStation Cranial Software	Medical Device	Product Defect Correction	Class II	Hospital
17/11/2021	ACUSON Sequoia ultrasound systems	Medical Device	Product Defect Correction	Class II	Hospital
17/11/2021	Allura Xper and Azurion systems	Medical Device	Product Defect Correction	Class II	Hospital
17/11/2021	Codan Blood Exchange Burette Custom Kit	Medical Device	Recall	Class II	Hospital
17/11/2021	HemosIL Liquid Anti-Xa	Medical Device	Product Defect Correction	Class II	Hospital
17/11/2021	Pulmonary Valve, Cryopreserved-L	Biological	Hazard Alert	Class II	Hospital
17/11/2021	Puritan Bennett 980 Series Ventilator	Medical Device	Product Defect Correction	Class I	Hospital
16/11/2021	Abbott FreeGo Enteral Feeding pump	Medical Device	Product Defect Correction	Class II	Hospital
16/11/2021	The QIAcube Connect MDx. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital

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15/11/2021	ADAPT Platform, Nav3 Platform, NAV3i Platform, NavSuite 3 Kit and NavSuite 3 Upgrade Kit	Medical Device	Product Defect Alert	Class III	Hospital
15/11/2021	DOTAREM (gadoteric acid) 279.32 mg/mL 10 mL injection solution vial	Medicine	Recall	Class II	Hospital
15/11/2021	Duodenoscope	Medical Device	Product Defect Correction	Class II	Hospital
12/11/2021	All Vscan Extend devices	Medical Device	Product Defect Correction	Class II	Hospital
12/11/2021	Paclitaxel (Albumin-Bound) In Polyolefin Bag (Freeflex) For Intravenous Infusion 262.5mg	Medicine	Recall	Class II	Hospital
11/11/2021	DS Maref LX9 Sequential Pneumatic Compression Device	Medical Device	Product Defect Correction	Class II	Consumer
11/11/2021	M22 and Stellar M22 System Coupling Gel	Medical Device	Recall	Class II	Retail
10/11/2021	Precice Intramedullary limb lengthening (IMLL) device system, including the Precice IMLL and Precice Short trade names	Medical Device	Product Defect Correction	Class II	Hospital
9/11/2021	BioPlex 2200 APLS IgM and BioPlex 2200 APLS IgA. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
9/11/2021	COPAN eSwab	Medical Device	Product Defect Correction	Class III	Hospital
9/11/2021	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Product Defect Correction	Class III	Hospital
9/11/2021	Philips EPIQ & Affiniti Ultrasound Systems	Medical Device	Product Defect Correction	Class II	Hospital
8/11/2021	CATALYS Precision Laser System and iDESIGN Refractive Studio	Medical Device	Product Defect Correction	Class II	Hospital
8/11/2021	Multigate Custom Procedure Packs containing Needle 23G 1IN TW (0.6mm x 25mm)	Medical Device	Product Defect Alert	Class III	Hospital
5/11/2021	COULTER 4C-ES Cell Controls. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Alert	Class III	Hospital
5/11/2021	CovClear COVID-19 Antigen Test. An in vitro diagnostic medical device.	Medical Device	Product Defect Alert	Class I	Hospital
5/11/2021	NULAX Natural Fruit Laxative Blocks, 250g and 500g	Medicine	Recall	Class II	Retail
5/11/2021	Thermo Scientific Remel R30163701 Shigella dysenteriae polyvalent antisera. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital

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4/11/2021	Dimension Vista 1500 & 500 Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
4/11/2021	NovoRapid FlexPen, NovoMix 30 Penfill and Fiasp FlexTouch.	Medicine	Product Defect Alert	Class II	Retail
4/11/2021	Sentec Digital Monitors	Medical Device	Product Defect Correction	Class II	Hospital
3/11/2021	Centricity Universal Viewer Zero Footprint	Medical Device	Product Defect Correction	Class II	Hospital
3/11/2021	Mentor Smooth Round Saline Diaphragm Valve Implant	Medical Device	Recall	Class II	Hospital
3/11/2021	Ultra-High Molecular Weight Polyethylene Liners	Medical Device	Hazard Alert	Class II	Hospital
3/11/2021	Various Merit Medical Catheters, Delivery Kits and Shunts	Medical Device	Product Defect Correction	Class II	Hospital
2/11/2021	Artis zee /Q /Q.zen systems with software version VD12	Medical Device	Product Defect Correction	Class II	Hospital
2/11/2021	BD BACTEC blood culture vials. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
2/11/2021	Enhanced Viewer software (part of IntelPACS software)	Medical Device	Product Defect Correction	Class II	Hospital
1/11/2021	mySugr Bolus Calculator (on Android)	Medical Device	Product Defect Correction	Class II	Consumer
29/10/2021	MONOPLUS VIOLET USP 4/0	Medical Device	Recall	Class II	Hospital
29/10/2021	Pathodextra Strep Group D Latex. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
28/10/2021	15 cm tremoflo C100 Test Loads	Medical Device	Recall	Class II	Hospital
28/10/2021	Alinity s System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
28/10/2021	Multiple VIDAS Immuno-Assay Products. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
28/10/2021	VeriSeq NIPT Sample Prep Kits. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
27/10/2021	CombiDiagnost R90 and ProxiDiagnost N90 Systems.	Medical Device	Product Defect Correction	Class III	Hospital
27/10/2021	Cryo 6 and StimSure	Medical Device	Product Defect Correction	Class II	Retail
27/10/2021	The HeartMate Touch App	Medical Device	Product Defect Correction	Class I	Hospital
26/10/2021	CME/BD BodyGuard Infusion Pump System	Medical Device	Product Defect Correction	Class II	Hospital
26/10/2021	SOMATOM go.NOW, go.Up, go.All, go.Top, go.Fit Scanners	Medical Device	Product Defect Correction	Class II	Hospital

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25/10/2021	Invisalign Aligner System	Medical Device	Recall	Class III	Retail
22/10/2021	Hurricane RX Biliary Balloon Dilatation Catheter	Medical Device	Recall	Class II	Hospital
21/10/2021	ARTIS pheno, ARTIS icono biplane, ARTIS icono floor	Medical Device	Product Defect Correction	Class II	Hospital
21/10/2021	Azurion R2.1.x System	Medical Device	Product Defect Correction	Class II	Hospital
21/10/2021	CareLink SmartSync Device Manager Application	Medical Device	Product Defect Correction	Class II	Hospital
21/10/2021	IVA Long Products (Multipurpose Introducer Sheath)	Medical Device	Recall	Class II	Hospital
21/10/2021	The Neuro Zti EVO and CLA cochlear implants	Medical Device	Recall	Class II	Consumer
20/10/2021	18F-DCFPyL Injection (PSR)	Medicine	Recall	Class II	Hospital
20/10/2021	Aptio Automation Interface Module to the ADVIA Centaur XP/XPT Instrument. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
20/10/2021	The Rocket Pleural Vent	Medical Device	Recall	Class III	Hospital
20/10/2021	The Transseptal Needle and Transseptal Needle with Catheter	Medical Device	Recall	Class I	Hospital
19/10/2021	Allura Xper systems with software releases R7.6.x, R7.7.x, R7.8.x, =R8.1.17.x, =R8.2.17.x	Medical Device	Product Defect Correction	Class II	Hospital
19/10/2021	Freelite Human Lambda Free Kit (for use on the SPAPLUS). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
19/10/2021	Ingenia MR-RT systems (with MRCAT Pelvis ExamCard)	Medical Device	Product Defect Correction	Class III	Hospital
19/10/2021	Philips EPIQ & Affiniti Ultrasound Systems	Medical Device	Product Defect Correction	Class II	Hospital
19/10/2021	ZARONTIN ethosuximide 250mg capsule bottle	Medicine	Product Defect Correction	Class II	Wholesale
18/10/2021	3M Red Dot Radiolucent Monitoring Electrode with Foam Tape	Medical Device	Recall	Class II	Hospital
18/10/2021	Greiner Bio-One Vacuette Tube, 2 mL 9NC coagulation sodium citrate 3.2% 13x75 blue cap-white ring, sandwich tube. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
15/10/2021	Philips Azurion systems	Medical Device	Product Defect Correction	Class II	Hospital
15/10/2021	Revolution CT, Revolution CT ES, Revolution Apex, Revolution CT with Apex edition	Medical Device	Product Defect Correction	Class II	Hospital

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14/10/2021	Atellica IM 1300 Analyzer and Atellica IM 1600 Analyzer. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
14/10/2021	Harcor Security Seals Pty Ltd - ARTG: 340516	Medical Device	Product Defect Alert	Class II	Hospital
14/10/2021	Percept PC BrainSense B35200	Medical Device	Hazard Alert	Class II	Hospital
14/10/2021	Shifa Dental Supplies - ARTG: 340250	Medical Device	Product Defect Alert	Class II	Hospital
13/10/2021	ARCHITECT i-System and ARCHITECT c-System - An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
13/10/2021	DxC AU Glucose Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
13/10/2021	Oncentra Brachy	Medical Device	Product Defect Correction	Class II	Hospital
12/10/2021	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Recall	Class II	Hospital
12/10/2021	Miniso Master Franchisee Pty Ltd - ARTG: 333679 and 334653	Medical Device	Product Defect Alert	Class II	Hospital
12/10/2021	Owen Kelly & Associates - ARTG: 338637	Medical Device	Product Defect Alert	Class II	Hospital
12/10/2021	QConnect HEPR. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
11/10/2021	Cryo 6	Medical Device	Product Defect Correction	Class II	Retail
11/10/2021	Draeger Perseus Anaesthesia Machines	Medical Device	Product Defect Correction	Class II	Hospital
11/10/2021	HH Harding Holding Pty Ltd - ARTG: 341723 and 342097	Medical Device	Product Defect Alert	Class II	Hospital
11/10/2021	Owen Kelly & Associates - ARTG: 338635	Medical Device	Product Defect Alert	Class II	Hospital
11/10/2021	P2 Healthcare Particulate Respirators	Medical Device	Recall	Class II	Wholesale
11/10/2021	We Like Pty Ltd - ARTG: 342363	Medical Device	Product Defect Alert	Class II	Hospital
8/10/2021	Argon Super-core Biopsy needle	Medical Device	Recall	Class II	Hospital
8/10/2021	Assurity and Endurity pacemakers	Medical Device	Hazard Alert	Class I	Hospital
8/10/2021	Cardiosave Li-Ion Battery Packs used in Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pumps	Medical Device	Product Defect Correction	Class II	Hospital
8/10/2021	EnSite X Display Workstation	Medical Device	Product Defect Correction	Class II	Hospital

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8/10/2021	MYLA V4.7 (V4.7.1) and V4.8 (V4.8.1 or V4.8.2). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
8/10/2021	ROSA One 3.1 Brain application	Medical Device	Product Defect Correction	Class I	Hospital
7/10/2021	DELfIA Xpress Free hCG β kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
7/10/2021	Rocket Thoracentesis Catheter 8Fg & Accessories	Medical Device	Recall	Class III	Hospital
7/10/2021	The Product Group Pty Ltd - ARTG: 337703	Medical Device	Product Defect Alert	Class II	Hospital
6/10/2021	CryoMini, Cryo 6	Medical Device	Product Defect Correction	Class II	Retail
6/10/2021	PrisMax System	Medical Device	Product Defect Correction	Class II	Hospital
6/10/2021	The S.M.A.R.T. Flex Stent 5-8mm stent and The S.M.A.R.T. Flex Stent 9 and 10mm	Medical Device	Recall	Class II	Hospital
6/10/2021	Zimmer Cryo 6	Medical Device	Product Defect Correction	Class II	Retail
5/10/2021	Cryo 6	Medical Device	Product Defect Correction	Class II	Retail
5/10/2021	Evolve IPKIS P2 Particulate Respirators and Evolve IPKIS P2 Surgical Respirators.	Medical Device	Recall	Class II	Retail
5/10/2021	MiniMed 640G and 670G insulin pump	Medical Device	Recall	Class I	Consumer
1/10/2021	An La Ghien - ARTG: 340654	Medical Device	Product Defect Alert	Class II	Hospital
1/10/2021	AVT Resources Pty Ltd - ARTG: 340205	Medical Device	Product Defect Alert	Class II	Hospital
1/10/2021	Castle Trading Corporation - ARTG: 341644	Medical Device	Product Defect Alert	Class II	Hospital
1/10/2021	HH Harding Holding Pty Ltd - ARTG: 333185 and 333441	Medical Device	Product Defect Alert	Class II	Hospital
1/10/2021	HH Harding Holding Pty Ltd - ARTG: 334145 and 341493	Medical Device	Product Defect Alert	Class II	Hospital
1/10/2021	IMMULITE/IMMULITE 1000 AlaTOP Allergy Screen and IMMULITE 2000/IMMULITE 2000 XPi AlaTOP Allergy Screen. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
1/10/2021	Michael Darby - ARTG: 335621	Medical Device	Product Defect Alert	Class II	Hospital
1/10/2021	Mortuary Cadaver Bag - Adult Size	Medical Device	Recall	Class II	Hospital
1/10/2021	Needle 23G 1IN TW (0.6mm x 25mm)	Medical Device	Recall	Class II	Hospital

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1/10/2021	Philips EPIQ CVxi Diagnostic Ultrasound Systems	Medical Device	Product Defect Correction	Class II	Hospital
1/10/2021	RayStation/RayPlan radiation therapy treatment planning system	Medical Device	Product Defect Correction	Class II	Hospital
1/10/2021	VIDAS TOXO Compétition, Anti-HCV, HBs Ag Ultra, HBs Ag Ultra, Anti-HBs Total II, HCG, Progesterone, HbC IgM II, Myoglobin, BRAHMS PCT, High sensitive Troponin I, Anti-HEV IgM, and D-Dimer Exclusion II. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
1/10/2021	Xodus Electrosurgical Tip Cleaner	Medical Device	Recall	Class II	Hospital
30/09/2021	Artis zeego patient table and AppSW VD20C/VD20N	Medical Device	Product Defect Correction	Class II	Hospital
30/09/2021	ATS 36 eye drop systems	Medical Device	Product Defect Correction	Class II	Hospital
30/09/2021	Cardioblate CryoFlex Surgical Ablation Console	Medical Device	Product Defect Correction	Class II	Hospital
30/09/2021	Sodium Chloride Injection 0.9% 10mL Ampoule	Medicine	Recall	Class II	Wholesale
30/09/2021	Stem – Kit Reagents 50 tests. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
29/09/2021	3M Lingual Retainer Wire	Medical Device	Recall	Class II	Retail
29/09/2021	Australian Xinkongjian Group Pty Ltd - ARTG: 341495	Medical Device	Product Defect Alert	Class II	Hospital
29/09/2021	BYD N95 Healthcare Particulate Respirator	Medical Device	Recall	Class II	Hospital
29/09/2021	Cooling System Cryo 6	Medical Device	Product Defect Correction	Class II	Retail
29/09/2021	Heng Rui Australian Investment - ARTG: 333718	Medical Device	Product Defect Alert	Class II	Hospital
29/09/2021	Laleen Health International Pty Ltd - ARTG: 334845 and 333921	Medical Device	Product Defect Alert	Class II	Hospital
29/09/2021	Laleen Health International Pty Ltd - ARTG: 340005 and 334109	Medical Device	Product Defect Alert	Class II	Hospital
29/09/2021	MEDRAD Twist & Go Syringes (TAG 150 SYR)	Medical Device	Recall	Class III	Hospital
29/09/2021	Runsmart Corporate Pty Ltd - ARTG: 333819	Medical Device	Product Defect Alert	Class II	Hospital
28/09/2021	Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pump (IABP)	Medical Device	Product Defect Correction	Class I	Hospital
28/09/2021	Philips M5072A Infant/Child SMART Pads Cartridge	Medical Device	Recall	Class II	Consumer

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28/09/2021	Product names: SIGNA Premier, SIGNA Pioneer, SIGNA Architect, Discovery MR750w 3.0T, Discovery MR750 3.0T, SIGNA Voyager, Optima MR450w 1.5T, SIGNA Artist, SIGNA Creator, SIGNA Explorer, 1.5T Signa HDxt (HD29)	Medical Device	Product Defect Correction	Class II	Hospital
28/09/2021	SYNCHRON Systems Alcohol (ETOH) Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
27/09/2021	Beaver Xstar Crescent Knife, 2.5mm, 55 degrees, bevel down.	Medical Device	Recall	Class II	Hospital
27/09/2021	Gulmay Medical 150 or Xstrahl 150 superficial system	Medical Device	Product Defect Correction	Class II	Hospital
27/09/2021	Ilizarov Wire Tensioner	Medical Device	Recall	Class II	Hospital
27/09/2021	RUZURGI amifampridine 10 mg tablet bottle	Medicine	Recall	Class II	Consumer
24/09/2021	cobas EGFR Mutation Test v2. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
24/09/2021	CryoMini, Cryo 6, StimSure	Medical Device	Product Defect Correction	Class II	Retail
24/09/2021	Digital Linear Accelerator	Medical Device	Product Defect Correction	Class II	Hospital
24/09/2021	MIC Gastrostomy Feeding Tube and MIC Jejunal Feeding Tube	Medical Device	Product Defect Correction	Class II	Consumer
24/09/2021	Permobil TiLite Aero Z and ZRA wheelchair models	Medical Device	Product Defect Correction	Class II	Consumer
23/09/2021	Operating Room Tables (ORT200 and ORT300)	Medical Device	Product Defect Correction	Class II	Hospital
22/09/2021	Monaco RTP System	Medical Device	Product Defect Correction	Class II	Hospital
22/09/2021	Pfizer (Australia) STERILE POTASSIUM CHLORIDE CONCENTRATE potassium chloride 750 mg/10 mL injection ampoule	Medicine	Product Defect Correction	Class II	Hospital
21/09/2021	Fluid Warming System and administration sets	Medical Device	Product Defect Correction	Class I	Hospital
20/09/2021	Mindray A9 anaesthetic machine	Medical Device	Product Defect Correction	Class II	Hospital
20/09/2021	Progressa Bed and Centrella Smart+ Bed	Medical Device	Product Defect Correction	Class III	Hospital
17/09/2021	10mm Femoral Collarless Polished Cemented Stem (CPCS) Distal Centralizers	Medical Device	Recall	Class II	Hospital
17/09/2021	Intravascular Heat Exchange Catheters	Medical Device	Product Defect Correction	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
17/09/2021	Miami J Select Collar and Set	Medical Device	Product Defect Correction	Class II	Hospital
15/09/2021	Novation Crown Cup GXL Liner	Medical Device	Hazard Alert	Class II	Hospital
15/09/2021	ONLINE TDM Phenobarbital (PHNO2) (200 tests) and ONLINE TDM Phenytoin (PHNY2) (200 tests). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
15/09/2021	Philips Expression IP5	Medical Device	Product Defect Correction	Class II	Hospital
15/09/2021	Philips IQon Spectral CT and Brilliance iCT	Medical Device	Product Defect Correction	Class II	Hospital
14/09/2021	Access hsTnI Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
14/09/2021	Australia Top 1 Health Management Pty Ltd - ARTG: 338932	Medical Device	Product Defect Alert	Class II	Hospital
14/09/2021	Australian Health Way Pty Ltd - ARTG: 342987	Medical Device	Product Defect Alert	Class II	Hospital
14/09/2021	Bug Bandits - ARTG: 341692	Medical Device	Product Defect Alert	Class II	Hospital
14/09/2021	ELI280, MLBUR280 and BUR280 Electrocardiographs	Medical Device	Product Defect Correction	Class II	Hospital
14/09/2021	Maroon Tree Pty Ltd - ARTG: 343733	Medical Device	Product Defect Alert	Class II	Hospital
14/09/2021	Mombasa Trading Pty Ltd - ARTG: 333971	Medical Device	Product Defect Alert	Class II	Hospital
14/09/2021	Rudhran Holdings Pty Ltd - ARTG: 334345	Medical Device	Product Defect Alert	Class II	Hospital
14/09/2021	Sixty Third Raven Pty Ltd - ARTG: 340389	Medical Device	Product Defect Alert	Class II	Hospital
14/09/2021	TAMBOCOR flecainide acetate 100mg tablet blister pack	Medicine	Recall	Class II	Retail
13/09/2021	GORE CARDIOFORM Septal Occluder device	Medical Device	Recall	Class II	Hospital
13/09/2021	MOSAIQ Oncology Information System	Medical Device	Product Defect Correction	Class I	Hospital
10/09/2021	Inorganic Phosphorus. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
8/09/2021	Arslan Mukhtar - ARTG: 338753	Medical Device	Product Defect Alert	Class II	Hospital
8/09/2021	C315HIS Delivery Catheter	Medical Device	Recall	Class II	Hospital
8/09/2021	Intex International Group Pty Ltd - ARTG: 339478	Medical Device	Product Defect Alert	Class II	Hospital
8/09/2021	MK Visy Pty Ltd - ARTG: 341502	Medical Device	Product Defect Alert	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
8/09/2021	MLM Corp Pty Ltd - ARTG: 339642	Medical Device	Product Defect Alert	Class II	Hospital
8/09/2021	R&H Imports - ARTG: 343443	Medical Device	Product Defect Alert	Class II	Hospital
8/09/2021	Towards Holding Group Pty Ltd - ARTG: 339997	Medical Device	Product Defect Alert	Class II	Hospital
8/09/2021	Towards Holding Group Pty Ltd - ARTG: 341718	Medical Device	Product Defect Alert	Class II	Hospital
7/09/2021	Alinity m SARS-CoV-2 AMP Kit. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
7/09/2021	CME T34 3rd edition pump	Medical Device	Recall	Class II	Hospital
7/09/2021	Fludeoxyglucose F18 Injection (F-18 FDG)	Medicine	Product Defect Correction	Class II	Hospital
6/09/2021	Various dental implant and biological materials	Medical Device	Hazard Alert	Class II	Consumer
3/09/2021	MLM Corp Pty Ltd - ARTG: 339809	Medical Device	Product Defect Alert	Class II	Hospital
3/09/2021	MLM Corp Pty Ltd - ARTG: 339811	Medical Device	Product Defect Alert	Class II	Hospital
3/09/2021	MLM Corp Pty Ltd - ARTG: 340307	Medical Device	Product Defect Alert	Class II	Hospital
3/09/2021	OctoStretch with Stretch Leveler, FlexoStretch, Stretch Leveler, LikoStretch 1900, Liko Stretch Mod 600 IC	Medical Device	Product Defect Correction	Class II	Hospital
3/09/2021	Orso International Pty Ltd - ARTG: 339637	Medical Device	Product Defect Alert	Class II	Hospital
3/09/2021	Paragon Stem High Offset Size 3	Medical Device	Hazard Alert	Class II	Hospital
3/09/2021	ResistancePlus MG Flexible. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
2/09/2021	CHATTANOOGA brand ultrasound gels and lotions	Medical Device	Recall	Class I	Retail
2/09/2021	HCU 40 Heater-Cooler Unit	Medical Device	Product Defect Correction	Class II	Hospital
2/09/2021	Runsmart Corporate Pty Ltd - ARTG: 333609	Medical Device	Product Defect Alert	Class II	Hospital
2/09/2021	Silicone Boyle Davis Gag Cover Child Blue, Box of 30, Non-Sterile	Medical Device	Recall	Class II	Hospital
2/09/2021	Sterile Blade Single-Use Accessories	Medical Device	Recall	Class II	Hospital
2/09/2021	Willieston International Pty Ltd - ARTG: 340753	Medical Device	Product Defect Alert	Class II	Hospital
2/09/2021	Willieston International Pty Ltd - ARTG: 340771	Medical Device	Product Defect Alert	Class II	Hospital

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1/09/2021	CAP1 3 IMMUNOTYPING. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
31/08/2021	AtomLab 500 and AtomLab 500Plus Dose Calibrator	Medical Device	Product Defect Correction	Class II	Hospital
31/08/2021	Procedure packs containing BD SmartSite needle-free component	Medical Device	Product Defect Correction	Class II	Hospital
27/08/2021	Atlan A3X0 Anaesthesia System	Medical Device	Product Defect Correction	Class II	Hospital
27/08/2021	Braun ThermoScan PRO 6000 Ear Thermometer	Medical Device	Product Defect Correction	Class II	Retail
27/08/2021	cerabone granules (multiple sizes) and mucoderm (Multiple sizes)	Medical Device	Product Defect Correction	Class II	Consumer
27/08/2021	DLP Left Heart Vent Catheters, 16Fr / 18Fr	Medical Device	Recall	Class II	Hospital
27/08/2021	Operating Room Tables (ORT200 and ORT300)	Medical Device	Product Defect Correction	Class II	Hospital
27/08/2021	VIOTROL ToRCH-M. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
26/08/2021	Atrium Pneumostat Chest Drain Valve	Medical Device	Product Defect Correction	Class I	Hospital
26/08/2021	corpuls3 SLIM and corpuls3 Touch SLIM	Medical Device	Product Defect Correction	Class I	Hospital
26/08/2021	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Recall	Class II	Hospital
26/08/2021	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Recall	Class II	Hospital
26/08/2021	Philips SureSigns VS4 Vital Signs Monitor	Medical Device	Product Defect Correction	Class II	Hospital
26/08/2021	Technetium-99m MAA	Medicine	Recall	Class II	Hospital
25/08/2021	AIRO TruCT Mobile CT System	Medical Device	Product Defect Correction	Class II	Hospital
25/08/2021	Babylog VN500, Evita V300 and Evita V500	Medical Device	Product Defect Correction	Class I	Hospital
25/08/2021	Five S 3.5 x 65, Sterile Use, Flexible Video Intubation Laryngoscope	Medical Device	Recall	Class II	Hospital
25/08/2021	Flow Sensors in Datex-Ohmeda Anaesthesia Machines	Medical Device	Product Defect Correction	Class I	Hospital
25/08/2021	Kangaroo Skin Level Balloon Gastrostomy Kits	Medical Device	Product Defect Correction	Class III	Hospital
25/08/2021	Merit Customer Procedure Packs Containing Baxter Medication Delivery Products	Medical Device	Recall	Class I	Hospital

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25/08/2021	syngo.via RT Image Suite / Sim&GO and syngo.via RT Image Suite	Medical Device	Product Defect Correction	Class II	Hospital
24/08/2021	Namic Stopcocks	Medical Device	Recall	Class II	Hospital
23/08/2021	AEQUALIS PYROCARBON Humeral Head Implant	Medical Device	Hazard Alert	Class II	Hospital
19/08/2021	Damato Ruthenium Plaque Template	Medical Device	Product Defect Correction	Class III	Hospital
19/08/2021	Monosyn Suture	Medical Device	Recall	Class II	Hospital
19/08/2021	Philips Ingenia 1.5T, Ingenia 1.5T Evolution, Ingenia 1.5T S, Ingenia 1.5T CX, SmartPath to dStream for 1.5T, Ingenia 3.0T, Ingenia Ambition S, Ingenia Ambition X, Ingenia Elition S, Ingenia Elition X, Ingenia 3.0T CX, SmartPath to dStream for XR and 3.0T	Medical Device	Product Defect Correction	Class II	Hospital
18/08/2021	CombiDiagnost R90	Medical Device	Product Defect Correction	Class II	Hospital
18/08/2021	CombiDiagnost R90	Medical Device	Product Defect Correction	Class II	Hospital
18/08/2021	Exhalyzer D	Medical Device	Product Defect Correction	Class III	Hospital
18/08/2021	Gelfoam Sponge - Gelatin haemostatic agent	Medical Device	Product Defect Correction	Class I	Hospital
18/08/2021	Illinois Bone Marrow Aspiration Needle 15G x 79mm	Medical Device	Recall	Class II	Hospital
17/08/2021	ASA Hospitality Pty Ltd - ARTG: 337385	Medical Device	Product Defect Alert	Class II	Hospital
17/08/2021	Enviro Tech Holdings Pty Ltd - ARTG: 345617	Medical Device	Product Defect Alert	Class II	Hospital
17/08/2021	Enviro Tech Holdings Pty Ltd - ARTG: 341652	Medical Device	Product Defect Alert	Class II	Hospital
17/08/2021	GBT Express Pty Ltd - ARTG: 341174	Medical Device	Product Defect Alert	Class II	Hospital
17/08/2021	MIM software with SPECTRA Quant	Medical Device	Product Defect Correction	Class III	Hospital
17/08/2021	Peng United Star Pty Ltd - ARTG 340881	Medical Device	Product Defect Alert	Class II	Hospital
17/08/2021	Peng United Star Pty Ltd - ARTG: 339970	Medical Device	Product Defect Alert	Class II	Hospital
17/08/2021	Peng United Star Pty Ltd - ARTG: 340880	Medical Device	Product Defect Alert	Class II	Hospital
17/08/2021	Remel RapID NF system. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
17/08/2021	Rhodes & Beckett Trading Pty Ltd - ARTG: 341029	Medical Device	Product Defect Alert	Class II	Hospital

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17/08/2021	Son Loc Melbourne Pty Ltd - ARTG: 340322	Medical Device	Product Defect Alert	Class II	Hospital
17/08/2021	Stephan EVE Intensive/with Masimo rainbow SET technology	Medical Device	Product Defect Correction	Class II	Hospital
17/08/2021	Yex International Pty Ltd - ARTG: 342052	Medical Device	Product Defect Alert	Class II	Hospital
16/08/2021	Telemetric pressure catheter 096504-001 NEUROVENT - P-tel	Medical Device	Recall	Class II	Hospital
13/08/2021	Monaco Radiation Treatment Planning (RTP) System	Medical Device	Product Defect Correction	Class II	Hospital
12/08/2021	VIDAS EBV VCA IgM. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
11/08/2021	Fabian HFO, Fabian +nCPAP evolution, and Fabian Therapy evolution ventilators	Medical Device	Product Defect Correction	Class I	Hospital
11/08/2021	IK707 - Optilite Special Wash 1	Medical Device	Product Defect Correction	Class III	Hospital
11/08/2021	LeadCare II and LeadCare Plus test kits. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
11/08/2021	Various Procedure Packs containing SmartSite Needle-Free Connector Products	Medical Device	Product Defect Correction	Class II	Hospital
11/08/2021	Vysis CLL FISH Probe Kit. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
10/08/2021	Agilia SP PCA infusion pump	Medical Device	Product Defect Correction	Class II	Hospital
10/08/2021	BF-XT160 Bronchovideoscope	Medical Device	Product Defect Correction	Class II	Hospital
10/08/2021	PageWriter TC Cardiographs Models (TC20,30,50,70)	Medical Device	Product Defect Correction	Class II	Hospital
9/08/2021	AVSARTAN Irbesartan tablet 150mg and 300mg.	Medicine	Recall	Class II	Retail
9/08/2021	DxA 5000 with B57634. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
9/08/2021	Philips Continuous CT Fluoroscopy DVI Ceiling Mount – CCT Arm DVI Option - Monitor Bracket Assembly	Medical Device	Product Defect Correction	Class II	Hospital
6/08/2021	DuoDERM Extra Thin and DuoDERM CGF	Medical Device	Recall	Class II	Consumer
6/08/2021	Electric Infusion Pump – Administration set (also known as Batch Kit IRIS).	Medical Device	Product Defect Alert	Class II	Hospital
6/08/2021	EPIQ Ultrasound Systems	Medical Device	Product Defect Correction	Class II	Hospital

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6/08/2021	FLUCLOXACILLIN 0.9% SODIUM CHLORIDE IN MOBIFUSER FOR INTRAVENOUS INFUSION	Medicine	Recall	Class II	Hospital
6/08/2021	Henry Schein Halas - Mask, surgical, single use	Medical Device	Product Defect Alert	Class II	Retail
6/08/2021	Manjistadi Kashyam, Mahanarayana Oil, Kottamchukkadi Oil, and Ayyapala Oil	Medicine	Recall	Class II	Consumer
5/08/2021	BOND Ready-to-Use Primary Antibody CDX2 (EP25). An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
5/08/2021	PRISMAFLEX TPE2000 SET	Medical Device	Recall	Class II	Hospital
4/08/2021	BHR Square Headed Nail	Medical Device	Recall	Class II	Hospital
4/08/2021	EnVision FLEX Hematoxylin (Link) Kit and Vial. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
4/08/2021	Infusomat Space Line SafeSet	Medical Device	Recall	Class II	Hospital
4/08/2021	RUSCHELIT Super Safety Clear Tracheal Tube	Medical Device	Recall	Class II	Hospital
4/08/2021	β-Hydroxybutyrate LiquiColor. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
4/08/2021	Steelex Sternum Set	Medical Device	Recall	Class II	Hospital
3/08/2021	Alinity ci-series System Control Module (SCM). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
3/08/2021	Zippie Voyage early intervention stroller	Medical Device	Product Defect Correction	Class II	Consumer
2/08/2021	Better Health Pharmacy Pty Ltd - ARTG: 341453	Medical Device	Product Defect Alert	Class II	Hospital
2/08/2021	Better Health Pharmacy Pty Ltd - ARTG: 341462	Medical Device	Product Defect Alert	Class II	Hospital
2/08/2021	Trustee for DKT Family Trust - ARTG: 340030	Medical Device	Product Defect Alert	Class II	Hospital
2/08/2021	VITEK 2 GP ID Cards. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
30/07/2021	Lina Xcise Laparoscopic Morcellator	Medical Device	Product Defect Correction	Class II	Hospital
30/07/2021	Lway Trading Pty Ltd - ARTG: 332989	Medical Device	Product Defect Alert	Class II	Hospital
30/07/2021	Lway Trading Pty Ltd - ARTG: 332990	Medical Device	Product Defect Alert	Class II	Hospital

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30/07/2021	Philips Ingenia 1.5T, Ingenia 1.5T Evolution, Ingenia 3.0T, Ingenia Elition X Magnetic Resonance System	Medical Device	Product Defect Correction	Class I	Hospital
29/07/2021	CME Microset and BD BodyGuard Microset Infusion sets	Medical Device	Product Defect Correction	Class III	Hospital
29/07/2021	Horse blood agar (HBA) plates. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
28/07/2021	JAMSHIDI (TJ) BONE MARROW BIOPSY/ASPIRATION NEEDLE 11G X4	Medical Device	Recall	Class II	Hospital
28/07/2021	McKesson/ Change Healthcare Cardiology Hemo	Medical Device	Product Defect Correction	Class II	Hospital
28/07/2021	Neutrogena Ultra Sheer Sunscreen Spray SPF 50+ with Helioplex	Medicine	Recall	Class II	Consumer
28/07/2021	Optitrol NAT HIV Screening. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
28/07/2021	Trilogy Evo O2 and Trilogy Evo	Medical Device	Product Defect Correction	Class II	Consumer
27/07/2021	Elecsys CA 19-9 reagent for use on cobas e 801 analytical unit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
27/07/2021	EMBLEM S-ICD Subcutaneous Electrode	Medical Device	Recall	Class I	Hospital
27/07/2021	Horizon/McKesson/Change Healthcare Cardiology, Horizon/McKesson/Change Healthcare Cardiology Hemo and Horizon/McKesson/Change Healthcare Cardiology ECG Management	Medical Device	Product Defect Correction	Class II	Hospital
27/07/2021	Kaluza C Software. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
27/07/2021	SmartSite Needle-Free Connectors	Medical Device	Product Defect Correction	Class II	Hospital
26/07/2021	Alinity m System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
26/07/2021	ASA Hospitality Pty Ltd - ARTG: 340875	Medical Device	Product Defect Alert	Class II	Hospital
26/07/2021	HARMONIC HD 1000i Shears	Medical Device	Recall	Class I	Hospital
26/07/2021	Lway Trading Pty Ltd - ARTG: 334257	Medical Device	Product Defect Alert	Class II	Hospital
26/07/2021	PneumoDart Needle	Medical Device	Product Defect Correction	Class II	Hospital

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26/07/2021	RESUS-EZY Resuscitator - Patient Valve with Flow Diverter and Infant, Child and Adult Resuscitators	Medical Device	Recall	Class I	Retail
26/07/2021	The Trustee for DKT Family Trust - ARTG: 337182	Medical Device	Product Defect Alert	Class II	Hospital
26/07/2021	The Trustee for DKT Family Trust - ARTG: 338931	Medical Device	Product Defect Alert	Class II	Hospital
23/07/2021	CareSens N Meter set, CareSens N Voice Meter set, CareSens Dual Meter set, CareSens N Voice Meter set and CareSens N Premier Meter set . An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Retail
23/07/2021	CHAMPIX varenicline (as tartrate) 1.0mg tablet blister pack	Medicine	Recall	Class II	Retail
23/07/2021	Configura Advance Chair models	Medical Device	Product Defect Correction	Class II	Consumer
23/07/2021	Relistor 12mg/0.6 ml inj (7's)	Medical Device	Recall	Class III	Retail
22/07/2021	Restoris MCK Femoral Trial and Restoris MCK Patellofemoral Trial	Medical Device	Recall	Class III	Hospital
21/07/2021	Directlink Global - ARTG: 335565	Medical Device	Product Defect Alert	Class II	Hospital
21/07/2021	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Product Defect Alert	Class II	Hospital
20/07/2021	MEDUMAT Transport	Medical Device	Product Defect Correction	Class II	Hospital
20/07/2021	Pipeline Flex Embolization Device and Pipeline Flex Embolization Device with Shield Technology	Medical Device	Recall	Class I	Hospital
19/07/2021	Alinity s System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
19/07/2021	REYATAZ atazanavir (as sulfate) 300mg capsule bottle	Medicine	Product Defect Alert	Class III	Retail
16/07/2021	Copper CU2340 R1a Buffer. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
15/07/2021	ASA Hospitality Pty Ltd - ARTG: 335456	Medical Device	Product Defect Alert	Class II	Hospital
15/07/2021	BOC LIFE LINE Emergency Oxygen Resuscitation Kit	Medical Device	Product Defect Correction	Class I	Consumer
15/07/2021	OptetraK Logic Femoral Component, Posterior Stabilized, Cemented, Size 4, Left	Medical Device	Recall	Class III	Wholesale
15/07/2021	S-7XTRA Tub Wipes 200	Medical Device	Recall	Class III	Retail

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14/07/2021	ASA Hospitality Pty Ltd - ARTG: 341092	Medical Device	Product Defect Alert	Class II	Hospital
14/07/2021	ASA Hospitality Pty Ltd - Mask, <specify>	Medical Device	Product Defect Alert	Class II	Hospital
14/07/2021	Directlink Global - Public Respirator, Single Use	Medical Device	Product Defect Alert	Class II	Hospital
13/07/2021	CV-1500 Processor, CF-EZ1500DI Colonovideoscope, CF-EZ1500DL Colonovideoscope and GIF-EZ1500 Gastrointestinal Videoscope.	Medical Device	Product Defect Correction	Class II	Hospital
13/07/2021	Multiple Customized Tubing Sets	Medical Device	Product Defect Correction	Class II	Hospital
13/07/2021	NUCALA mepolizumab 100 mg solution for injection in pre-filled pen	Medicine	Recall	Class II	Retail
12/07/2021	Atellica IM BR 27.29 (BR) Assay 50 Test Kit and Assay 250 Test Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
12/07/2021	DROLEPTAN Droperidol 2.5mg/1mL injection ampoule - packs of 10	Medicine	Product Defect Correction	Class II	Hospital
12/07/2021	MIDCAL Gastric Calibration Ring	Medical Device	Product Defect Correction	Class III	Hospital
12/07/2021	Pipe Traders Australia Pty Ltd - GIKO 1200 and GIKO 1500 - Public N95 respirator	Medical Device	Product Defect Alert	Class II	Hospital
12/07/2021	SIMVAR 20 simvastatin 20 mg tablet blister pack	Medicine	Product Defect Correction	Class II	Retail
9/07/2021	HADLIMA adalimumab (rch) 40 mg solution for injection PushTouch auto-injector	Medicine	Product Defect Correction	Class III	Retail
9/07/2021	HBA Columbia Plates 10pcs. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
9/07/2021	SeroFIA Chlamydia IgG Kit, SeroELISA Chlamydia IgG Kit, and SeroELISA Chlamydia IgA Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
8/07/2021	18F-DCFPyL	Medicine	Product Defect Alert	Class II	Hospital
8/07/2021	Flow- i C20, Flow-i C30, Flow-i C40	Medical Device	Product Defect Correction	Class II	Hospital
8/07/2021	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Product Defect Correction	Class III	Hospital
7/07/2021	INSPYRE PYROCARBON Interpositional Implant	Medical Device	Hazard Alert	Class I	Hospital
7/07/2021	Sym Balance	Medicine	Product Defect Correction	Class II	Consumer

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6/07/2021	The VeriSeq NIPT Solution v2. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
5/07/2021	Daratumumab in 0.9% Sodium Chloride in Polyolefin Bag (Freeflex) for Intravenous Infusion	Medicine	Recall	Class II	Hospital
5/07/2021	OEC Elite systems and all OEC 3D mobile C-Arm systems	Medical Device	Product Defect Correction	Class II	Hospital
2/07/2021	ETEST Imipenem/Relebactam. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
2/07/2021	Lipid Control Level 1. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
1/07/2021	ExacTrac Dynamic Radiation Therapy Patient Positioning System	Medical Device	Product Defect Correction	Class II	Hospital
1/07/2021	Multiple GE Healthcare MR Machines	Medical Device	Product Defect Correction	Class II	Hospital
1/07/2021	Philips Respironics - Ventilator Devices	Medical Device	Product Defect Correction	Class I	Consumer
1/07/2021	Philips Respironics CPAP and Bi-Level PAP Devices	Medical Device	Product Defect Correction	Class I	Consumer
1/07/2021	TRIKAFTA elexacaftor / tezacaftor / ivacaftor and ivacaftor 100mg/50mg/75mg and 150mg film-coated tablet blister pack	Medicine	Product Defect Correction	Class III	Retail
30/06/2021	Easyvision Umere Toric (somofilcon A) soft contact lenses	Medical Device	Recall	Class III	Consumer
30/06/2021	PalaXtreme, 500ml DE/GB/FR/NL	Medical Device	Product Defect Correction	Class II	Retail
30/06/2021	Philips V60 and V60 Plus Ventilators	Medical Device	Product Defect Correction	Class I	Hospital
30/06/2021	Randox Zinc (Zn) Assay. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
30/06/2021	TFL-PLS SOLTIVE Premium SuperPulsed Laser System	Medical Device	Product Defect Correction	Class II	Hospital
29/06/2021	Multigate Hysteroscopy/Cystoscopy Packs containing Baxter TUR Admin Sets	Medical Device	Recall	Class III	Hospital
29/06/2021	Philips HeartStart Intrepid Monitor/Defibrillator	Medical Device	Product Defect Correction	Class I	Hospital
29/06/2021	RYALTRIS olopatadine 600 microgram/actuation and mometasone furoate 25 microgram/actuation nasal spray bottle	Medicine	Product Defect Correction	Class III	Retail

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
28/06/2021	cobas u pack (400 strip) for use on cobas u 601 analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
28/06/2021	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
28/06/2021	InterStim System Advanced Evaluation Percutaneous Extension Connector	Medical Device	Product Defect Correction	Class II	Hospital
25/06/2021	4K LCD Monitor	Medical Device	Product Defect Correction	Class II	Hospital
25/06/2021	LikoGuard L (3301030) and LikoGuard XL (3301040)	Medical Device	Product Defect Correction	Class II	Hospital
25/06/2021	Losartan potassium 50mg Film Coated Tablets 28 pack	Medicine	Recall	Class II	Hospital
25/06/2021	Product name: B.R.A.H.M.S Solution 2 KRYPTOR GOLD. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
24/06/2021	Access AMH calibrators. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
24/06/2021	Superglide Valve Ureter Stents	Medical Device	Product Defect Correction	Class II	Hospital
23/06/2021	Endurant II/IIIs Stent Graft System Radiopaque (RO) Marker Bond Detachment	Medical Device	Recall	Class I	Hospital
23/06/2021	GlideScope Go Video Monitors	Medical Device	Product Defect Correction	Class II	Hospital
23/06/2021	Medline Flexi Cystoscopy Pack containing Baxter Medication Delivery Care Products	Medical Device	Recall	Class II	Hospital
23/06/2021	STA R Max. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
22/06/2021	OrganOx metra Retained Unit	Medical Device	Product Defect Correction	Class II	Hospital
22/06/2021	SOL049 MonsGel Monsel's Ferric Subsulfate Gel	Medicine	Product Defect Correction	Class III	Retail
22/06/2021	Various VITROS Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
21/06/2021	BioFire FilmArray Pneumonia plus (PN plus). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
21/06/2021	EASYGRIP FLO-41 Precision MIS Delivery System	Medical Device	Product Defect Correction	Class III	Hospital
21/06/2021	M8 and S8 Lead Adaptors	Medical Device	Product Defect Correction	Class II	Consumer
21/06/2021	Olympus Endocuff Vision Products	Medical Device	Recall	Class III	Hospital
21/06/2021	Revolution CT (Collimator)	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
18/06/2021	AP Surgical Pty Ltd- Disposable Face mask- tie-back	Medical Device	Product Defect Alert	Class II	Retail
18/06/2021	ORTHO VISION Analyzer for BioVue and ORTHO VISION Max Analyzer for BioVue. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
18/06/2021	OXOID AST DISC CT0223B – Amoxycillin/Clavulanic acid AMC30. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
18/06/2021	Sterile Optical Fibers	Medical Device	Recall	Class II	Hospital
17/06/2021	Alinity c and ARCHITECT Activated Alanine Aminotransferase (A-ALT) reagent kit/assay. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
17/06/2021	basixALPHA Inflation Device	Medical Device	Recall	Class II	Hospital
17/06/2021	Merits Mobility Scooters & Chairs	Medical Device	Product Defect Correction	Class II	Consumer
17/06/2021	Suture Anchor BioComposite SwiveLock C, 5.5mm x 19.1mm, Closed Eyelit	Medical Device	Recall	Class II	Hospital
16/06/2021	da Vinci S/Si Harmonic ACE Curved Shears	Medical Device	Product Defect Correction	Class III	Hospital
16/06/2021	Fludeoxyglucose F18 Injection (F-18 FDG)	Medicine	Product Defect Correction	Class II	Hospital
16/06/2021	MYLA V4.8.0/4.8.1 and V4.7.0/V4.7.1 in conjunction with BCI Connect. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
16/06/2021	TMJ Total Joint Replacement System	Medical Device	Hazard Alert	Class II	Consumer
15/06/2021	Detmold D95-P2 Respirators	Medical Device	Recall	Class II	Hospital
15/06/2021	Detmold Medical D95+ Surgical Respirator Masks	Medical Device	Recall	Class II	Hospital
15/06/2021	EnVeo R, EnVeo PRO and Evolut PRO+ Delivery Catheter	Medical Device	Recall	Class II	Hospital
15/06/2021	Laryngeal Airway Mask	Medical Device	Recall	Class II	Hospital
11/06/2021	ACCOLADE and ESSENTIO pacemakers and VISIONIST cardiac resynchronization therapy pacemakers (CRT-Ps)	Medical Device	Hazard Alert	Class I	Hospital
11/06/2021	CARESCAPE Patient Data Module (PDM)	Medical Device	Product Defect Correction	Class I	Hospital
11/06/2021	The Medtronic StimLoc Burr hole cover	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
11/06/2021	Vita-B12 Injection 1mg (Hydroxocobalamin Acetate)	Medicine	Recall	Class III	Retail
10/06/2021	ACE Kinetic Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
10/06/2021	INGENIO, VITALIO, and ADVANTIO pacemakers and INVIVE cardiac resynchronization therapy pacemakers	Medical Device	Hazard Alert	Class I	Hospital
10/06/2021	Introducer Localization Set for ATEC	Medical Device	Product Defect Correction	Class II	Hospital
9/06/2021	Access CEA Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
9/06/2021	Kii Optical Advanced Fixation	Medical Device	Product Defect Correction	Class III	Hospital
9/06/2021	Spark Clear Aligners	Medical Device	Recall	Class III	Consumer
8/06/2021	Philips FM20/FM30/FM40/FM50 Avalon Foetal Monitors	Medical Device	Product Defect Correction	Class II	Hospital
7/06/2021	ARTIS pheno with software version VE10B	Medical Device	Product Defect Correction	Class II	Hospital
7/06/2021	Tempus Pro (with Trizeps 7 Hardware)	Medical Device	Product Defect Correction	Class I	Hospital
7/06/2021	The NT2000iX generator	Medical Device	Product Defect Correction	Class II	Hospital
4/06/2021	Arjo medical beds assembled with IndiGo module	Medical Device	Product Defect Correction	Class II	Hospital
4/06/2021	BiPAP A40 Pro and A40 EFL	Medical Device	Product Defect Correction	Class II	Hospital
4/06/2021	CUTAN OPTIDOSE ALCOHOL FOAM ANTISEPTIC HANDRUB Ethanol	Medicine	Recall	Class II	Hospital
4/06/2021	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Recall	Class II	Hospital
4/06/2021	SoKINOX NO delivery and monitoring system	Medical Device	Product Defect Correction	Class I	Hospital
4/06/2021	The EasyScreen Respiratory Pathogen Detection Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
3/06/2021	Medical Delivery Products	Medical Device	Recall	Class I	Hospital
3/06/2021	Palindrome RT Chronic Hemodialysis Catheters and Palindrome RT repair kits	Medical Device	Recall	Class I	Hospital
3/06/2021	Technetium-99m Cardiolite	Medicine	Recall	Class II	Hospital
2/06/2021	Affinity Four Birthing Bed	Medical Device	Product Defect Correction	Class II	Hospital
2/06/2021	Covidien DAR airway products	Medical Device	Recall	Class II	Hospital

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2/06/2021	HeartWare Ventricular Assist Device (HVAD) System	Medical Device	Hazard Alert	Class I	Hospital
2/06/2021	JELONET 5x5cm Carton/50.	Medical Device	Recall	Class II	Hospital
2/06/2021	Philips Expression MR Invasive Blood Pressure (IBP) Transducer Cable	Medical Device	Product Defect Correction	Class III	Hospital
1/06/2021	Atellica CH 930 Analyser, Atellica IM 1300 Analyser and Atellica IM 1600 Analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
1/06/2021	Clinell Universal Wipes - Pack of 200	Medical Device	Recall	Class II	Consumer
1/06/2021	OSPOLOT sulthiame 200mg tablet bottle	Medicine	Product Defect Alert	Class II	Consumer
1/06/2021	Reveal LINQ with TruRhythm Insertable Cardiac Monitoring Systems	Medical Device	Product Defect Correction	Class II	Hospital
28/05/2021	Abtectcell III 0.8%. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
28/05/2021	YSIO X.pree	Medical Device	Product Defect Correction	Class II	Hospital
27/05/2021	cobas 6500 urine analyser series (cobas u 701 microscopy analyser in combination with cobas u 601 urine analyser). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
27/05/2021	LK016.CB – Freelite Human Kappa Free Kit and LK016.10CB – Freelite Human Kappa Free Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
27/05/2021	NEFA (Non Esterified Fatty Foods) assay - An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
27/05/2021	T2 Nail Insertion Sleeve Instrument	Medical Device	Recall	Class II	Hospital
26/05/2021	Atellica UAS 800 Urine Sediment Analyser and Atellica 1500 Automated Urinalysis System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
26/05/2021	Big Start Pty Ltd- Disposable Medical Face Mask	Medical Device	Product Defect Alert	Class II	Retail
26/05/2021	COOL IROM BRACE, SHORT, S, Black	Medical Device	Product Defect Correction	Class III	Retail
26/05/2021	Kogan Australia Pty Ltd - 3 Ply Personal Protective Disposable Face Mask (50 Pack)	Medical Device	Product Defect Alert	Class II	Consumer
26/05/2021	PrisMax System	Medical Device	Product Defect Correction	Class I	Hospital

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26/05/2021	SCS Screwdriver	Medical Device	Recall	Class II	Retail
25/05/2021	ADVIA Chemistry XPT System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
25/05/2021	Lipid Controls Level 1, 2 and 3. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
25/05/2021	SCREWFIX	Medical Device	Recall	Class II	Hospital
24/05/2021	Jardini Pty Ltd - ARTG: 335996	Medical Device	Product Defect Correction	Class II	Hospital
24/05/2021	Omni-Tel Pty Ltd - Quovo Mask - Mask, surgical, single use	Medical Device	Product Defect Alert	Class II	Retail
24/05/2021	Philips Continuous CT Fluoroscopy DVI Ceiling Mount – CCT Arm DVI Option - Monitor Bracket Assembly	Medical Device	Product Defect Correction	Class II	Hospital
24/05/2021	The VENOVO Venous Stent System	Medical Device	Recall	Class I	Hospital
24/05/2021	UTN Group Pty Ltd - ARTG: 335629	Medical Device	Product Defect Alert	Class II	Hospital
24/05/2021	UTN Group Pty Ltd - ARTG: 335631	Medical Device	Product Defect Alert	Class II	Hospital
21/05/2021	MRI system	Medical Device	Product Defect Correction	Class II	Hospital
21/05/2021	Safescaper Twist Curve and Safescraper Twist	Medical Device	Recall	Class II	Retail
20/05/2021	AU Creatine Kinase-MB (CK-MB) Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
20/05/2021	clariti 1 day toric (somofilcon A) soft contact lenses	Medical Device	Recall	Class III	Retail
18/05/2021	fabian Therapy evolution, fabian +nCPAP evolution and fabian HFO ventilators	Medical Device	Product Defect Correction	Class I	Hospital
18/05/2021	Phadia EliA SymphonyS Well. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
18/05/2021	WO300 OR1 FUSION CONTROL software release 1.4.0 / 1.4.1	Medical Device	Product Defect Correction	Class II	Hospital
14/05/2021	All ABL800 analyzers measuring cCrea. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
14/05/2021	Pharmacy Action Dry Cough Relief Oral Liquid	Medicine	Product Defect Correction	Class II	Retail
14/05/2021	Technetium-99m DTPA	Medicine	Recall	Class II	Hospital
13/05/2021	18F-DCFPyL (PSR)	Medicine	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
13/05/2021	3PLUS1 Multilevel Plasma Calibrator Set Neuroleptics. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
13/05/2021	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Recall	Class II	Hospital
13/05/2021	Hydralyte Strawberry Kiwi Effervescent Electrolyte Tablets	Medicine	Recall	Class II	Consumer
13/05/2021	Oxinium Femoral Head 12/14 36 MM L/+8	Medical Device	Hazard Alert	Class II	Hospital
13/05/2021	Recothrom 5000IU Kit	Medicine	Product Defect Alert	Class I	Hospital
13/05/2021	SOMATOM X.Cite systems	Medical Device	Product Defect Correction	Class III	Hospital
13/05/2021	Various 'ITW Australia Pty Ltd' sunscreen products	Medicine	Recall	Class III	Retail
13/05/2021	X-Wing Base	Medical Device	Recall	Class III	Hospital
12/05/2021	PEEK Knotless CorkScrew Suture Anchor With #2 Suture, 3.9 x 11.2 mm	Medical Device	Product Defect Correction	Class II	Hospital
12/05/2021	The Medline Surgical Clipper with charging base	Medical Device	Product Defect Correction	Class III	Hospital
11/05/2021	Atellica CH 930 Analyser Photometer Lamp. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
11/05/2021	Ingenia Ambition X and Ingenia Ambition S	Medical Device	Product Defect Correction	Class I	Hospital
11/05/2021	Philips Efficia CM Patient Monitors	Medical Device	Product Defect Correction	Class III	Hospital
11/05/2021	RayStation 6, 7, 8A, 8B, 9A, 9B, 10A, 10B, RayPlan 2, including some service packs	Medical Device	Product Defect Correction	Class II	Hospital
11/05/2021	ZNN CMN Femoral Nail	Medical Device	Hazard Alert	Class II	Hospital
10/05/2021	BD Venflon Pro Safety I.V. Cannula with polyurethane catheter and injection port 22GA, 18GA, 17GA, 16GA and 14GA.	Medical Device	Recall	Class II	Hospital
10/05/2021	KIOVIG normal immunoglobulin (human) 1g/10mL solution for injection vial	Medicine	Product Defect Alert	Class III	Hospital
10/05/2021	Tc99m Cardiolite 5*D	Medicine	Product Defect Alert	Class III	Hospital
10/05/2021	Transpac IV Monitoring Kits with SafeSet Reservoirs	Medical Device	Product Defect Correction	Class II	Hospital
7/05/2021	Gruppo Bioimpianti Polyethylene Liners and Cups for Hip Arthroplasty	Medical Device	Hazard Alert	Class II	Hospital

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6/05/2021	BOND Epitope Retrieval Solution 1, BOND Epitope Retrieval Solution 2 and BOND Wash Solution 10X Concentrate. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Alert	Class III	Hospital
6/05/2021	Cornea, Organ culture – Left	Biological	Hazard Alert	Class II	Hospital
6/05/2021	Nimbus 4 & Nimbus Professional Mattress	Medical Device	Product Defect Correction	Class II	Consumer
5/05/2021	Range of Proctoscopes & Anoscopes	Medical Device	Recall	Class II	Hospital
5/05/2021	RX Misano Analyser and RX Misano Analyser (with Printer). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
5/05/2021	ZEISS CLARUS models 500 and 700 (Fundus Cameras)	Medical Device	Product Defect Correction	Class II	Hospital
4/05/2021	Angiographic Guidewire Components	Medical Device	Recall	Class II	Hospital
4/05/2021	DTC Project Imports Pty Ltd - Airway protection face mask.	Medical Device	Product Defect Alert	Class II	Hospital
4/05/2021	Ideal Corporate Accessories - Mask, surgical, single use	Medical Device	Product Defect Alert	Class II	Hospital
4/05/2021	Jac International Trading Pty Ltd - ARTG: 332682	Medical Device	Product Defect Alert	Class II	Hospital
4/05/2021	KCM Hygiene Pty Ltd - ARTG: 342345	Medical Device	Product Defect Alert	Class II	Hospital
4/05/2021	META Safescraper Twist (Curved) & META Micoss Bone scraper.	Medical Device	Recall	Class II	Retail
4/05/2021	Mincorli Pty Ltd - ARTG: 338930	Medical Device	Product Defect Alert	Class II	Hospital
4/05/2021	Phadia 2500E instrument. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
4/05/2021	South Yarra News & Lotto - ARTG: 340302	Medical Device	Product Defect Alert	Class II	Hospital
4/05/2021	Various ICD / CRT-D devices with Blackwell batteries	Medical Device	Hazard Alert	Class I	Hospital
3/05/2021	BAM AU Pty Ltd - Airway protection face mask	Medical Device	Product Defect Alert	Class II	Consumer
3/05/2021	The BD Alaris Pump Module Model 8100	Medical Device	Product Defect Correction	Class I	Hospital
3/05/2021	VICI and VICI VERTO Venous Stent Systems	Medical Device	Recall	Class I	Hospital
30/04/2021	Femoral Head Allograft	Biological	Recall	Class II	Hospital
30/04/2021	Living Healthy Women's Multivitamin	Medicine	Recall	Class II	Retail
30/04/2021	Xper Flex Cardio Physio Monitoring System	Medical Device	Product Defect Correction	Class II	Hospital

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29/04/2021	CombiDiagnost R90	Medical Device	Product Defect Correction	Class III	Hospital
29/04/2021	DigitalDiagnost C90	Medical Device	Product Defect Correction	Class III	Hospital
29/04/2021	Groshong NxT Peripherally Inserted Central Catheters (PICC)	Medical Device	Product Defect Correction	Class II	Hospital
28/04/2021	CASE and CardioSoft ECG systems	Medical Device	Product Defect Correction	Class II	Hospital
28/04/2021	GT Construction Australia - ARTG: 334303	Medical Device	Product Defect Alert	Class II	Hospital
28/04/2021	Jardini Pty Ltd - ARTG: 334624	Medical Device	Product Defect Correction	Class II	Hospital
28/04/2021	Jardini Pty Ltd - ARTG: 334625	Medical Device	Product Defect Correction	Class II	Hospital
28/04/2021	Jardini Pty Ltd - ARTG: 335619	Medical Device	Product Defect Alert	Class II	Hospital
28/04/2021	Prestige Worldwide Imports Pty Ltd - ARTG: 335564	Medical Device	Product Defect Alert	Class II	Hospital
28/04/2021	Prestige Worldwide Imports Pty Ltd - ARTG: 335569	Medical Device	Product Defect Alert	Class II	Hospital
28/04/2021	Prestige Worldwide Imports Pty Ltd - ARTG: 335616	Medical Device	Product Defect Alert	Class II	Hospital
28/04/2021	Prestige Worldwide Imports Pty Ltd - ARTG: 335617	Medical Device	Product Defect Alert	Class II	Hospital
28/04/2021	Prestige Worldwide Imports Pty Ltd - ARTG: 335703	Medical Device	Product Defect Alert	Class II	Hospital
28/04/2021	Prestige Worldwide Imports Pty Ltd - ARTG: 336113	Medical Device	Product Defect Alert	Class II	Hospital
28/04/2021	SILK VISTA (stent flow-diverter for interventional neuroradiology)	Medical Device	Product Defect Correction	Class II	Hospital
28/04/2021	SOMAC pantoprazole 20mg (as sodium sesquihydrate) enteric-coated tablet blister pack	Medicine	Product Defect Correction	Class III	Retail
28/04/2021	Spectrum White CBD 100mg/ml Oil 50ml	Medicine	Recall	Class III	Consumer
27/04/2021	ADVIA Centaur Syphilis Assay. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
27/04/2021	Alcon Custom Pak	Medical Device	Product Defect Correction	Class II	Hospital
27/04/2021	Cyclophosphamide IV bag	Medicine	Recall	Class II	Hospital
27/04/2021	Synaptive Trackable Suction	Medical Device	Recall	Class II	Hospital
23/04/2021	Unimax Retrival Bag	Medical Device	Recall	Class III	Wholesale
22/04/2021	Access Sensitive Estradiol. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital

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22/04/2021	McCulloch Retractor Frame	Medical Device	Product Defect Correction	Class III	Hospital
21/04/2021	Automated Manifold Kit with Transducer (BT-2000)	Medical Device	Recall	Class II	Hospital
21/04/2021	NeuMoDx Saliva Collection Kit. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class I	Hospital
21/04/2021	Omnia Soft Tissue Punches	Medical Device	Recall	Class II	Retail
20/04/2021	Access 25(OH) Vitamin D Total for use in Access 2 and DxI Immunoassay systems. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
20/04/2021	EnSite X EP System Amplifier	Medical Device	Recall	Class II	Hospital
20/04/2021	GS777 Wall Transformer (all models) and ProBP 3400 (handheld, desk mount, wall mount models)	Medical Device	Product Defect Correction	Class II	Hospital
20/04/2021	Mucosal Punch EV	Medical Device	Recall	Class II	Retail
20/04/2021	Softmed – Surgical Face Masks	Medical Device	Product Defect Alert	Class II	Retail
20/04/2021	The Intego/Intego Pro	Medical Device	Product Defect Correction	Class II	Retail
20/04/2021	Welch Allyn Diagnostic Cardiology Suite with Spirometry models	Medical Device	Product Defect Correction	Class II	Hospital
19/04/2021	DirectInject, 5cc	Medical Device	Recall	Class III	Hospital
19/04/2021	Iron Gen.2 for use on cobas c 501/502 and COBAS INTEGRA 400 plus. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
19/04/2021	Neomycin sulfate (X-Gen) 500mg tab, 100's	Medicine	Recall	Class II	Hospital
19/04/2021	NovaSeq 6000 S2 Flow Cell, a component of the NovaSeq 6000 S2 Reagent Kit	Medical Device	Product Defect Correction	Class III	Hospital
19/04/2021	POLARSHEATH Steerable Sheath	Medical Device	Product Defect Correction	Class I	Hospital
19/04/2021	Upsilon Y Mesh Kit with Colpassist Vaginal Positioning Device	Medical Device	Recall	Class II	Hospital
16/04/2021	Angel cPRP Processing Set, Arthrex Angel PRP Kit, and Arthrex Angel BMC Kit	Medical Device	Recall	Class I	Hospital
16/04/2021	Aspen Medical Respirators.	Medical Device	Product Defect Alert	Class II	Hospital
16/04/2021	E-PRIME Vitamin E gel capsules	Medicine	Recall	Class II	Consumer

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16/04/2021	Ethicon Megadyne Electrosurgical Generators	Medical Device	Product Defect Correction	Class III	Hospital
16/04/2021	syngo.via software VB30 version	Medical Device	Product Defect Correction	Class II	Hospital
16/04/2021	The Miami J Select	Medical Device	Recall	Class II	Hospital
16/04/2021	Whole Blood Calibrator Set for Immunosuppressant Level 0-6, 0-3 and level 7. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
15/04/2021	Calibration Serum Level 3 (CAL 3). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
15/04/2021	DIPHOTERINE solution (DAPD), HEXAFLUORINE solution (DAFP)	Medical Device	Product Defect Correction	Class II	Retail
15/04/2021	Ethicon Hernia Mesh Family of Products	Medical Device	Product Defect Correction	Class II	Hospital
15/04/2021	ORTHO VISION and ORTHO VISION Max Analysers for ORTHO BioVue Cassettes. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
14/04/2021	Access Sensitive Estradiol. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
14/04/2021	Dräger Ventilators	Medical Device	Product Defect Correction	Class I	Hospital
13/04/2021	Alcon Custom Pak - various models	Medical Device	Recall	Class II	Hospital
13/04/2021	ambIT PIB.PCA pump	Medical Device	Product Defect Correction	Class III	Hospital
13/04/2021	Philips 1.5T Achieva conversion, 3.0T Achieva TX, Achieva 1.5T/3.0T/CV/IT/XR, Achieva Dstream 1.5T/3.0T, Ingenia 1.5T/3.0T, Ingenia Ambition X/S, Ingenia CX 1.5T/3.0T, Ingenia Elition S/X, Intera 1.5T, Multiva, Prodiva	Medical Device	Product Defect Correction	Class III	Hospital
12/04/2021	Biopsybell Biopsy Needles	Medical Device	Recall	Class II	Hospital
12/04/2021	Central Water Plant System	Medical Device	Product Defect Correction	Class II	Hospital
12/04/2021	MyLab Alpha, MyLabGamma, MyLabDelta	Medical Device	Product Defect Correction	Class II	Hospital
9/04/2021	Revolution CT, Revolution CT ES, Revolution Apex and Revolution CT Apex Edition	Medical Device	Product Defect Correction	Class II	Hospital
9/04/2021	Tibbs Arterial Cannula Micro Olive	Medical Device	Recall	Class II	Hospital
8/04/2021	Cornea QEB 10126 L (Left)	Biological	Hazard Alert	Class II	Hospital

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8/04/2021	Cornea QEB 10518 R (Right)	Biological	Hazard Alert	Class II	Hospital
8/04/2021	Xpert BCR-ABL Ultra. An in vitro diagnostic medical (IVD)	Medical Device	Recall	Class II	Hospital
7/04/2021	Artis zee / Q / Q.zen	Medical Device	Product Defect Correction	Class II	Hospital
7/04/2021	Artis zee ceiling and Artis zee III ceiling	Medical Device	Product Defect Correction	Class II	Hospital
7/04/2021	BYD Australia Pty Ltd - BYD Care Single use Surgical Mask	Medical Device	Product Defect Alert	Class II	Consumer
7/04/2021	NM/CT 850, NM/CT 860, NM/CT 870 DR with Smart Console	Medical Device	Product Defect Correction	Class II	Hospital
6/04/2021	ABL90 FLEX and ABL90 FLEX PLUS analysers with E3800 CPU unit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
6/04/2021	Amcor Flexibles (Australia) - ARTG: 334438	Medical Device	Product Defect Alert	Class II	Hospital
6/04/2021	ASC Trading Pty Ltd - ARTG: 333836	Medical Device	Product Defect Alert	Class II	Hospital
6/04/2021	ASC Trading Pty Ltd - ARTG: 334041	Medical Device	Product Defect Alert	Class II	Hospital
6/04/2021	ASC Trading Pty Ltd - ARTG: 334256	Medical Device	Product Defect Alert	Class II	Hospital
6/04/2021	Aust Acacia Investment Pty Ltd - ARTG: 341005	Medical Device	Product Defect Alert	Class II	Hospital
6/04/2021	Aust Acacia Investment Pty Ltd - ARTG: 341006	Medical Device	Product Defect Alert	Class II	Hospital
6/04/2021	Australian Pacific Medical Pty Ltd - ARTG: 336063	Medical Device	Product Defect Alert	Class II	Hospital
6/04/2021	Da Shi - ARTG: 334604	Medical Device	Product Defect Alert	Class II	Hospital
6/04/2021	JC Medical Australia Pty Ltd - ARTG: 283681	Medical Device	Product Defect Alert	Class II	Hospital
6/04/2021	Lohas Holding Pty Ltd	Medical Device	Product Defect Alert	Class II	Hospital
6/04/2021	Perfect Care Dental Pty Ltd - ARTG: 334550	Medical Device	Product Defect Alert	Class II	Hospital
6/04/2021	Thunderstorm Scientific Pty Ltd - ARTG: 340297	Medical Device	Product Defect Alert	Class II	Hospital
6/04/2021	Thunderstorm Scientific Pty Ltd - ARTG: 340401	Medical Device	Product Defect Alert	Class II	Hospital
6/04/2021	Tina Wells Pty Ltd - ARTG: 332563	Medical Device	Product Defect Alert	Class II	Hospital
6/04/2021	Tinawells Pty Ltd - ARTG: 336117	Medical Device	Product Defect Alert	Class II	Hospital
6/04/2021	Tinawells Pty Ltd - ARTG: 340298	Medical Device	Product Defect Alert	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
6/04/2021	Tinawells Pty Ltd - ARTG: 340491	Medical Device	Product Defect Alert	Class II	Hospital
1/04/2021	2090 CareLink Programmer, 29901 Encore Programmer, CareLink SmartSync Device Manager, CareLink Network Application Software 2491 and MyCareLink Heart Mobile Application	Medical Device	Product Defect Correction	Class I	Hospital
1/04/2021	CareLink SmartSync Device Manager	Medical Device	Product Defect Correction	Class I	Hospital
1/04/2021	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Recall	Class II	Hospital
1/04/2021	FRED easyport plus defibrillator	Medical Device	Product Defect Correction	Class II	Hospital
1/04/2021	PermaFlo A2 -Flowable Composite	Medical Device	Recall	Class II	Wholesale
31/03/2021	Cellular Matrix/ACP-HA Kit	Medical Device	Product Defect Correction	Class II	Hospital
31/03/2021	LIFEPAK CR2 Defibrillator	Medical Device	Product Defect Correction	Class I	Consumer
31/03/2021	Roche Diabetes mySugr Bolus Calculator	Medical Device	Product Defect Correction	Class II	Consumer
30/03/2021	Cardiosave Hybrid IABP and Cardiosave Rescue IABP	Medical Device	Product Defect Correction	Class III	Hospital
30/03/2021	Flocare Infinity II enteral feeding pumps	Medical Device	Product Defect Correction	Class II	Consumer
29/03/2021	Medcure (KL4 Pty Ltd) Herbal Products containing "Acorus Calamus".	Medicine	Recall	Class II	Consumer
29/03/2021	Richard Wolf Morce Power Plus Morcellator and Cutting Tubes	Medical Device	Product Defect Correction	Class II	Hospital
26/03/2021	BOND Polymer Refine Detection. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
26/03/2021	SCITROPIN A somatropin (rbe) 5mg/1.5mL injection cartridge	Medicine	Product Defect Correction	Class III	Retail
26/03/2021	Westlab Reusable Medical Face Shield	Medical Device	Product Defect Correction	Class II	Consumer
25/03/2021	AQT90 FLEX analysers and E3800 CPU Units. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
25/03/2021	BD Infusion Sets for Alaris Pumps (GP, VP, CC and SE) & Non-Dedicated Infusion sets and accessories	Medical Device	Recall	Class I	Hospital
25/03/2021	cobas SARS-CoV-2 & Influenza A/B Test for use on the cobas Liat System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital

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25/03/2021	Nordic Naturals Arctic Cod Liver Oil Capsules	Medicine	Product Defect Correction	Class II	Wholesale
25/03/2021	UriSelect 4. In vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
24/03/2021	PICO70 Arterial Blood Samplers. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class I	Hospital
24/03/2021	VenaSeal Closure System	Medical Device	Product Defect Correction	Class II	Hospital
23/03/2021	Covidien Surgiwand II Suction and Irrigation Devices	Medical Device	Recall	Class II	Hospital
23/03/2021	Kangaroo Enteral Feeding Pump Sets	Medical Device	Product Defect Correction	Class II	Hospital
22/03/2021	BVI - CustomEyes Kits containing BD Syringes and/or Needles	Medical Device	Product Defect Correction	Class II	Hospital
22/03/2021	MyWay Walker Chassis	Medical Device	Product Defect Correction	Class II	Consumer
22/03/2021	syngo.via software version VB50A and VB50B	Medical Device	Product Defect Correction	Class II	Hospital
22/03/2021	ZIPRASIDONE GH ziprasidone (as hydrochloride) 20 mg capsule blister pack	Medicine	Product Defect Alert	Class II	Retail
19/03/2021	Assayed Bovine Multi-Sera – Level 1. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
19/03/2021	Assurity and Endurity pacemakers	Medical Device	Hazard Alert	Class I	Hospital
18/03/2021	ADVIA 2120/2120i Haematology Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
18/03/2021	ORTHO VISION Analyzer for ORTHO BioVue Cassettes and ORTHO VISION Max Analyzer for ORTHO BioVue Cassettes. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
18/03/2021	Percept PC BrainSense - Model A610	Medical Device	Product Defect Correction	Class II	Hospital
18/03/2021	Percept PC BrainSense B35200 - Model A610	Medical Device	Product Defect Correction	Class II	Hospital
18/03/2021	SIEMENS SOMATOM systems: go.Now, go.Up, go.All, go.Top, go.Sim, go.Open Pro	Medical Device	Product Defect Correction	Class II	Hospital
17/03/2021	Histoacryl Blue 0.5mL and Histoacryl Transparent 0.5mL	Medical Device	Recall	Class II	Hospital
17/03/2021	Ilesto, Inventra, Iperia, Itreivia, Ilivia, Intica, Intica Neo ICDs and CRT-Ds	Medical Device	Hazard Alert	Class I	Hospital
17/03/2021	Recothrom 5000 IU kit	Medicine	Product Defect Alert	Class I	Hospital

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17/03/2021	Spark Clear Aligner Systems	Medical Device	Product Defect Correction	Class III	Retail
16/03/2021	AntiBioBotanical and Ly)mex	Medicine	Recall	Class II	Consumer
16/03/2021	CEFALEXIN SANDOZ cefalexin (as monohydrate) 250mg/5mL & 125mg/5mL powder for suspension bottle	Medicine	Product Defect Correction	Class III	Retail
15/03/2021	AC International Pty Ltd - Mask, <specify>	Medical Device	Product Defect Alert	Class II	Hospital
15/03/2021	Aurelia Union Pty Ltd - Mask, Surgical, Single Use	Medical Device	Product Defect Alert	Class II	Hospital
15/03/2021	Australia Fudao Pty Ltd - Public Respirator, Single Use	Medical Device	Product Defect Alert	Class II	Hospital
15/03/2021	Australia Fudao Pty Ltd - Surgical / Medical Respirator, Single Use	Medical Device	Product Defect Alert	Class II	Hospital
15/03/2021	Australia Resources Pty Ltd - Mask, Surgical, Single Use	Medical Device	Product Defect Alert	Class II	Hospital
15/03/2021	Haematological concentrate system kits	Medical Device	Product Defect Correction	Class II	Hospital
15/03/2021	Promotek Pty Ltd - Mask, Surgical, Single Use	Medical Device	Product Defect Alert	Class II	Hospital
15/03/2021	Promotek Pty Ltd - Mask, Surgical, Single Use	Medical Device	Product Defect Alert	Class II	Hospital
15/03/2021	Promotek Pty Ltd - Public N95 respirator	Medical Device	Product Defect Alert	Class II	Hospital
15/03/2021	RetCam Envision	Medical Device	Recall	Class II	Hospital
12/03/2021	NuVasive Precice Systems: Precice Bone Transport, Precice Stryde, Precice Unyte, Precice Freedom	Medical Device	Recall	Class II	Hospital
12/03/2021	Sensis and Sensis Vibe Systems on VD12A software version	Medical Device	Product Defect Correction	Class II	Hospital
11/03/2021	CyberKnife System STC	Medical Device	Product Defect Correction	Class II	Hospital
11/03/2021	Enhanced Enlite Sensor (MMT-7008) and Guardian Sensor 3 (MMT-7020)	Medical Device	Product Defect Correction	Class II	Consumer
11/03/2021	Good Life Nutrition/ Wealthy Super Urinary Gout Support (pack size 60 / 90/ 100)	Medicine	Recall	Class II	Consumer
11/03/2021	Hysteromat E.A.S.I / (Hysteroscopic irrigation/distention system)	Medical Device	Recall	Class II	Hospital
11/03/2021	IMMAGE Immunochemistry Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
11/03/2021	Precice Intramedullary limb lengthening device (IMLL) Systems	Medical Device	Product Defect Correction	Class II	Hospital

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10/03/2021	Connexx Smart Connect	Medical Device	Recall	Class III	Consumer
10/03/2021	Karma Flexx Wheelchairs	Medical Device	Product Defect Correction	Class I	Consumer
9/03/2021	Heartware HVAD System	Medical Device	Product Defect Correction	Class I	Hospital
9/03/2021	Willieston International Pty Ltd - Disposable Medical Mask - Mask, surgical. single use	Medical Device	Product Defect Alert	Class II	Hospital
5/03/2021	CONFIRM Anti-Prostate Specific Antigen (PSA). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
5/03/2021	Med-Con Pty Ltd - Surgical Face Masks	Medical Device	Product Defect Alert	Class II	Hospital
5/03/2021	Schnitzler Paediatric Restraint System	Medical Device	Recall	Class II	Hospital
4/03/2021	Acumed 7.00mm x 2.00mm Stem (ARH System or ARH Solutions)	Medical Device	Recall	Class II	Hospital
4/03/2021	Cardinal Health Clear Leggings and Angiographic Drapes	Medical Device	Recall	Class II	Hospital
4/03/2021	DiaClon Anti-M/N* and DiaClon Anti-N. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
4/03/2021	HeartWare HVAD System - HVAD Power Cables, Monitor Data Cables, and Controller Ports	Medical Device	Product Defect Correction	Class I	Hospital
4/03/2021	Maternal Screening Control Level 1. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
3/03/2021	Alcian Blue pH 2.5/ Alcian Blue & Tissue Marker Blue. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
3/03/2021	Atellica NEPH 630 System 1.1 and BN ProSpec System 1.4.3. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
3/03/2021	Colleague P1.7 Large Volumetric Pump (LVP)	Medical Device	Product Defect Correction	Class II	Hospital
3/03/2021	ExacTrac Dynamic Radiation Therapy Patient Positioning System	Medical Device	Product Defect Correction	Class II	Hospital
3/03/2021	Monitoring Claim HbA1c Reagent Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
3/03/2021	Panther Fusion Tube Trays. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
3/03/2021	VIDAS CMV IgM. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital

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2/03/2021	Bravo reflux capsule and calibration-free reflux capsules	Medical Device	Recall	Class I	Hospital
2/03/2021	Cordis PRECISE PRO RX Carotid Stent System	Medical Device	Recall	Class II	Hospital
2/03/2021	CT5000 Ingenuity, Big Bore RT, Ingenuity CT, Brilliance 64	Medical Device	Product Defect Correction	Class II	Hospital
2/03/2021	Incisive CT Computed Tomography X-ray System	Medical Device	Product Defect Correction	Class II	Hospital
2/03/2021	Incisive CT Computed Tomography X-ray System	Medical Device	Product Defect Correction	Class II	Hospital
2/03/2021	IQon spectral CT, iCT, iCT SP	Medical Device	Product Defect Correction	Class III	Hospital
2/03/2021	Recothrom 5000IU Kit	Medicine	Product Defect Alert	Class I	Hospital
2/03/2021	Silk Vista Baby (flow-diverter for treatment of intracranial aneurysms)	Medical Device	Recall	Class II	Hospital
1/03/2021	Implacross PE insert 10° Ø 28/35mm	Medical Device	Recall	Class II	Hospital
1/03/2021	RayStation/RayPlan Systems	Medical Device	Product Defect Correction	Class II	Hospital
26/02/2021	KWIK-STIK 2, KWIK-STIK 6 Pack, LYFO DISK and QC Sets and Panels: KWIK-STIK 2 Pack. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
26/02/2021	LIFECODES HLA Kits and MATCHIT Software. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
25/02/2021	BARD MARQUEE Disposable Core Biopsy Instrument and Kits	Medical Device	Recall	Class II	Hospital
25/02/2021	BOND Ready-To-Use Primary Antibody CD19 (BT51E). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
25/02/2021	Dexcom G4 Platinum, G5 Mobile and G6 Sensor	Medical Device	Product Defect Correction	Class II	Consumer
25/02/2021	Haemonetics Blood Filtration Sets	Medical Device	Product Defect Correction	Class II	Hospital
25/02/2021	NIM Vital Console, software version V1.1.1 Rev 1.	Medical Device	Product Defect Correction	Class II	Hospital
25/02/2021	Pentax Video Bronchoscope and Pentax Video Cystoscope	Medical Device	Product Defect Correction	Class II	Hospital
25/02/2021	Philips HeartStart HS1 Home, HS1 OnSite, FRx or FR2/FR2+AED	Medical Device	Recall	Class I	Hospital
25/02/2021	T34 Syringe Pump	Medical Device	Product Defect Correction	Class II	Consumer
24/02/2021	Karl Storz: Plastic container for sterilisation	Medical Device	Product Defect Correction	Class II	Hospital

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24/02/2021	Patient Specific Liposomal Amphotericin	Medicine	Recall	Class II	Hospital
23/02/2021	Multiple Philips MRI systems	Medical Device	Product Defect Correction	Class III	Hospital
23/02/2021	Q-Flow - Surgical Light	Medical Device	Product Defect Correction	Class II	Hospital
23/02/2021	VaccZyme Human Anti-Diphtheria Toxoid IgG EIA Kits. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
22/02/2021	CryoMACS Freezing Bag 750	Medical Device	Recall	Class II	Hospital
22/02/2021	Magnus 1180 Operating Table Column	Medical Device	Product Defect Correction	Class II	Hospital
22/02/2021	Root Monitoring Systems	Medical Device	Recall	Class II	Hospital
22/02/2021	Various Philips MRI Systems running software release R5.3.1	Medical Device	Product Defect Correction	Class III	Hospital
19/02/2021	Merit Medical Surgical Procedure Kits containing BD Syringes and Needles	Medical Device	Product Defect Correction	Class II	Hospital
19/02/2021	Metagenics Parex and COSTAT	Medicine	Recall	Class II	Consumer
19/02/2021	Syringe filters Minisart NML / Ophthalsart	Medical Device	Recall	Class II	Hospital
18/02/2021	EverFlo OPI	Medical Device	Product Defect Correction	Class II	Hospital
18/02/2021	SIEMENS SOMATOM go.Now. and SOMATOM go.Up	Medical Device	Product Defect Correction	Class II	Hospital
17/02/2021	IMMUNE RX	Medicine	Recall	Class II	Consumer
17/02/2021	Medtronic Valiant Navion Thoracic Stent Graft System	Medical Device	Recall	Class I	Hospital
17/02/2021	Microvention PHIL Starter Kit and RePHIL	Medical Device	Recall	Class II	Hospital
16/02/2021	SERVINO and SoKINOX NO delivery and monitoring system	Medical Device	Product Defect Correction	Class II	Hospital
16/02/2021	Unomedical Low Concentration Oxygen Masks	Medical Device	Recall	Class II	Hospital
15/02/2021	Cardinal Health Isolation Gown, Lab Coat and Kendall Gown	Medical Device	Recall	Class II	Hospital
12/02/2021	Gloria Herbs - Liver Detox	Medicine	Recall	Class II	Consumer
12/02/2021	IQon Spectral CT and with software versions V4.7.7.43064 / V4.7.7.43202 / V4.7.7.43208	Medical Device	Product Defect Correction	Class III	Hospital
12/02/2021	The Alinity i HIV Ag/Ab Combo Calibrator. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital

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12/02/2021	VeriSeq Microlab STAR Accessories and Microplate, 96 Deep Well (amber). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
11/02/2021	Hilde Hemmes' Herbals Wormwood Herb	Medicine	Recall	Class II	Consumer
11/02/2021	MediHerb Stealth Complex	Medicine	Recall	Class II	Consumer
11/02/2021	Paracea Forte Tablets (60)	Medicine	Recall	Class II	Consumer
10/02/2021	ACUSON Sequoia ultrasound systems with VA11A software	Medical Device	Product Defect Correction	Class II	Hospital
10/02/2021	AMBISOME amphotericin B (amphotericin) B 50mg powder for injection vial	Medicine	Product Defect Correction	Class II	Hospital
10/02/2021	Jason membrane 15x20mm, 20x30mm and 30x40mm	Medical Device	Recall	Class II	Retail
9/02/2021	Disposable Bipolar Ablators	Medical Device	Recall	Class II	Hospital
9/02/2021	Karma Flexx wheelchairs	Medical Device	Product Defect Correction	Class II	Consumer
9/02/2021	Lenest 30 ED levonorgestrel/ethinylestradiol 150 micrograms/30 micrograms tablet composite pack	Medicine	Product Defect Correction	Class III	Retail
9/02/2021	Trinity Biolox Delta Ceramic Head, Size 32XL and 36XL	Medical Device	Recall	Class II	Hospital
8/02/2021	Iodine 131 Capsule	Medicine	Recall	Class II	Hospital
5/02/2021	Biograph Horizon systems currently running VJ21B	Medical Device	Product Defect Correction	Class II	Hospital
5/02/2021	HF440 with DM Electronic Boards	Medical Device	Product Defect Correction	Class II	Hospital
5/02/2021	Prismaflex Control Unit	Medical Device	Product Defect Correction	Class I	Hospital
5/02/2021	syngo.via software update VB20A	Medical Device	Product Defect Correction	Class II	Hospital
4/02/2021	Alligator Grasping Forcep 2.4 x 2300mm 5mm Jaw and Rat Tooth Alligator Grasping 2.4 x 2300mm 5mm Jaw	Medical Device	Recall	Class III	Hospital
4/02/2021	Sensis/Sensis Vibe systems with software version VD12	Medical Device	Product Defect Correction	Class II	Hospital
4/02/2021	SOMATOM CT scanners running on syngo CT VB20A_SP3	Medical Device	Product Defect Correction	Class II	Hospital
4/02/2021	SOMATOM go.Up, SOMATOM go.All, SOMATOM go.Top, SOMATOM go.Sim, SOMATOM go.Open Pro and SOMATOM X.cite	Medical Device	Product Defect Correction	Class II	Hospital

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2/02/2021	BioFire FilmArray Blood Culture Identification (BCID) Panel and BioFire Blood Culture Identification 2 (BCID2) Panel. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
2/02/2021	Defibrillation Electrode	Medical Device	Recall	Class I	Hospital
2/02/2021	Mar-Med Uni-Cot	Medical Device	Product Defect Correction	Class II	Retail
2/02/2021	Point Blank Medical - Premier Guard Facemask - Mask, surgical, single use	Medical Device	Product Defect Alert	Class II	Hospital
2/02/2021	RELIANCE VISION SC 380-400-415V 3Ph 50Hz STEAM HTD and RELIANCE VISION SC 380-400-415V 3Ph 50Hz ELECTRIC HTD	Medical Device	Product Defect Correction	Class II	Hospital
2/02/2021	Sungo Australia - Mask, surgical, single use	Medical Device	Product Defect Alert	Class II	Hospital
1/02/2021	Alinity m System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
1/02/2021	Biovent Consulting - LONGXIN and ZERUI Facemasks - Mask, surgical, single use	Medical Device	Product Defect Alert	Class II	Retail
1/02/2021	Dimension Vista High Density Lipoprotein Cholesterol (HDL) Flex Reagent Cartridge. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
1/02/2021	Humphrey Field Analyser	Medical Device	Product Defect Correction	Class III	Retail
29/01/2021	Affinis Inverse Glenosphere	Medical Device	Recall	Class II	Hospital
29/01/2021	Fluorodeoxyglucose F18 Injection (18F-FDG)	Medicine	Recall	Class II	Hospital
28/01/2021	RayStation 8B, 8B SP1, 8B SP2, 9A, 9B, 9B SP1, 10A, 10A SP1 and 10B	Medical Device	Product Defect Correction	Class II	Hospital
28/01/2021	TSI Distraction Screws	Medical Device	Recall	Class II	Hospital
27/01/2021	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
27/01/2021	Rebilda Post System Set	Medical Device	Product Defect Correction	Class II	Retail
27/01/2021	Renuvion APR Handpiece	Medical Device	Recall	Class III	Retail
25/01/2021	All EPIQ Systems	Medical Device	Product Defect Correction	Class I	Hospital
25/01/2021	FetaLink	Medical Device	Product Defect Correction	Class II	Hospital

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25/01/2021	Fluorodeoxyglucose F18 Injection (18F-FDG)	Medicine	Product Defect Alert	Class II	Hospital
25/01/2021	Uni-Cot (Tourni-Cot Universal)	Medical Device	Product Defect Correction	Class II	Retail
22/01/2021	MetaVision Suite for ICU version 6.11.0078	Medical Device	Product Defect Correction	Class II	Hospital
22/01/2021	Philips Incisive CT Systems	Medical Device	Product Defect Correction	Class III	Hospital
21/01/2021	Dräger Disposable VentStar Anaesthesia (N) 180 Circuit and Dräger Disposable VentStar Basic (N)	Medical Device	Product Defect Correction	Class I	Hospital
20/01/2021	SPF 30 Natural Coconut Body Sunscreen	Medicine	Recall	Class II	Consumer
20/01/2021	VIDAS CVM IgM. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
20/01/2021	Zemaira 1000 mg/Vial - US - ALPHA-1-PROTEINASE INHIBITOR	Medicine	Recall	Class II	Hospital
19/01/2021	Single-Use Polypectomy Snares: Captivator, Captivator II, Captiflex, and Sensation	Medical Device	Recall	Class II	Hospital
19/01/2021	Snaplink Buccal Tube	Medical Device	Product Defect Correction	Class II	Retail
18/01/2021	Atellica IM and ADVIA Centaur XP/XPT Free Prostate-Specific Antigen (fPSA). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
18/01/2021	Model A710 Intellis Clinician Programmer Application	Medical Device	Product Defect Correction	Class II	Hospital
18/01/2021	Peak Carbonlite Rollator	Medical Device	Recall	Class II	Consumer
18/01/2021	Philips V680 Ventilators	Medical Device	Product Defect Correction	Class II	Hospital
18/01/2021	syngo.via all systems with software version VB40A or VB40B	Medical Device	Product Defect Correction	Class II	Hospital
15/01/2021	Catalyst and Catalyst HD systems with treatment field synchronization using Elekta iCom or Varian ADI interfaces	Medical Device	Product Defect Correction	Class II	Hospital
15/01/2021	Philips V680 Ventilators	Medical Device	Product Defect Correction	Class I	Hospital
14/01/2021	PA-003, c4D Software application v 6.1.0 and 6.1.1	Medical Device	Product Defect Correction	Class II	Hospital
14/01/2021	Phenocell C 0.8%. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
14/01/2021	Trace Elements. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
13/01/2021	EVOS 2.4 MM LOCKING SCREW T7 SELF-TAPPING	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
13/01/2021	Liko Multirall Q-link Strap Lock	Medical Device	Product Defect Correction	Class I	Consumer
13/01/2021	PrisMax System	Medical Device	Product Defect Correction	Class II	Hospital
13/01/2021	Yukon Polyaxial Screw	Medical Device	Recall	Class I	Wholesale
12/01/2021	ReActiv8	Medical Device	Product Defect Correction	Class III	Hospital
11/01/2021	Philips EPIQ Systems using Image Boost with xPlane Colour Flow or Doppler	Medical Device	Product Defect Correction	Class II	Hospital
11/01/2021	VaccZyme Human Anti-Salmonella typhi Vi IgG EIA kit. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class III	Hospital
8/01/2021	Technetium-99m Myoview	Medicine	Recall	Class II	Hospital
7/01/2021	Horizon/ McKesson/ Change Healthcare Cardiology ECG Management	Medical Device	Product Defect Correction	Class II	Hospital
7/01/2021	ID-DiaCell, ID-DiaPanel and ID-DiaScreen. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
6/01/2021	EOS Edge imaging system	Medical Device	Product Defect Correction	Class II	Hospital
6/01/2021	METHOPT TEARS - Viscous eye drops with hypromellose 0.5mg/mL	Medical Device	Recall	Class II	Wholesale
5/01/2021	ARTIS icono floor and ARTIS pheno systems with software version VE20B	Medical Device	Product Defect Correction	Class II	Hospital
5/01/2021	Getinge CM320	Medical Device	Product Defect Correction	Class II	Hospital
5/01/2021	i-STAT EG7+ and CG8+ cartridges. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
5/01/2021	MIA FORA NGS HLA Flex 11 Kit and MIA FORA NGS HLA MFlex 11 Kit. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
5/01/2021	Uni-Cot	Medical Device	Product Defect Correction	Class II	Hospital
4/01/2021	Femoral Head (L) MC - Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
4/01/2021	Infinity Acute Care Systems and Infinity M540 Stand Alone Patient Monitors	Medical Device	Product Defect Correction	Class I	Hospital
29/12/2020	Pinnacle Cup Devices used with the Optional Apex Hold Eliminator (HE)	Medical Device	Product Defect Correction	Class II	Hospital
24/12/2020	Alpha Active 3, Alpha Active 4 & Alpha Active 5 medical pump	Medical Device	Product Defect Correction	Class II	Consumer

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
24/12/2020	Liquid Unassayed Multiquel and Liquicheck Unassayed Chemistry Control. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
23/12/2020	EVO IQ Large Volumetric Pump (LVP)	Medical Device	Product Defect Correction	Class I	Hospital
23/12/2020	Hydralyte Ready to Use Electrolyte Solution - Orange Flavoured, Colour Free Lemonade Flavoured and Apple Blackcurrant Flavoured	Medicine	Product Defect Correction	Class III	Retail
23/12/2020	NObreath V2 Fractional Exhaled Nitric Oxide (FeNO) Device	Medical Device	Product Defect Correction	Class II	Hospital
23/12/2020	Quadrox-I Pediatric Oxygenator HMO 31000 with Pediatric Venous Hardshell Cardiomy Reservoir VHK 31000	Medical Device	Recall	Class I	Hospital
23/12/2020	ZERBAXA ceftolozane sulfate/tazobactam sodium 1000 mg/500 mg powder for injection vial	Medicine	Recall	Class I	Hospital
22/12/2020	HeartWare Ventricular Assist Device (HVAD) System	Medical Device	Hazard Alert	Class I	Hospital
22/12/2020	Infants' Friend Oral Liquid Bottle 100mL	Medicine	Recall	Class II	Consumer
22/12/2020	Revolution Apex, Revolution CT with Apex Edition, Revolution CT, and Revolution CT ES Systems	Medical Device	Product Defect Correction	Class II	Hospital
21/12/2020	Colonovideoscope and Gastrointestinal Videoscope	Medical Device	Product Defect Correction	Class II	Hospital
21/12/2020	EXOGEN Ultrasound Gel Pump bottles	Medical Device	Recall	Class II	Hospital
21/12/2020	METHOTREXATE ACCORD methotrexate 1000 mg/10mL injection vial	Medicine	Product Defect Alert	Class II	Hospital
21/12/2020	ORTHO VISION Analyser for ORTHO BioVue Cassettes & Max Analyser for ORTHO BioVue Cassettes. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
21/12/2020	Spectra Optia Apheresis System	Medical Device	Product Defect Correction	Class II	Hospital
21/12/2020	Tempus LS with SW version 1.3.4	Medical Device	Product Defect Correction	Class I	Hospital
21/12/2020	TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 tenofovir disoproxil maleate 300 mg and emtricitabine 200 mg film coated tablet bottle	Medicine	Recall	Class II	Consumer
21/12/2020	VITROS Chemistry Products TP Slides. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
18/12/2020	Minstrel Lift with Scale	Medical Device	Product Defect Correction	Class II	Hospital
18/12/2020	Ortho BioVue System Cassette products. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
17/12/2020	AXS Universal Aspiration Tubing 300cm (118.11 in)	Medical Device	Recall	Class III	Hospital
17/12/2020	Multiple Olympus devices	Medical Device	Recall	Class II	Hospital
17/12/2020	Phadia AB EliA dsDNA Well. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
16/12/2020	96 Deep Well Plates in VeriSeq Microlab STAR Accessories. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class I	Hospital
16/12/2020	Artis zee/Q/Q.zen systems with software version VD11E	Medical Device	Product Defect Correction	Class II	Hospital
16/12/2020	Artis Zee/Zeego with software version VC21C.	Medical Device	Product Defect Correction	Class II	Hospital
16/12/2020	H900 HUMIDIFIER 220-240V	Medical Device	Product Defect Correction	Class II	Hospital
16/12/2020	Medtronic HeartWare Monitor AC Adapter (MAC Adapter)	Medical Device	Recall	Class II	Hospital
16/12/2020	Multi Essentials	Medicine	Recall	Class II	Retail
16/12/2020	RevMedx Trauma Dressing (RTD) - Sterile Non-woven Gauze Pad	Medical Device	Recall	Class II	Consumer
16/12/2020	Rotor Bearing Screws for Nuclear Medicine Systems	Medical Device	Product Defect Correction	Class I	Hospital
16/12/2020	Sensis Vibe software versions VD10B, VD11A and VD11B	Medical Device	Product Defect Correction	Class II	Hospital
16/12/2020	TomoTherapy Systems at software version 5.1.5 and TomoTherapy Systems with iDMS at software version 1.2.0	Medical Device	Product Defect Correction	Class II	Hospital
15/12/2020	Cobas 8000 core unit, cobas pro sample supply unit and cobas c 513 analyser An in vitro diagnostic medical devices (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
15/12/2020	Delta Neonatal Valves	Medical Device	Recall	Class I	Hospital
15/12/2020	EMBLEM S-ICD Subcutaneous Electrode (Model 3501)	Medical Device	Hazard Alert	Class I	Hospital
15/12/2020	Medline Surgical Clipper Charger	Medical Device	Recall	Class II	Hospital
15/12/2020	Philips EPIQ & Affiniti Ultrasound Systems	Medical Device	Product Defect Correction	Class II	Hospital
15/12/2020	Portex Loss of Resistance Device	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
15/12/2020	VERITAS Collagen Matrix 12x25 cm Patches	Medical Device	Product Defect Correction	Class II	Hospital
14/12/2020	Aster Home Nursing Services Facemasks	Medical Device	Product Defect Alert	Class II	Hospital
14/12/2020	CATHETER KIT ANTIMICROBIAL and CATHETER VENTRICULAR ANTIMICROBIAL	Medical Device	Recall	Class II	Hospital
10/12/2020	Alaris GP Volumetric Pump with Plus software	Medical Device	Product Defect Correction	Class II	Hospital
10/12/2020	All Cathay Herbal Laboratories medicines containing Fallopia multiflora	Medicine	Recall	Class II	Retail
10/12/2020	Atellica CH 930, IM 1300 & IM 1600 installed with Atellica Solution software versions V1.23.2 (SMN 11469032) or lower. An in vitro diagnostic medical devices (IVDs).	Medical Device	Product Defect Correction	Class II	Hospital
10/12/2020	Shifeng Surgical Face Mask - Mask, surgical, single use	Medical Device	Product Defect Alert	Class II	Retail
9/12/2020	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
9/12/2020	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
9/12/2020	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
9/12/2020	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
9/12/2020	JETStream WorkSpace Versions 2.0 or higher	Medical Device	Product Defect Correction	Class II	Hospital
9/12/2020	Technetium-99m HDP	Medicine	Recall	Class II	Hospital
9/12/2020	Thoracentesis/paracentesis set	Medical Device	Product Defect Correction	Class I	Hospital
9/12/2020	ZEISS IOLMaster 700	Medical Device	Product Defect Correction	Class II	Hospital
8/12/2020	Altrix Precision Temperature Management System	Medical Device	Product Defect Correction	Class III	Hospital
8/12/2020	CareLink Personal software and CareLink system	Medical Device	Product Defect Correction	Class II	Consumer
8/12/2020	Contour Portare 2 and Contour Portare-X	Medical Device	Product Defect Correction	Class II	Hospital
8/12/2020	EMBLEM Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs)	Medical Device	Hazard Alert	Class I	Hospital
8/12/2020	EMBLEM Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs)	Medical Device	Hazard Alert	Class I	Hospital
8/12/2020	Ultra Feel Examination Nitrile Blue PF Gloves	Medical Device	Recall	Class II	Retail
7/12/2020	Artis zee/Q/Q.zen systems with Siemens Healthineers table (Tilt/Step, OR) and with software version VD11E system.	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
4/12/2020	Medisafe Distal Duck Kits, Half Size Duck Bag Humidity Packs, Duck Bag Full Din and Duck Bag Super Size	Medical Device	Recall	Class II	Hospital
4/12/2020	Olympus Gastroduodenoscopes	Medical Device	Product Defect Correction	Class II	Hospital
4/12/2020	Philips V680 ventilators	Medical Device	Product Defect Correction	Class II	Hospital
3/12/2020	Artis zeego systems with software version VD11E.	Medical Device	Product Defect Correction	Class II	Hospital
3/12/2020	Bilirubin Direct, Bilirubin Total (NBD), Creatinine (Jaffe), and Creatinine (Enzymatic) assay. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
3/12/2020	cobas z 480 analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
3/12/2020	Sentinel Zinc. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
2/12/2020	Optilite Freelite Kappa Free Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Alert	Class II	Hospital
1/12/2020	Infant Nasal cannula with 7' Supply Tube	Medical Device	Recall	Class II	Hospital
1/12/2020	LARGACTIL chlorpromazine hydrochloride 50mg/2mL injection ampoule	Medicine	Recall	Class III	Hospital
1/12/2020	Life Basics by Nourished Life SPF 30 Natural Coconut Body Sunscreen	Medicine	Product Defect Correction	Class III	Consumer
1/12/2020	SOMATOM CT scanners running syngo CT VB20A_SP2.	Medical Device	Product Defect Correction	Class II	Hospital
30/11/2020	Hot AXIOS Stent and Electrocautery - Enhanced Delivery System	Medical Device	Recall	Class II	Hospital
30/11/2020	Multiple Sterile Zimmer Biomet Products	Medical Device	Recall	Class II	Hospital
27/11/2020	ADVIA 1800 Chemistry System, ADVIA 2400 Chemistry System, ADVIA Chemistry XPT and Atellica CH 930 Analyzer -	Medical Device	Product Defect Correction	Class II	Hospital
27/11/2020	Flexor Check-Flo Introducer and Flexor Tuohy-Borst Side-Arm Introducer (Shuttle Select)	Medical Device	Recall	Class I	Hospital
25/11/2020	Bedrobinol Medicinal Cannabis	Medicine	Recall	Class III	Retail
25/11/2020	CareLink (CL) software and CL System using CareLink reports	Medical Device	Product Defect Correction	Class II	Consumer
25/11/2020	Philips Efficia CM monitors, CO2 module and Gas Modules	Medical Device	Product Defect Correction	Class II	Hospital

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24/11/2020	Covidien TA Auto Suture Vascular Stapler and Loading Unit with DST Series Technology	Medical Device	Recall	Class II	Hospital
24/11/2020	EyePro Eyelid Occlusive Dressing	Medical Device	Product Defect Correction	Class III	Hospital
24/11/2020	RIA 2 Reamer Head	Medical Device	Product Defect Correction	Class II	Hospital
24/11/2020	Theradiag LISA-TRACKER Adalimumab and LISA-TRACKER Infliximab. An in-vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
23/11/2020	ONLINE TDM Phenytoin (PHNY2) For use on the cobas c 503 module. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
20/11/2020	BOND Enzyme Pretreatment Kit	Medical Device	Product Defect Correction	Class II	Hospital
20/11/2020	Inspyre Pyrocarbon Interpositional Shoulder Implant	Medical Device	Hazard Alert	Class II	Hospital
20/11/2020	LOTUS Edge Valve System	Medical Device	Recall	Class I	Hospital
20/11/2020	Xpert Xpress 6.1 Software. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
19/11/2020	SIS Medical OPN NC Super High Pressure PTCA Balloons	Medical Device	Product Defect Correction	Class II	Hospital
18/11/2020	PERI-STRIPS DRY with VERITAS Collagen Matrix Staple Line Reinforcement (PSDV)	Medical Device	Product Defect Correction	Class II	Hospital
18/11/2020	RayStation and RayPlan	Medical Device	Product Defect Correction	Class II	Hospital
17/11/2020	Capnostream 35 Portable Respiratory Monitor	Medical Device	Product Defect Correction	Class II	Hospital
17/11/2020	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Recall	Class II	Hospital
17/11/2020	TRACOE twist plus tracheostomy tube and TRACOE expirc set twist plus	Medical Device	Product Defect Alert	Class II	Hospital
16/11/2020	Blooms the Chemist Metformin XR 1000 metformin hydrochloride 1000 mg modified release tablet blister pack	Medicine	Recall	Class II	Wholesale
13/11/2020	Mayfield 2000 Skull Clamp (A2000)	Medical Device	Product Defect Correction	Class II	Hospital
13/11/2020	Paragon CRT Dual Axis	Medical Device	Recall	Class III	Retail
13/11/2020	Philips Sterilizable Internal Defibrillator Paddles	Medical Device	Product Defect Correction	Class I	Hospital
13/11/2020	Softmed surgical face masks	Medical Device	Product Defect Alert	Class II	Retail

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
13/11/2020	Welch Allyn Eli380 ECG RESTING ELECTROCARDIOGRAPH	Medical Device	Product Defect Correction	Class II	Hospital
11/11/2020	HLS Set Advanced	Medical Device	Product Defect Correction	Class I	Hospital
11/11/2020	LARS LIG ACROMIO CLAVICULAR 30 FIBRES (AC30DB/L020305)	Medical Device	Recall	Class II	Hospital
11/11/2020	SIEMENS SOMATOM: Perspective, Scope Power running syngo.CT	Medical Device	Product Defect Correction	Class II	Hospital
10/11/2020	6PLUS 1 Multilevel Salivo Calibrator Set, MassChrom Cortisol and Saliva Controls Level I and II. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
10/11/2020	EV1000 Clinical Platform	Medical Device	Product Defect Correction	Class II	Hospital
10/11/2020	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
10/11/2020	Mazor X Surgical System (SST2) – Positioner Type II	Medical Device	Product Defect Correction	Class II	Hospital
10/11/2020	The Infinity ACL Tibial Elbow and Tip Guides	Medical Device	Recall	Class II	Wholesale
9/11/2020	Evolut Transcatheter Aortic Valves	Medical Device	Hazard Alert	Class II	Hospital
9/11/2020	Philips V60 Ventilator	Medical Device	Product Defect Correction	Class II	Hospital
9/11/2020	Philips V60 Ventilator	Medical Device	Product Defect Correction	Class II	Hospital
6/11/2020	Phenylephrine Syringe 1mg/10mL	Medicine	Recall	Class I	Hospital
6/11/2020	Rocket KCH Fetal Bladder Drain	Medical Device	Recall	Class II	Hospital
6/11/2020	Technetium-99m Cardiolite	Medicine	Recall	Class III	Hospital
5/11/2020	ARCHITECT EBV VCA IgM Calibrator. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
5/11/2020	Laerdal Compact Suction Unit 4	Medical Device	Recall	Class II	Consumer
4/11/2020	Artis zee/Q/Q.zen systems and Artis pheno	Medical Device	Product Defect Correction	Class II	Hospital
4/11/2020	GeneFinder COVID-19PlusRealAmp Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
3/11/2020	Alinity ci-series System Control Module (SCM). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
3/11/2020	Efficia DFM100 Defibrillator/Monitor	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
3/11/2020	Ingenuity TF PET/CT	Medical Device	Product Defect Correction	Class II	Hospital
3/11/2020	OPTIRAY 320 ULTRAJECT injection syringe and OPTIRAY 350 ULTRAJECT injection syringe	Medicine	Recall	Class I	Hospital
2/11/2020	CSF-Snap Shunt Ventricular Catheter Kit	Medical Device	Recall	Class II	Hospital
2/11/2020	Mako Integrated Cutting System (MICS) Handpiece	Medical Device	Recall	Class II	Hospital
2/11/2020	Osteosynthesis Compression Staple EasyClip & EasyClip Xpress implants	Medical Device	Product Defect Correction	Class II	Hospital
30/10/2020	Atellica IM 1300 and 1600 Analyser. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
30/10/2020	Fluorodeoxyglucose F18 Injection (18F-FDG)	Medicine	Recall	Class II	Hospital
30/10/2020	Reagent Cartridges v2 from NextSeq 550Dx High Output Reagent Kit v2.5 (75 cycles). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
28/10/2020	SuperFeast He Shou Wu 100g	Medicine	Recall	Class II	Retail
27/10/2020	MAC VU360 ECG systems	Medical Device	Product Defect Correction	Class II	Hospital
27/10/2020	Nuvasive- PRECICE Bone Transport Nail	Medical Device	Hazard Alert	Class II	Hospital
26/10/2020	Olympus Leak Test Adaptor used with Acu-slnQ Complete Endoscope Cleaning Aid System	Medical Device	Recall	Class III	Hospital
23/10/2020	Puritan Bennett 980 Series Ventilator	Medical Device	Product Defect Correction	Class II	Hospital
22/10/2020	Disposable Isopleat Rectangle Anaesthetic Filter	Medical Device	Recall	Class III	Hospital
22/10/2020	Fabian HFO and Fabian +nCPAP Evolution Ventilators	Medical Device	Product Defect Correction	Class I	Hospital
22/10/2020	The Actreen Product Range	Medical Device	Recall	Class II	Hospital
22/10/2020	VITROS Chemistry Products Performance Verifier II. An in vitro diagnostic device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
21/10/2020	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Product Defect Correction	Class II	Hospital
21/10/2020	Liquid-filled Intra-gastric Balloons	Medical Device	Product Defect Correction	Class I	Hospital
21/10/2020	Philips Zenition 70 Systems	Medical Device	Product Defect Correction	Class III	Hospital
20/10/2020	VITROS System Software Version 3.6. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
19/10/2020	Handicare SwiftHook component, in use with Handicare mobile lifts and ceiling lifts	Medical Device	Recall	Class II	Hospital
15/10/2020	3M Red Dot Monitoring Electrode with Foam Tape	Medical Device	Recall	Class II	Hospital
15/10/2020	CAIR NeutraClear Stopcock with 2 Neutraclear Connectors	Medical Device	Product Defect Correction	Class II	Hospital
15/10/2020	Equinox Platform Fracture Stem, 6.5mm, Left and Right	Medical Device	Hazard Alert	Class II	Hospital
15/10/2020	Flow Sensors in GE / Datex-Ohmeda Anaesthesia Machines	Medical Device	Product Defect Correction	Class I	Hospital
15/10/2020	Heater-Cooler Unit HCU 40	Medical Device	Product Defect Correction	Class II	Hospital
15/10/2020	Ortho AutoVue Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Alert	Class II	Hospital
15/10/2020	Various Shen Neng Herbal Medicines containing Fallopia multiflora	Medicine	Recall	Class II	Retail
14/10/2020	3580 (Kaiser Pharmaceutical) Dang Gui Yin Zi (Tangkuei & Tribulus Combination) - recall in accordance with s.30EA of the Therapeutic Goods Act 1989.	Medicine	Recall	Class II	Retail
14/10/2020	Handicare mobile lifts and ceiling lifts equipped with the SwiftHook component	Medical Device	Product Defect Correction	Class II	Retail
14/10/2020	Niobe MNS with the EPOCH upgrade	Medical Device	Product Defect Correction	Class II	Hospital
14/10/2020	RayStation 4.0, 4.5, 4.7, 4.9, 5, 6, 7, 8A, 8B, 9A, 9B, 10A, RayPlan 1, 2, 7, 8A, 8B, 9A, 9B, 10A	Medical Device	Product Defect Correction	Class II	Hospital
13/10/2020	Alinity ci-series. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
13/10/2020	Geistlich Bio-Oss Pen	Medical Device	Product Defect Correction	Class II	Retail
13/10/2020	Kunbao Wan & Tong Ren Da Huo Luo Pill	Medicine	Recall	Class II	Retail
13/10/2020	Sunny Pills	Medicine	Recall	Class II	Retail
12/10/2020	Caretip 5ml Oral Dispenser Sterile	Medical Device	Product Defect Correction	Class II	Hospital
12/10/2020	Equinox Cage Glenoid, Posterior Augment - Left and Right, Medium	Medical Device	Hazard Alert	Class II	Hospital
9/10/2020	ALTERA Spinal Implants	Medical Device	Recall	Class II	Hospital
9/10/2020	Coolsense topical anaesthetic device	Medical Device	Recall	Class III	Hospital
9/10/2020	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
9/10/2020	Gentian Cystatin C Calibrator Kits. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
9/10/2020	Hydroframe With Manuka Honey	Medical Device	Product Defect Correction	Class II	Consumer
9/10/2020	Kangaroo Connect 500ml and 1000ml Bag Set, Non-Sterile	Medical Device	Product Defect Alert	Class II	Hospital
8/10/2020	DM36 Dreama Slim Support Pad for Jenx Dreama Sleep Mattress	Medical Device	Product Defect Correction	Class II	Consumer
7/10/2020	Draeger Patient Monitoring Devices	Medical Device	Product Defect Correction	Class I	Hospital
7/10/2020	Mobile X-ray Device	Medical Device	Product Defect Correction	Class II	Hospital
7/10/2020	Tibbs Arterial Cannula, Large cone	Medical Device	Recall	Class II	Hospital
7/10/2020	Trevo XP ProVue Retriever	Medical Device	Recall	Class I	Hospital
6/10/2020	Bien-Air Surgery SA Remote Foot Pedals	Medical Device	Product Defect Correction	Class II	Hospital
6/10/2020	SLE4000 & SLE5000 – Control Monitor Boards	Medical Device	Product Defect Correction	Class I	Hospital
6/10/2020	Spectra Optia Apheresis System	Medical Device	Product Defect Correction	Class II	Hospital
2/10/2020	HemoSphere oximetry cable	Medical Device	Product Defect Correction	Class III	Hospital
2/10/2020	Nylatex wraps	Medical Device	Product Defect Correction	Class II	Retail
2/10/2020	Sodium iodide(131I) 2000MBq/mL Therapy Solution oral liquid BP vial	Medicine	Recall	Class II	Hospital
1/10/2020	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
1/10/2020	McGrath MAC video laryngoscopes	Medical Device	Product Defect Correction	Class II	Hospital
1/10/2020	Shou Wu Tablets	Medicine	Recall	Class II	Retail
1/10/2020	Warehouse Equipment - ARTG: 338568	Medical Device	Product Defect Alert	Class II	Hospital
30/09/2020	ExacTrac Dynamic Radiation Therapy Patient Positioning System	Medical Device	Product Defect Correction	Class II	Hospital
29/09/2020	AMS 700 with MS Pump	Medical Device	Hazard Alert	Class II	Hospital
29/09/2020	Revolution Apex and Revolution CT with Apex edition	Medical Device	Product Defect Correction	Class II	Hospital
29/09/2020	The BladderScan Prime Plus	Medical Device	Product Defect Correction	Class II	Hospital
28/09/2020	Ancar Ophthalmic Table	Medical Device	Product Defect Correction	Class III	Retail

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
25/09/2020	ADVIA Centaur HBsAgII. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
25/09/2020	ADVIA Chemistry and Atellica CH Fructosamine (FRUC) Assay. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
25/09/2020	Blood Monitoring Unit BMU 40	Medical Device	Product Defect Correction	Class I	Hospital
25/09/2020	Kowa VK-2s Kowa Retinal Camera	Medical Device	Product Defect Correction	Class II	Hospital
24/09/2020	ARTIS icono and ARTIS pheno systems.	Medical Device	Product Defect Correction	Class II	Hospital
24/09/2020	Medi Quattro First Aid Cream	Medicine	Recall	Class II	Retail
24/09/2020	Perfect Dry Lux	Medical Device	Product Defect Correction	Class II	Consumer
24/09/2020	Ultrasound Navigation Software and Ultrasound Integration Software for Cranial/ENT Navigation	Medical Device	Product Defect Correction	Class II	Hospital
23/09/2020	Artis One	Medical Device	Product Defect Correction	Class II	Hospital
23/09/2020	BOLTON SURGICAL - BOLT CUTTER	Medical Device	Product Defect Correction	Class III	Hospital
23/09/2020	Mobile OR-Table MEERA, YUNO and YUNO II	Medical Device	Product Defect Correction	Class I	Hospital
22/09/2020	AEROWIPE Cleansing Wipes supplied in various first aid kits	Medical Device	Product Defect Correction	Class II	Consumer
22/09/2020	Equinox Reverse Shoulder Compression Screw/Locking Cap Kit 4.5x18mm and 4.5x22mm	Medical Device	Recall	Class II	Hospital
22/09/2020	Philips Shoulder and Neurovascular Coils	Medical Device	Product Defect Correction	Class III	Hospital
22/09/2020	Thermo Scientific Oxoid F100 Nitrofurantoin. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
21/09/2020	Genius 2 Tympanic Thermometers integrated in Mindray patient monitors	Medical Device	Product Defect Correction	Class II	Hospital
21/09/2020	GORE TAG Conformable Thoracic Stent Graft with ACTIVE CONTROL System	Medical Device	Product Defect Correction	Class II	Hospital
21/09/2020	Mimics Medical 23	Medical Device	Product Defect Correction	Class III	Hospital
21/09/2020	Uroskop Omnia Max	Medical Device	Product Defect Correction	Class II	Hospital
18/09/2020	Fem+ and #1 Body	Medicine	Recall	Class II	Retail
18/09/2020	Trust First Aid Cream tube	Medicine	Recall	Class II	Retail

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
17/09/2020	Hurricane RX Biliary Balloon Dilatation Catheter	Medical Device	Recall	Class II	Hospital
17/09/2020	JUVOcare Shower Commode Caster Forks	Medical Device	Product Defect Correction	Class II	Retail
17/09/2020	NanoScan Cold Kit	Medicine	Recall	Class II	Hospital
16/09/2020	ANDORATE single use Valve sets (buttons) for Olympus scopes	Medical Device	Recall	Class II	Hospital
16/09/2020	Cath Foley Silicone 2Way: 12F, 16F & 18F	Medical Device	Recall	Class II	Hospital
15/09/2020	Access Unconjugated Estriol. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class I	Hospital
15/09/2020	Corpuls3 devices	Medical Device	Product Defect Correction	Class I	Hospital
15/09/2020	Sysmex Automated Blood Coagulation Analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
15/09/2020	Various Suture-Based Repair Systems	Medical Device	Recall	Class II	Hospital
14/09/2020	SOMATOM Definition AS (Family), Definition Edge & Definition Flash	Medical Device	Product Defect Correction	Class II	Hospital
11/09/2020	MS-2 Step composite pack [MIFEPRISTONE LINEPHARMA 200 MG TABLET mifepristone 200 mg tablet blister; GyMiso misoprostol 200 microgram tablet blister]	Medicine	Product Defect Correction	Class II	Retail
11/09/2020	VICRYL (polyglactin 910) Suture	Medical Device	Recall	Class II	Hospital
10/09/2020	Anti-Brucella-abortus-ELISA. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
10/09/2020	Emteva Pure Intermittent Catheter	Medical Device	Recall	Class II	Consumer
10/09/2020	Pipeline Flex Embolization Device	Medical Device	Product Defect Correction	Class I	Hospital
10/09/2020	Rashkind Balloon Septostomy Catheters	Medical Device	Recall	Class I	Hospital
9/09/2020	Affinis Inverse Drill-bits	Medical Device	Product Defect Correction	Class II	Hospital
9/09/2020	Kingston Mobile Chair	Medical Device	Product Defect Correction	Class II	Consumer
9/09/2020	t:slim X2 and t:slim X2 insulin pump with Basal-IQ technology	Medical Device	Product Defect Correction	Class II	Consumer
8/09/2020	EVIS EXERA II BRONCHOVIDEOSCOPE	Medical Device	Recall	Class II	Hospital
8/09/2020	Parkinson's Kinetigraph (PKG) System	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
7/09/2020	CHF-CB30S CHOLEDOCHOFIBREScope	Medical Device	Recall	Class I	Hospital
7/09/2020	Herbsense Hair Boost 60 tablets	Medicine	Recall	Class II	Retail
4/09/2020	MyCareLink Relay Home Communicator	Medical Device	Product Defect Correction	Class II	Consumer
4/09/2020	PROFEMUR CoCr and Ti modular necks	Medical Device	Recall	Class II	Hospital
4/09/2020	PROZAC 20 fluoxetine 20mg (as hydrochloride) capsule blister pack	Medicine	Product Defect Alert	Class III	Retail
4/09/2020	Spinning Spiros connectors and Spinning Spiros IV sets	Medical Device	Recall	Class II	Hospital
4/09/2020	Various Arrotex buprenorphine-containing topical products.	Medicine	Recall	Class II	Retail
4/09/2020	Various Cipla buprenorphine-containing topical products	Medicine	Recall	Class II	Retail
3/09/2020	Symbia S and Symbia T Scanner Systems	Medical Device	Product Defect Correction	Class II	Hospital
3/09/2020	Technetium-99m HDP	Medicine	Recall	Class II	Hospital
2/09/2020	18 F-fluoro-ethyl-tyrosine	Medicine	Product Defect Correction	Class III	Hospital
2/09/2020	BenchMark ULTRA Stainer Module. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
2/09/2020	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
2/09/2020	syngo.via	Medical Device	Product Defect Correction	Class II	Hospital
1/09/2020	Dako Autostainer. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
1/09/2020	Dimension Vista System - Alkaline Phosphatase (ALPI) Flex reagent cartridge. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
1/09/2020	syngo.via RT Image Suite	Medical Device	Product Defect Correction	Class II	Hospital
31/08/2020	Aptio Automation. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
31/08/2020	Grass Subdermal Needle Electrode	Medical Device	Recall	Class III	Hospital
31/08/2020	Medfusion 3500 and 4000 Syringe Pumps	Medical Device	Product Defect Correction	Class I	Hospital
31/08/2020	Percutaneous Neonatal Pigtail Nephrostomy Set	Medical Device	Product Defect Correction	Class II	Hospital
27/08/2020	LAP-BAND Adjustable Gastric Banding System	Medical Device	Hazard Alert	Class II	Hospital
27/08/2020	Notus Vivere Emergency Ventilator	Medical Device	Product Defect Correction	Class II	Wholesale

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26/08/2020	Custom Pak "AUS-DR LI CATARACT"	Medical Device	Product Defect Correction	Class II	Hospital
26/08/2020	MEDUMAT Standard emergency and transport ventilator	Medical Device	Product Defect Correction	Class I	Hospital
26/08/2020	Neurolite Cold Kit	Medicine	Recall	Class II	Hospital
26/08/2020	TaqPath COVID-19 Combo Kit. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
26/08/2020	WRO 300H Water Purification System	Medical Device	Product Defect Correction	Class III	Hospital
25/08/2020	Bone, morsellised, frozen, irradiated (Fine Milled Bone)	Biological	Hazard Alert	Class II	Hospital
24/08/2020	All systems running on software version syngo.plaza VB30A, VB30B and VB30C including all hotfixes	Medical Device	Product Defect Correction	Class II	Hospital
24/08/2020	Heater Unit HU 35, 230 V	Medical Device	Product Defect Correction	Class III	Hospital
24/08/2020	Philips HeartStart MRx Monitor / Defibrillator	Medical Device	Product Defect Correction	Class II	Hospital
24/08/2020	SpeedStitch Needles	Medical Device	Recall	Class II	Hospital
24/08/2020	Velosorb fast braided fast absorbable suture	Medical Device	Recall	Class I	Hospital
21/08/2020	Covidien Endo GIA Auto Suture universal articulating loading units	Medical Device	Recall	Class I	Hospital
21/08/2020	PROFEMUR Long and X-Long Titanium Modular Necks	Medical Device	Recall	Class II	Hospital
20/08/2020	BD Alaris System PCU / LVP / SYR / PCA	Medical Device	Product Defect Correction	Class I	Hospital
20/08/2020	Heater-Cooler Unit HCU 40	Medical Device	Product Defect Correction	Class II	Hospital
20/08/2020	Neo Natal Cots (Trendelenburg Mechanism)	Medical Device	Recall	Class II	Hospital
19/08/2020	ORTHO VISION Analyzer for ORTHO BioVue Cassettes and ORTHO VISION Max Analyzer for ORTHO BioVue Cassettes. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
19/08/2020	Score Cementless Knee	Medical Device	Product Defect Correction	Class II	Hospital
17/08/2020	Artis zee and Artis Q systems (with manual installation of VD11C Patch 11)	Medical Device	Product Defect Correction	Class II	Hospital
17/08/2020	VISULENS 550 and VISUREF 150	Medical Device	Product Defect Correction	Class II	Retail

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14/08/2020	Atellica UAS 800 Analyser and Atellica 1500 Automated Urinalysis System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
14/08/2020	Elekta Unity	Medical Device	Product Defect Correction	Class II	Hospital
14/08/2020	Femoral Head Allograft - Fine Milled Bone	Biological	Hazard Alert	Class II	Hospital
14/08/2020	Various BIOSYS Devices	Medical Device	Product Defect Correction	Class III	Hospital
14/08/2020	Zenith Alpha Abdominal Endovascular Graft	Medical Device	Recall	Class I	Hospital
11/08/2020	Cornea (Normothermic)	Biological	Hazard Alert	Class II	Hospital
11/08/2020	New model Contour Portare 2 & Portare-X - Patient & Trauma Stretchers	Medical Device	Product Defect Correction	Class III	Hospital
11/08/2020	Yankauer sucker, s/steel green handle	Medical Device	Recall	Class II	Hospital
10/08/2020	Elecsys Anti-TPO Assay. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
10/08/2020	GYNECARE TVT Family of Products	Medical Device	Product Defect Correction	Class II	Hospital
7/08/2020	CONMED CE200 Beamer Electrosurgical Unit	Medical Device	Product Defect Correction	Class II	Hospital
7/08/2020	Intra-Aortic Balloon Catheters (IABs)	Medical Device	Recall	Class I	Hospital
7/08/2020	Universa Firm Ureteral Stent Set	Medical Device	Recall	Class II	Hospital
6/08/2020	G5/S1 OXYGEN CELL	Medical Device	Recall	Class III	Hospital
6/08/2020	SENSIS Vibe Hemo systems with MicroPod EtCO2	Medical Device	Product Defect Correction	Class II	Hospital
5/08/2020	Alinity m System. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
5/08/2020	Randox Ammonia. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
4/08/2020	eSie Flow quantification package used with ACUSON SC2000 ultrasound systems and syngo SC2000 Workplace	Medical Device	Recall	Class II	Hospital
3/08/2020	Alinity hq Analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
3/08/2020	High Sensitivity Troponin I (TNIH) Flex Reagent Cartridge. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
3/08/2020	Multiplanar Reconstruction (MPR) in syngo.share view diagnostic versions VA24, VA25, VA26, VA27, VA28	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
3/08/2020	Offset Cup Impactors	Medical Device	Recall	Class II	Hospital
3/08/2020	POLARSTEM COLLAR Reamer Guide	Medical Device	Recall	Class II	Hospital
3/08/2020	Thermo Scientific Remel Bordetella pertussis Agglutinating Serum 2mL. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
31/07/2020	ABSTRAL fentanyl (as citrate) 100 microgram sublingual tablet blister pack	Medicine	Recall	Class II	Retail
31/07/2020	BioCeuticals Vitamin D3 Drops Forte Liquid 20mL	Medicine	Recall	Class II	Consumer
30/07/2020	AC Adapter supplied with PC-50S PIXEL CHART	Medical Device	Recall	Class III	Retail
30/07/2020	The SoKINOX/SERVINO NO delivery and monitoring system	Medical Device	Product Defect Correction	Class I	Hospital
29/07/2020	PROTEXIS Latex Micro Surgical Gloves	Medical Device	Recall	Class II	Hospital
28/07/2020	PVS Single Use Accessory Kit, Size S & M.	Medical Device	Recall	Class II	Hospital
27/07/2020	ANTERION with Cataract App	Medical Device	Product Defect Correction	Class II	Retail
27/07/2020	CARESCAPE R860 Ventilator	Medical Device	Product Defect Correction	Class II	Hospital
27/07/2020	Guideline 4000 5.0, GL5 Main Processing Unit	Medical Device	Recall	Class II	Wholesale
27/07/2020	Nature's Way Kids Smart Vita Gummies Omega 3 DHA Fish Oil, Pastilles (soft gummies) 60's	Medicine	Recall	Class I	Retail
27/07/2020	Various Sun Herbal Medicines containing Fallopia multiflora	Medicine	Recall	Class II	Retail
24/07/2020	EVO IQ Large Volumetric Pump (LVP)	Medical Device	Product Defect Correction	Class II	Hospital
24/07/2020	VITROS XT 3400 Chemistry System & VITROS XT 7600 Integrated System. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
23/07/2020	Accelerator a3600 Aliquoter Module System and Flexlab Aliquoter Modules. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
23/07/2020	Kick 2 Navigation Systems	Medical Device	Product Defect Correction	Class II	Hospital
23/07/2020	LIFEPAK 500 Automated External Defibrillators (AED)	Medical Device	Product Defect Correction	Class I	Retail
23/07/2020	Siemens SOMATOM go.Up, go.All, go.Top, go.Sim and X.cite running syngo.CT VA20A or syngo.CT VA30A	Medical Device	Product Defect Correction	Class II	Hospital

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22/07/2020	Bellovac Wound Drain Sets	Medical Device	Product Defect Correction	Class II	Hospital
22/07/2020	Rocket KCH Foetal Bladder Drain	Medical Device	Product Defect Correction	Class II	Hospital
22/07/2020	SynchroMed II Software Application Version 1.1.342	Medical Device	Product Defect Correction	Class II	Hospital
21/07/2020	MoPyc Radial Head Prostheses	Medical Device	Product Defect Correction	Class II	Hospital
21/07/2020	Rocket FBS Kit for Lactate with Sampling Wand	Medical Device	Product Defect Correction	Class II	Hospital
21/07/2020	Signa Architect MRI Systems	Medical Device	Product Defect Correction	Class II	Hospital
20/07/2020	99mTc-Cardiolite (1A)	Medicine	Product Defect Alert	Class III	Hospital
20/07/2020	BD Alaris Systems	Medical Device	Product Defect Correction	Class I	Hospital
20/07/2020	BD MAX SARS-CoV-2 Reagent 445003. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
17/07/2020	Arjo Citadel Plus beds.	Medical Device	Product Defect Correction	Class II	Hospital
17/07/2020	Dentsply Sirona (SICAT Implant 2.0 Software)	Medical Device	Product Defect Correction	Class II	Retail
17/07/2020	MINIRIN (desmopressin acetate) 10 micrograms/actuation Nasal Spray	Medicine	Recall	Class II	Retail
17/07/2020	Rusch Greenlite Mac	Medical Device	Recall	Class II	Hospital
17/07/2020	VITROS Chemistry Products. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
16/07/2020	Cios Spin & Cios Alpha	Medical Device	Product Defect Correction	Class II	Hospital
16/07/2020	Guardian Connect App Connectivity to Carelink Personal Software	Medical Device	Product Defect Correction	Class II	Consumer
16/07/2020	Philips 3.7V Rechargeable Li-Polymer Battery for Expression MR400 MRI Patient Monitoring System Modules	Medical Device	Product Defect Correction	Class II	Hospital
16/07/2020	Tissue-Tek Film Coverslipper. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
15/07/2020	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Recall	Class III	Hospital
14/07/2020	Thomas Splint	Medical Device	Product Defect Correction	Class II	Hospital
13/07/2020	Artis zee/zeego and AXIOM Artis	Medical Device	Product Defect Correction	Class III	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
13/07/2020	Randox Lipase Reagents. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
9/07/2020	GOLD CROSS Potassium Permanganate Powder 50g	Medicine	Recall	Class II	Retail
8/07/2020	Caesarea Medical Electronics BodyGuard 575 ColorVision Pump	Medical Device	Product Defect Correction	Class III	Hospital
8/07/2020	US PowerLoc Max 20G & SAFESTEP 20G	Medical Device	Recall	Class II	Hospital
7/07/2020	Hemochron Signature Elite. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
7/07/2020	Lasertube Laser Guard Foil	Medical Device	Recall	Class I	Hospital
6/07/2020	0.9% Sodium Chloride bags 500mL and 1000mL	Medicine	Recall	Class II	Hospital
6/07/2020	MatrixMIDFACE Emergency Screw ø1.8mm, self-tapp, L 12mm, in Clip	Medical Device	Hazard Alert	Class II	Hospital
6/07/2020	TruSystem 3000	Medical Device	Product Defect Correction	Class II	Hospital
3/07/2020	Nature's Way Kids Smart Vita Gummies Omega 3 DHA Fish Oil, Pastilles (soft gummies) 120's	Medicine	Recall	Class I	Retail
3/07/2020	SUTUREFIX ULTRA 1.7mm Drill, Small	Medical Device	Recall	Class II	Hospital
1/07/2020	Captivator and Captiflex Polypectomy Snares	Medical Device	Recall	Class II	Hospital
1/07/2020	DM36 Dreama slim support pad for Jenx Dreama sleep mattress	Medical Device	Product Defect Correction	Class II	Consumer
30/06/2020	ACCURIAN RF Cannula (18G, sterile, single-use)	Medical Device	Recall	Class II	Hospital
30/06/2020	AIRSENSE 10 ELITE ANZ TENDER 4G CPAP Device	Medical Device	Product Defect Correction	Class III	Consumer
30/06/2020	Automated Haematology Analyser XN-550. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
30/06/2020	CARTO 3 System Version V7.1.80, CARTO VISITAG Module	Medical Device	Product Defect Correction	Class II	Hospital
30/06/2020	Dilution Plates. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
29/06/2020	Alinity ci-series System Control Module	Medical Device	Product Defect Correction	Class II	Hospital
29/06/2020	Customized Tubing Set HQV 46352 Pre-connected Pump Pack	Medical Device	Product Defect Correction	Class II	Hospital

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29/06/2020	Phadia AB EliA ANA Positive Control 250. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
26/06/2020	Single Use Spring Tip Guidewire	Medical Device	Product Defect Correction	Class II	Hospital
26/06/2020	Software option "Synthetic CT" of syngo.via RT Image Suite	Medical Device	Product Defect Correction	Class I	Hospital
26/06/2020	Welch Allyn Patient Cables and Lead Sets	Medical Device	Recall	Class II	Hospital
25/06/2020	DxA 5000 SW version 1.5 and all before. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class I	Hospital
25/06/2020	FUJIFILM Synapse PACS Version 5.5.x and 5.7.x	Medical Device	Product Defect Correction	Class I	Hospital
24/06/2020	Anti-Intrinsic factor ELISA. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
24/06/2020	CARESCAPE ONE Monitor	Medical Device	Product Defect Correction	Class II	Hospital
24/06/2020	MatrixNEURO Screws	Medical Device	Recall	Class II	Hospital
24/06/2020	The Alinity h-series (Alinity hq Analyzer and Alinity hs Slide Maker Stainer Module). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
23/06/2020	Anaesthesia Breathing Circuit	Medical Device	Recall	Class II	Hospital
23/06/2020	Drager Perseus A500 Anaesthesia Machine	Medical Device	Product Defect Correction	Class II	Hospital
23/06/2020	Fusion Comfort Chair	Medical Device	Product Defect Correction	Class II	Consumer
23/06/2020	Ovation Abdominal Stent Graft System Platform	Medical Device	Recall	Class I	Wholesale
23/06/2020	Volumetric Infusion Pump with Polypropylene (PP) Lines	Medical Device	Product Defect Correction	Class I	Hospital
22/06/2020	ABSTRAL fentanyl (as citrate) 200 microgram sublingual tablet blister pack	Medicine	Recall	Class II	Retail
22/06/2020	Alinity m System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
22/06/2020	Tc99m Cardiolite	Medicine	Recall	Class II	Hospital
22/06/2020	TEPADINA 100 mg powder for concentrate for solution for infusion	Medicine	Product Defect Correction	Class II	Hospital
19/06/2020	Infant Child Reduced Energy Electrodes for Physio-Control LIFEPAK Defibrillators	Medical Device	Recall	Class I	Retail
19/06/2020	TEPADINA 100mg	Medicine	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
18/06/2020	FDG Injection	Medicine	Recall	Class II	Hospital
18/06/2020	K-401 (Single Use Guide Sheath Kit)	Medical Device	Recall	Class II	Hospital
18/06/2020	Nucleus 7 & Kanso Sound Processors	Medical Device	Product Defect Correction	Class III	Hospital
18/06/2020	Siemens SOMATOM X.cite running syngo.CT VA30A	Medical Device	Product Defect Correction	Class II	Hospital
18/06/2020	SOMATOM Perspective, SOMATOM Emotion 6 (2007) & SOMATOM Emotion 16 (2007) with syngo.CT software versions VC20B (all released versions)	Medical Device	Product Defect Correction	Class II	Hospital
18/06/2020	Virgin Silk Suture	Medical Device	Recall	Class II	Hospital
17/06/2020	ADVIA Centaur XP - Rubella G and Rubella M Calibrator Assigned Value Cards. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
17/06/2020	IntelePACS InteleViewer	Medical Device	Product Defect Correction	Class II	Hospital
17/06/2020	Philips 866173 IntelliVue G7m Anaesthesia Gas Modules	Medical Device	Product Defect Correction	Class II	Hospital
15/06/2020	Novatin acitretin 10mg and 25 mg capsule blister pack	Medicine	Product Defect Correction	Class I	Retail
12/06/2020	MagNA Pure 96 System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
11/06/2020	HYGENIC Dental Dam Forceps, Simple Dam Kit, Winged Fiesta Kit and Wingless Fiesta Kit	Medical Device	Recall	Class III	Retail
11/06/2020	SmartSync Device Manager	Medical Device	Hazard Alert	Class II	Hospital
10/06/2020	ACTIV.A.C Therapy Units	Medical Device	Product Defect Correction	Class II	Hospital
10/06/2020	Elisa 300, 500, 600, 800 and Elisa 800	Medical Device	Product Defect Correction	Class III	Hospital
9/06/2020	SOMATOM - Force, Definition AS, Definition Edge, Definition Flash, Drive, Confidence, and EdgePlus - running syngo.CT VB20	Medical Device	Product Defect Correction	Class II	Hospital
5/06/2020	Combicath and Pleurocath Catheters	Medical Device	Recall	Class II	Hospital
5/06/2020	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
4/06/2020	Atrial Lead Position Check	Medical Device	Product Defect Correction	Class II	Hospital
4/06/2020	CFx Longevity Estimator	Medical Device	Product Defect Correction	Class I	Hospital
4/06/2020	Stericool Hydrogen Peroxide Plasma Steriliser	Medical Device	Product Defect Correction	Class III	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
4/06/2020	Tepadina 100mg powder for injection	Medicine	Recall	Class II	Hospital
3/06/2020	Arrow AutoCAT2 Intra-Aortic Balloon Pump and Arrow AC3 Optimus Intra-Aortic Balloon Pump	Medical Device	Product Defect Correction	Class I	Hospital
3/06/2020	HiLite Chair	Medical Device	Product Defect Correction	Class II	Consumer
3/06/2020	RP500e Handheld Barcode Scanner. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
3/06/2020	Zenith Alpha Abdominal Endovascular Graft	Medical Device	Recall	Class II	Hospital
2/06/2020	M6-C Artificial Cervical Discs	Medical Device	Product Defect Correction	Class II	Hospital
2/06/2020	Mexiletine HCL capsules 50mg [NICH-IKO]	Medicine	Recall	Class II	Hospital
2/06/2020	Spectra Optia Apheresis System	Medical Device	Product Defect Correction	Class II	Hospital
2/06/2020	TEPADINA 100 mg powder for concentrate for solution for infusion, 1 vial	Medicine	Recall	Class II	Hospital
29/05/2020	COULTER Body Fluid Control Level 1. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
29/05/2020	Philips M3015A Microstream CO2 Extension	Medical Device	Product Defect Correction	Class II	Hospital
28/05/2020	TACROLIMUS APOTEX tacrolimus 0.5 mg capsule blister pack	Medicine	Product Defect Correction	Class III	Retail
27/05/2020	LokomatPro L6	Medical Device	Product Defect Correction	Class II	Hospital
26/05/2020	Bivona Cuffless Adjustable Neck Flange Hyperflex Pediatric Tracheostomy Tube	Medical Device	Recall	Class I	Hospital
26/05/2020	Pharmacy Select Sodium Bicarbonate Mouthwash 1% 200mL & 500mL	Medical Device	Product Defect Correction	Class III	Retail
25/05/2020	CentraLink Data Management Systems and Atellica Data Manager	Medical Device	Product Defect Correction	Class II	Hospital
25/05/2020	Cooling Patch for Pain Relief & Painreliev Cooling Patch	Medicine	Recall	Class II	Retail
25/05/2020	IMMULITE 2000 Immunoassay System and IMMULITE 2000 XPi Immunoassay System Waste Bottle Flexible Tube. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
25/05/2020	McGRATH X3 Disposable Laryngoscope Blades	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
25/05/2020	VITROS Chemistry Products AMYL Slides Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
22/05/2020	Fresenius Kabi Freeflex Infusion Bags	Medicine	Product Defect Correction	Class II	Hospital
22/05/2020	Oxoid DrySpot Staphytest Plus. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
21/05/2020	CARESCAPE Patient Data Module (PDM)	Medical Device	Product Defect Correction	Class I	Hospital
21/05/2020	GlideScope Core OneTouch Smart Cable	Medical Device	Recall	Class I	Hospital
21/05/2020	ThermoShield Neonatal HME	Medical Device	Recall	Class II	Hospital
20/05/2020	A.L.P.S. Proximal Humerus	Medical Device	Recall	Class II	Hospital
19/05/2020	MAMMOMAT Revelation system versions VC10B, VC10C or VC10D using Tomo Biopsy Unit	Medical Device	Product Defect Correction	Class II	Hospital
18/05/2020	ABL800 with FLEXQ sampler tray. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class I	Hospital
18/05/2020	Alinity c Processing Module. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
18/05/2020	Non-Contact Infrared Thermometer	Medical Device	Product Defect Correction	Class II	Hospital
15/05/2020	Giraffe Incubators and Giraffe OmniBeds	Medical Device	Product Defect Correction	Class I	Hospital
15/05/2020	Tandem Diabetes Care t:slim X2 Insulin Pump	Medical Device	Product Defect Correction	Class I	Consumer
14/05/2020	All Elekta Unity Systems	Medical Device	Product Defect Correction	Class I	Hospital
14/05/2020	Levofloxacin 500mg Tablets (pack of 10)	Medicine	Product Defect Alert	Class III	Retail
14/05/2020	Multifire VersaTack Auto Suture Hernia Staplers & Multifire Endo Hernia Auto Suture Straight Hernia Staplers	Medical Device	Recall	Class II	Hospital
13/05/2020	Atellica IM 1300 Analyser / Atellica IM 1600 Analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
13/05/2020	Automated Haematology Analyser XN series (XN-10 and XN-20). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
13/05/2020	Thioridazin-neuraxpharm 25 mg, 50 mg, and 100 mg film-coated tablets	Medicine	Recall	Class II	Retail

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
12/05/2020	ADVIA 1800/2400/XPT Chemistry system, Atellica CH Analyser & Dimension systems. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
12/05/2020	Freeze Dried Musculoskeletal Allograft	Biological	Product Defect Correction	Class III	Hospital
11/05/2020	All Elekta Unity Systems	Medical Device	Product Defect Correction	Class II	Hospital
11/05/2020	Medilog AR	Medical Device	Product Defect Correction	Class II	Hospital
11/05/2020	Multitom Rax	Medical Device	Product Defect Correction	Class II	Hospital
11/05/2020	PENTARAY AV Catheters, PENTARAY NAV eco Catheters	Medical Device	Product Defect Correction	Class II	Hospital
8/05/2020	Blackmores Professional Duo Celloids S.C.F. (170s) & (84s)	Medicine	Recall	Class II	Consumer
8/05/2020	Elekta Unity system - MR Linac	Medical Device	Product Defect Correction	Class II	Hospital
8/05/2020	EliA Stool Extraction Kit & EliA Stool Extraction Kit 2. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
8/05/2020	Giraffe Shuttle Devices	Medical Device	Recall	Class II	Hospital
8/05/2020	Philips HeartStart XL Defibrillator/Monitor	Medical Device	Product Defect Correction	Class I	Hospital
8/05/2020	Pneumograph, Chest, NM, 3160	Medical Device	Product Defect Correction	Class II	Hospital
8/05/2020	Skeletal Kinetics Bone Void Filler (SK Callos Inject (Mx) 5cc)	Medical Device	Hazard Alert	Class II	Hospital
5/05/2020	IMMAGE Immunochemistry Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
5/05/2020	Outer Sheath 4.5/5.0, 6.5 and Screw Instrument Tray 6.5/80MM	Medical Device	Recall	Class II	Hospital
5/05/2020	Sakura Cryostat Microtome. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
5/05/2020	VITEK 2 Software Version 9.01/9.02. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
4/05/2020	FL36 bed model	Medical Device	Product Defect Correction	Class II	Wholesale
4/05/2020	MiniMed 640G pump	Medical Device	Recall	Class II	Consumer
4/05/2020	Tendon Tibialis Anterior, non-irradiated	Biological	Hazard Alert	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
1/05/2020	Aptio Automation, FlexLab Automation & FlexLab HS Automation. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
30/04/2020	ARCHITECT iGentamicin Reagent Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
30/04/2020	DDU-2000 Series Automated External Defibrillator (AED)	Medical Device	Recall	Class I	Consumer
30/04/2020	ForeSight Elite Monitor - Tissue saturation oximeter	Medical Device	Product Defect Correction	Class III	Hospital
30/04/2020	Header Bags Packaging of Custom Tubing Packs	Medical Device	Recall	Class II	Hospital
29/04/2020	15 cm IRE Single Electrode RFID Activation	Medical Device	Recall	Class II	Hospital
29/04/2020	ABL80 series analysers including ABL80 FLEX Full panel & ABL80 FLEX CO-OX Analysers. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
29/04/2020	Access Sensitive Estradiol Calibrators. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
29/04/2020	BeGraft Coronary Stent Graft System, diameter 3mm, length 18-24mm	Medical Device	Recall	Class II	Hospital
29/04/2020	CARESCAPE ONE Monitor	Medical Device	Product Defect Correction	Class I	Hospital
29/04/2020	R3 Acetabular Shells	Medical Device	Recall	Class II	Hospital
29/04/2020	Restoration Anatomic Shell (RAS) sizes 54mm – 68mm, (Left & Right)	Medical Device	Hazard Alert	Class II	Hospital
29/04/2020	Syngo Dynamics	Medical Device	Product Defect Correction	Class II	Hospital
28/04/2020	Beta-2 Microglobulin. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
28/04/2020	Brilliance iCT, Brilliance iCT SP system, and IQon Spectral CT	Medical Device	Product Defect Correction	Class II	Hospital
28/04/2020	Haemodialysis Blood Cartridge Sets	Medical Device	Product Defect Correction	Class I	Hospital
28/04/2020	Nile Alternative Fixation Spinal System Band	Medical Device	Recall	Class II	Hospital
24/04/2020	ARTIS icono floor	Medical Device	Product Defect Correction	Class II	Hospital
24/04/2020	ARTIS pheno	Medical Device	Product Defect Correction	Class II	Hospital
24/04/2020	Philips Sterilizable Defibrillator Internal Paddles	Medical Device	Product Defect Correction	Class II	Hospital
24/04/2020	Various Polyethylene Implants	Medical Device	Hazard Alert	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
23/04/2020	Medicina ENFit NGP and Ryles Nasogastric Feeding Tubes	Medical Device	Product Defect Correction	Class II	Hospital
23/04/2020	Philips Allura and Azurion systems	Medical Device	Product Defect Correction	Class II	Hospital
22/04/2020	XperGuide Software in Philips Azurion 2.0 system	Medical Device	Product Defect Correction	Class II	Hospital
21/04/2020	Access hsTnI Reagent	Medical Device	Product Defect Correction	Class II	Hospital
20/04/2020	Coagulation Factor V Deficient Plasma. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
20/04/2020	Jamshidi Bone Marrow Biopsy/Aspiration Needle	Medical Device	Recall	Class II	Hospital
20/04/2020	Optilite IE700 analyser (SW V7.0/7.0.1). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
16/04/2020	ORTHO VISION and ORTHO VISION Max Analyser. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
15/04/2020	AQT90 series analysers. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
15/04/2020	IPS e.max ZirCAD Cerec LT A2 & A3 C17/5	Medical Device	Recall	Class II	Retail
15/04/2020	Siemens SOMATOM go.Now, go.Up, go.All, go.Top running syngo.CT VA20A	Medical Device	Product Defect Correction	Class II	Hospital
14/04/2020	Gibco Gurr Buffer Tablets. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
14/04/2020	Monaco Treatment Planning System 5.40 or 5.40.01	Medical Device	Product Defect Correction	Class II	Hospital
14/04/2020	Spectranetics Bridge Occlusion Balloon Catheter	Medical Device	Product Defect Correction	Class II	Hospital
9/04/2020	Adrenocorticotrophic Hormone (ACTH) Assay used on IMMULITE, IMMULITE 1000, IMMULITE 2000, IMMULITE 2000 XPi. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
9/04/2020	CareLink 2090 Programmer & Encore 29901 Programmer	Medical Device	Product Defect Correction	Class II	Hospital
8/04/2020	Therascreen EGFR RGQ PCR Kit & EGFR Plasma RGQ PCR Kit. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
7/04/2020	The FlexLab (Accelerator a3600 and Aptio Automation) modular systems. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
7/04/2020	YAG/SLT Devices	Medical Device	Product Defect Correction	Class II	Hospital

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6/04/2020	Multiple Philips MRI Systems	Medical Device	Product Defect Correction	Class III	Hospital
3/04/2020	Chest Support	Medical Device	Product Defect Correction	Class I	Consumer
3/04/2020	Defibrotide 200mg/2.5mL vial	Medicine	Recall	Class I	Hospital
3/04/2020	Defibrotide 200mg/2.5mL vial	Medicine	Recall	Class I	Hospital
3/04/2020	Defibrotide 200mg/2.5mL vial	Medicine	Recall	Class I	Hospital
2/04/2020	ADVIA Chemistry Systems 1800/2400/XPT & Atellica CH 930 Analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
2/04/2020	Afinion Analyser systems. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Retail
2/04/2020	Aircal Device 3m	Medical Device	Recall	Class II	Hospital
2/04/2020	ELI 380 Electrocardiograph	Medical Device	Product Defect Correction	Class III	Hospital
2/04/2020	iChemVELOCITY Urine Chemistry System & iQ200 Series Urine Microscopy Analyser. An in vitro diagnostic medical (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
2/04/2020	VITEK 2 Systems Software Version 8.01. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
31/03/2020	Sentinel Diagnostics Plasmaproteins Cal 3X & Immuno Control Set. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
31/03/2020	Sodium Fluoride (18F) Injection	Medicine	Product Defect Alert	Class II	Hospital
30/03/2020	Langston Dual Lumen Catheter	Medical Device	Recall	Class II	Hospital
30/03/2020	VisuMax	Medical Device	Product Defect Correction	Class III	Hospital
27/03/2020	Epix Latis Grasper	Medical Device	Recall	Class II	Hospital
27/03/2020	PP2279 Granada agar. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
27/03/2020	T34 and T34L Ambulatory Syringe Pumps	Medical Device	Product Defect Correction	Class II	Hospital
27/03/2020	TruVidia Wireless Camera Receiver	Medical Device	Product Defect Correction	Class III	Hospital
25/03/2020	Philips V60 Ventilators	Medical Device	Product Defect Correction	Class I	Hospital
24/03/2020	da Vinci Xi and da Vinci X Surgical System	Medical Device	Product Defect Correction	Class II	Hospital

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24/03/2020	HeartStart MRx Monitor / Defibrillator	Medical Device	Product Defect Correction	Class I	Hospital
24/03/2020	Rapid Plus 1 system	Medical Device	Product Defect Correction	Class II	Hospital
23/03/2020	LeMaitre 5F Plus Over the Wire Embolectomy Catheter	Medical Device	Recall	Class II	Hospital
23/03/2020	Philips TRx4851A Telemetry Transceivers used with Patient Information Center IX C.02.xx or C.03.01.	Medical Device	Product Defect Correction	Class I	Hospital
20/03/2020	AK 98 Hemodialysis Devices software version V3.0	Medical Device	Product Defect Correction	Class II	Hospital
20/03/2020	CORFLO PEG Kit	Medical Device	Recall	Class II	Hospital
20/03/2020	Footprint Ultra PK Suture Anchor 4.5mm & 5.5mm	Medical Device	Recall	Class II	Hospital
19/03/2020	Alere NT-proBNP for ARCHITECT and Alinity i Calibrators and Controls. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
19/03/2020	Philips SensaVue	Medical Device	Product Defect Correction	Class III	Hospital
19/03/2020	Sterile plastic bushings accessory	Medical Device	Recall	Class II	Hospital
18/03/2020	Corpuls3 devices	Medical Device	Product Defect Correction	Class I	Hospital
18/03/2020	Dade Ci-Trol 1. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
18/03/2020	FluoroQuench. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
17/03/2020	Microvascular Coupler Device 2.0 mm & 2.5 mm	Medical Device	Recall	Class II	Hospital
17/03/2020	Radiometer safeCLINITUBES Blood Samplers. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
16/03/2020	MICROPLAS plasmafilter	Medical Device	Recall	Class I	Hospital
16/03/2020	MyWay Harnesses	Medical Device	Recall	Class II	Consumer
16/03/2020	SOMATOM Force CT Scanner	Medical Device	Product Defect Correction	Class II	Hospital
13/03/2020	F18-FDG Injection	Medicine	Product Defect Correction	Class III	Hospital
13/03/2020	RayStation and RayPlan Systems	Medical Device	Product Defect Correction	Class II	Hospital
13/03/2020	Sotalol Carinopharm 40 mg / 4 ml solution for injection	Medicine	Recall	Class I	Hospital
12/03/2020	Azurion Interventional Fluoroscopic X-ray system	Medical Device	Product Defect Correction	Class II	Hospital

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12/03/2020	Curam Duo 400/57 Powder for Oral Suspension	Medicine	Product Defect Correction	Class II	Retail
12/03/2020	Expression MR400 MRI Patient Monitoring System	Medical Device	Product Defect Correction	Class II	Hospital
12/03/2020	Wassenburg Dryer320	Medical Device	Product Defect Correction	Class II	Hospital
11/03/2020	ADVIA 120/2120/2120i CBC TIMEPAC and ADVIA 120/2120/2120i CN-Free CBC TIMEPAC. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
11/03/2020	NAVIO Soft Tissue Protector supplied in NAVIO Instrument Kit	Medical Device	Product Defect Correction	Class II	Hospital
11/03/2020	Sensor Nitinol Guidewire with Hydrophilic Tip	Medical Device	Recall	Class II	Hospital
10/03/2020	Global Cup 3-Hole Porous & HA Coated Size 44 & 64	Medical Device	Recall	Class III	Hospital
10/03/2020	N Latex CDT Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
10/03/2020	Radiometer ABL800 series blood gas analysers. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
6/03/2020	R-F Cobra Injector Cannula 18g & 20g	Medical Device	Recall	Class III	Hospital
5/03/2020	Atellica CH 930 Analyser. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
3/03/2020	MAGEC System - Model X Rods	Medical Device	Hazard Alert	Class II	Hospital
3/03/2020	Siemens Ysio Fully Automated with Software Version VB10	Medical Device	Product Defect Correction	Class II	Hospital
2/03/2020	HiRes Ultra Cochlear Implants	Medical Device	Hazard Alert	Class II	Hospital
2/03/2020	TEG MANAGER Software with TEG 5000	Medical Device	Product Defect Correction	Class II	Hospital
28/02/2020	Allergan Breast Implants	Medical Device	Hazard Alert	Class II	Hospital
28/02/2020	JT Medical POLYTECH Breast Implants	Medical Device	Hazard Alert	Class II	Hospital
28/02/2020	KWIK-STIK 2 Pack Trichosporon dermatis derived from ATCC 204094. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
28/02/2020	MENTOR SILTEX Microtextured and Smooth Breast Implants and Tissue Expanders	Medical Device	Hazard Alert	Class II	Hospital
28/02/2020	Motiva Sterile Silicone Breast Implants	Medical Device	Hazard Alert	Class II	Hospital
28/02/2020	Paragel Cohesive Gel Implant	Medical Device	Hazard Alert	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
28/02/2020	Sebbin Round Breast Implants Microtextured (Firm High Cohesive Gel Mammary implants)	Medical Device	Hazard Alert	Class II	Hospital
28/02/2020	Various Nagor Mammary Implants	Medical Device	Hazard Alert	Class II	Hospital
27/02/2020	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Recall	Class II	Hospital
27/02/2020	Medtronic Conexus Telemetry	Medical Device	Product Defect Correction	Class II	Hospital
27/02/2020	PP2022 Horse Blood Agar (HBA)/MacConkey agar split plates. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
26/02/2020	MULTIX Impact software version VA10E	Medical Device	Product Defect Correction	Class II	Hospital
24/02/2020	AXIOM Aristos FX Plus	Medical Device	Product Defect Correction	Class II	Hospital
20/02/2020	ARTIS zeego and Artis zee/Q/Q.zen systems with Siemens Healthineers Table (Tilt/Step, OR)	Medical Device	Product Defect Correction	Class II	Hospital
19/02/2020	Atellica CH Ethyl Alcohol (ETOH). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
19/02/2020	BD Alaris Systems	Medical Device	Product Defect Correction	Class I	Hospital
19/02/2020	Endocuff Vision	Medical Device	Product Defect Correction	Class II	Hospital
19/02/2020	Factor VIII assays on Stago Instruments. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
19/02/2020	Medtronic Covidien Force TriVerse electrosurgical devices within Medline Procedure Packs	Medical Device	Product Defect Correction	Class II	Hospital
19/02/2020	Pipeline Flex Embolization Device and Pipeline Flex Embolization Device with Shield Technology	Medical Device	Recall	Class I	Hospital
18/02/2020	ADVIA Chemistry Direct Bilirubin (DBIL_2) and Total Bilirubin (TBIL_2) Assays. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
18/02/2020	Atellica CH Direct Bilirubin (DBil_2) and Total Bilirubin (TBil_2) Assays. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
18/02/2020	Dimension Total Bilirubin (TBI) Flex reagent cartridge. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
18/02/2020	Dimension Vista Total Bilirubin (TBIL) Flex reagent cartridge. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
18/02/2020	Organ Transport Container, Femoral Head Pack	Medical Device	Recall	Class II	Hospital
18/02/2020	Site Rite 8 Ultrasound System	Medical Device	Product Defect Correction	Class II	Hospital
18/02/2020	uE3 KRYPTOR. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
17/02/2020	CLINITEK Status+ Analysers and CLINITEK Status Connect Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
17/02/2020	Microbore Extension Sets	Medical Device	Recall	Class II	Hospital
14/02/2020	Imager 5F II Angiographic Catheter	Medical Device	Recall	Class I	Hospital
13/02/2020	Palamix UNO	Medical Device	Product Defect Correction	Class II	Hospital
13/02/2020	Various Surgical Instruments within Surgical Sets	Medical Device	Recall	Class II	Hospital
12/02/2020	PALEXIA SR 100 mg tapentadol (as hydrochloride) sustained release tablets	Medicine	Product Defect Correction	Class II	Consumer
12/02/2020	RAPIDLyte Arterial Line Draw Syringes	Medical Device	Recall	Class II	Hospital
12/02/2020	Stealth Spring Clips 6mm	Medical Device	Recall	Class II	Hospital
11/02/2020	Arista AH 3g	Medical Device	Product Defect Correction	Class III	Hospital
11/02/2020	BiomarC Preloaded Tissue Marker Device	Medical Device	Product Defect Correction	Class II	Hospital
11/02/2020	IMMULITE Systems Estradiol assay. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
11/02/2020	Peters Surgical Monopolar Instrument	Medical Device	Product Defect Correction	Class II	Hospital
11/02/2020	Radiometer ABL90FLEX and ABL90FLEX Plus. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
10/02/2020	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
10/02/2020	Inogen One G3 Concentrator	Medical Device	Product Defect Correction	Class II	Consumer
10/02/2020	Ranitidine Hydrochloride, USP	Medicine	Recall	Class II	Retail
7/02/2020	Covidien Force TriVerse electrosurgical device	Medical Device	Recall	Class II	Hospital
7/02/2020	McGrath X3 Disposable Laryngoscope Blades	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
6/02/2020	Bock Nursing Care Beds - Battery	Medical Device	Product Defect Correction	Class II	Consumer
6/02/2020	Bock Nursing Care Beds - Lifting Poles	Medical Device	Product Defect Correction	Class II	Consumer
6/02/2020	Philips Efficia Combined Cable/3 or 5 Leadsets	Medical Device	Product Defect Correction	Class I	Hospital
5/02/2020	Arrow FlexTip Plus Epidural Catheterisation Sets and Kits	Medical Device	Recall	Class I	Hospital
5/02/2020	Hemospray Endoscopic Hemostat	Medical Device	Recall	Class I	Hospital
5/02/2020	i-STAT CHEM 8+, CG4+ and G3+ Cartridges (blue). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
5/02/2020	Taewoong Medical Niti-S Bumpy Biliary Covered Short Stents	Medical Device	Recall	Class II	Hospital
4/02/2020	Ellipse Implantable Cardioverter Defibrillators	Medical Device	Product Defect Correction	Class III	Hospital
4/02/2020	F18-FDG	Medicine	Recall	Class III	Hospital
4/02/2020	Rotor-Gene Q software version 2.3.4. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class I	Hospital
3/02/2020	ARTIS Pheno Systems	Medical Device	Product Defect Correction	Class II	Hospital
3/02/2020	Biocartis BTA00606 Idylla EGFR Mutation Test. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
3/02/2020	Breath-A-Tech (Standard and Hospital Grade) Spacers	Medical Device	Product Defect Correction	Class II	Retail
3/02/2020	PSPIX Digital Imaging Plate Scanner (first generation)	Medical Device	Product Defect Correction	Class II	Retail
31/01/2020	Alinity ci-series System Control Module (SCM). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
31/01/2020	FeverBugz stick on Thermometer	Medical Device	Product Defect Correction	Class III	Consumer
31/01/2020	Medtronic HeartWare HVAD System Battery Charger AC Adapter and Controller	Medical Device	Product Defect Correction	Class I	Hospital
31/01/2020	Teleflex Premium Diamond Edge Aortic Punch	Medical Device	Recall	Class II	Hospital
30/01/2020	Elecsys CA 19-9 reagent for use on the cobas e 801 analytical unit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
30/01/2020	IntelePACS – InteleViewer versions 4-17-1 and up	Medical Device	Product Defect Correction	Class II	Hospital
30/01/2020	Mayer's Haematoxylin Stain (Original Formulation). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
29/01/2020	BioFire FilmArray Blood Culture Identification (BCID) Panel Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
29/01/2020	BladderScan BVI 3000 Ultrasound System	Medical Device	Product Defect Correction	Class III	Hospital
29/01/2020	NC Trek RX Coronary Dilatation Catheter 4.0mm, 4.5mm and 5.0mm	Medical Device	Recall	Class I	Hospital
29/01/2020	Olympus Pleuravideoscope, LTF-160	Medical Device	Product Defect Correction	Class II	Hospital
29/01/2020	T34 Syringe Pump, 3rd edition	Medical Device	Product Defect Correction	Class II	Hospital
28/01/2020	Drager Infinity Central Station; software version VG2.1.2	Medical Device	Product Defect Correction	Class III	Hospital
28/01/2020	UTAK Validity Control 4. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
24/01/2020	Technetium-99m Cardiolite	Medicine	Recall	Class II	Hospital
23/01/2020	Cardinal Health Non-Reinforced Surgical Gowns & Fabric-Reinforced Surgical Gowns	Medical Device	Recall	Class II	Hospital
23/01/2020	Mako MICS Irrigation Clip	Medical Device	Recall	Class II	Hospital
22/01/2020	Atellica CH Reaction Cuvette Segment. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
22/01/2020	Autocon III 300 and Autocon III 400 High Frequency Generators	Medical Device	Product Defect Correction	Class III	Hospital
22/01/2020	Green Rusch Lite Disposable Metal Laryngoscope Blade	Medical Device	Recall	Class II	Hospital
21/01/2020	Liquichek Cardiac Markers Plus Control LT. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
21/01/2020	Neon3 Universal OCT Spinal Stabilisation	Medical Device	Recall	Class II	Hospital
17/01/2020	Liquichek Cardiac Markers Plus Control LT. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
17/01/2020	Monopolar Cable	Medical Device	Product Defect Correction	Class II	Hospital
17/01/2020	Telescopic Smoke Evacuation Pencil	Medical Device	Recall	Class II	Hospital
17/01/2020	Various Monopolar Instruments	Medical Device	Product Defect Correction	Class II	Hospital
16/01/2020	Arrow PICC Set	Medical Device	Product Defect Correction	Class III	Hospital
16/01/2020	Equinox Platform Fracture Humeral Stem, Cemented	Medical Device	Product Defect Correction	Class III	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
16/01/2020	IMMULITE Systems - Progesterone (PRG). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
16/01/2020	Letco Medical Estriol USP	Medicine	Recall	Class II	Retail
16/01/2020	O-arm O2 Imaging System – Motor Drive Belt	Medical Device	Product Defect Correction	Class II	Hospital
15/01/2020	Velara X-Ray Generator of the Philips Allura Xper, Integris, MultiDiagnost Eleva and OmniDiagnost Systems	Medical Device	Product Defect Correction	Class II	Hospital
14/01/2020	NUCLISENS Lysis Buffer. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class I	Hospital
13/01/2020	Maestro 4000 Cardiac Ablation System	Medical Device	Product Defect Correction	Class I	Hospital
13/01/2020	Philips Digitrak XT Holter Monitor	Medical Device	Product Defect Correction	Class III	Hospital
13/01/2020	Various Cios Systems	Medical Device	Product Defect Correction	Class II	Hospital
10/01/2020	Eclipse Treatment Planning System, versions 15.5 and 15.6	Medical Device	Product Defect Correction	Class II	Hospital
10/01/2020	SPY-PHI Drapes	Medical Device	Recall	Class II	Hospital
10/01/2020	TrueBeam / VitalBeam Radiotherapy System and EDGE RadioSurgery System	Medical Device	Product Defect Correction	Class II	Hospital
9/01/2020	LIFEPAK 15 Monitor/Defibrillator	Medical Device	Product Defect Correction	Class I	Hospital
9/01/2020	Ysio Max, Luminos dRF Max, Luminos Agile Max and Urooskop Omnia Max with software versions VE10Q and VE10U	Medical Device	Product Defect Correction	Class II	Hospital
8/01/2020	Certain BellaTek Encode Healing Abutments	Medical Device	Recall	Class II	Retail
8/01/2020	McKesson/Horizon/Change Healthcare Cardiology Hemo	Medical Device	Product Defect Correction	Class II	Hospital
8/01/2020	Sealer Foil Cartridge. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
7/01/2020	Atellica IM Humidity Pack. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
7/01/2020	Femcare Australia Filshie Clips, Standard Sterishot Kits and Minilap Sterishot Kits	Medical Device	Product Defect Correction	Class II	Hospital
7/01/2020	Gore Excluder Devices	Medical Device	Product Defect Correction	Class II	Hospital
7/01/2020	Immuno Concepts Image Navigator software Version 3 and 4 (ICINUP). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
6/01/2020	ADVIA Chemistry Lipase. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
6/01/2020	ADVIA Chemistry Systems - Enzymatic Creatinine_2. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
6/01/2020	Atellica CH Analyser - Enzymatic Creatinine (ECre_2) Assays. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
6/01/2020	Dimension Clinical Chemistry Systems Enzymatic Creatinine (EZCR) Assay. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
6/01/2020	Dimension Vista Systems - Enzymatic Creatinine. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
6/01/2020	Fludeoxyglucose F18 Injection (18F-FDG)	Medicine	Product Defect Correction	Class III	Hospital
6/01/2020	Kangaroo Enteral Feeding Kits	Medical Device	Product Defect Alert	Class II	Hospital
6/01/2020	Single-use insufflation tubing set with gas and Single-use gas filter with 3.20m of insufflation tube	Medical Device	Recall	Class II	Hospital
6/01/2020	Various RayStation and RayPlan Systems	Medical Device	Product Defect Correction	Class II	Hospital
2/01/2020	Mavidon Medical - LemonPrep Tubes and Single Use Cups	Medical Device	Recall	Class II	Hospital
24/12/2019	Dawson-Mueller Drainage Catheters	Medical Device	Recall	Class II	Hospital
24/12/2019	RX Daytona + with ISE and RX Daytona +. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
23/12/2019	'FeNOBreath', Fractional Exhaled Nitric Oxide. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
23/12/2019	CAIMAN Vessel sealing instrument, 240 mm working length, diameter 12 mm, muzzle length: 50 mm, sterile, disposable	Medical Device	Recall	Class II	Hospital
23/12/2019	Cordis S.M.A.R.T. Stents	Medical Device	Product Defect Correction	Class II	Hospital
23/12/2019	EnCor Breast Biopsy Probes	Medical Device	Product Defect Correction	Class II	Hospital
23/12/2019	Perl's Solution B 0.64% Hydrochloric Acid Solution. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital

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20/12/2019	Atellica IM NT-proBNP (PBNP) 100 Test Kit and 500 Test Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
20/12/2019	DEFIGARD Touch 7	Medical Device	Product Defect Correction	Class I	Hospital
20/12/2019	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
20/12/2019	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
20/12/2019	Giraffe Blue Spot PT Lite Phototherapy Systems	Medical Device	Product Defect Correction	Class II	Hospital
20/12/2019	Philips CombiDiagnost R90 GCF Systems	Medical Device	Product Defect Correction	Class II	Hospital
20/12/2019	Philips CombiDiagnost R90 PCF Systems	Medical Device	Product Defect Correction	Class II	Hospital
19/12/2019	F18-FDG Injection	Medicine	Product Defect Correction	Class III	Hospital
19/12/2019	Oragene DNA. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
19/12/2019	VesselNavigator application in combination with Azurion R1.2.x and R2.0.x	Medical Device	Product Defect Correction	Class II	Hospital
18/12/2019	All FTD CE-IVD. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
18/12/2019	Polysorb braided monofilament absorbable sutures	Medical Device	Recall	Class II	Hospital
18/12/2019	Tempus LS Defibrillator	Medical Device	Product Defect Correction	Class I	Hospital
16/12/2019	Carestation 620/650/650c A1 and Carestation 620/650/650c A2 Anaesthesia Systems	Medical Device	Product Defect Correction	Class II	Hospital
16/12/2019	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
16/12/2019	Femoral Head Allograft - Fine Milled Bone	Biological	Hazard Alert	Class I	Hospital
16/12/2019	Impress Peripheral Catheter	Medical Device	Product Defect Correction	Class II	Hospital
16/12/2019	Liquid Clinical Chemistry Control. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
13/12/2019	Philips 867036 IntelliVue MMX Multi-measurement module	Medical Device	Product Defect Correction	Class III	Hospital
13/12/2019	Q-VAX Q FEVER VACCINE 0.5mL injection syringe	Medicine	Recall	Class III	Retail
12/12/2019	Accu-Chek Aviva test strips. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Retail
11/12/2019	Technetium-99m HDP	Medicine	Recall	Class II	Hospital
10/12/2019	T2 Alpha Delta Strike Plate IMN Instruments	Medical Device	Recall	Class II	Hospital

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10/12/2019	Various GE Healthcare MRI Systems	Medical Device	Product Defect Correction	Class II	Hospital
9/12/2019	Estriol USP (Micronised)	Medicine	Product Defect Correction	Class II	Retail
6/12/2019	Cios Alpha systems	Medical Device	Product Defect Correction	Class II	Hospital
6/12/2019	Kit Cobas 4800 Sample Prep 2 960T CE-IVD. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class III	Hospital
5/12/2019	Ceramir Crown & Bridge QuikCap	Medical Device	Recall	Class III	Retail
5/12/2019	GSP Neonatal IRT Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
5/12/2019	iMRX System	Medical Device	Product Defect Correction	Class II	Hospital
5/12/2019	Mazor X Surgical System (SST2) – Positioner Type II	Medical Device	Product Defect Correction	Class II	Hospital
4/12/2019	Stellar 100 and 150 Portable Ventilators	Medical Device	Product Defect Correction	Class II	Consumer
3/12/2019	ARCHITECT Reaction Vessels. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
3/12/2019	Mobile Power Unit for Heartmate 3 LVAS	Medical Device	Product Defect Correction	Class I	Hospital
3/12/2019	Various SOMATOM Definition Edge, AS, Flash and DS systems with syngo.CT software versions VA4 4A_SP6	Medical Device	Product Defect Correction	Class II	Hospital
2/12/2019	Bediol Medicinal Cannabis	Medicine	Product Defect Correction	Class III	Consumer
2/12/2019	Medilogic – TM-317 Pneumodart	Medical Device	Recall	Class I	Hospital
2/12/2019	SOMATOM go.Now, SOMATOM go.Up, SOMATOM go.All, SOMATOM go.Top with syngo.CT software versions VA20A (all released versions)	Medical Device	Product Defect Correction	Class II	Hospital
29/11/2019	Brauer Teething Gel 20g tube	Medicine	Recall	Class I	Consumer
29/11/2019	Radiometer ABL90 FLEX and ABL90 FLEX Plus blood gas analysers. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
28/11/2019	3M Durapore Advanced Surgical Tape	Medical Device	Recall	Class I	Hospital
28/11/2019	EIT Cellular Titanium Cervical Cages and EIT Cellular Titanium Lumbar Cages	Medical Device	Product Defect Correction	Class III	Hospital
28/11/2019	F18-FDG	Medicine	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
28/11/2019	Xper Information Management System version 2.4.2 and 2.4.3	Medical Device	Product Defect Correction	Class II	Hospital
27/11/2019	ADVIA Chemistry Systems - CardioPhase High Sensitivity C-Reactive Protein (hsCRP) Calibrator. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
27/11/2019	Atellica CH 930 Analyser - High Sensitivity C-Reactive Protein (hsCRP) Calibrator. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
27/11/2019	Xpert HIV-1 Viral Load assay. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
26/11/2019	ARJO 'All Day' Slings	Medical Device	Product Defect Correction	Class II	Hospital
26/11/2019	CONMED Linvatec Electrosurgical Tip Cleaner	Medical Device	Recall	Class II	Hospital
25/11/2019	CV-11 component of UN3000 Fully Automated Integrated Urine Analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
22/11/2019	Adagio. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
22/11/2019	Eleganza 5 Beds	Medical Device	Product Defect Correction	Class II	Hospital
22/11/2019	Flexitron HDR/PDR and Flexitron Co-60 systems	Medical Device	Product Defect Correction	Class II	Hospital
22/11/2019	HABIB EUS RFA	Medical Device	Recall	Class II	Hospital
22/11/2019	HALYARD Closed Suction System for Neonates / Paediatrics (5 Fr)	Medical Device	Product Defect Correction	Class I	Hospital
22/11/2019	Monaco Treatment Planning System version 5.40 and above	Medical Device	Product Defect Correction	Class I	Hospital
22/11/2019	USS II Polyaxial 3D Head	Medical Device	Hazard Alert	Class I	Hospital
21/11/2019	Azurion Interventional Fluoroscopic X-Ray Systems	Medical Device	Product Defect Correction	Class III	Hospital
21/11/2019	Multiple RayStation / RayPlan Systems	Medical Device	Product Defect Correction	Class II	Hospital
21/11/2019	Python Catheters, BARD Latex-free Arterial Embolectomy Catheters, and Over-the-Wire Iatris Graft Cleaning Catheters	Medical Device	Recall	Class II	Hospital
21/11/2019	SOMATOM Force with software syngo.CT VA50A, SOMATOM Drive and SOMATOM Confidence with software syngo.CT VA62A	Medical Device	Product Defect Correction	Class II	Hospital

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19/11/2019	STAGO STA Unicalibrator. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
18/11/2019	Passive Biopsy Needle Kits	Medical Device	Recall	Class II	Hospital
15/11/2019	EliA ANA Positive Control 2500/5000. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
15/11/2019	TOMTEC – ARENA version software 2.20 and lower	Medical Device	Product Defect Correction	Class II	Hospital
14/11/2019	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
14/11/2019	Free Gliding SCFE Screw System	Medical Device	Recall	Class II	Hospital
14/11/2019	Philips Incisive CT Systems	Medical Device	Product Defect Correction	Class III	Hospital
13/11/2019	AQT90 Cleaning Solution Tubes. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
13/11/2019	ARCHITECT CRP Vario and Alinity c CRP Vario Reagent Kits. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
13/11/2019	Colour Cuff Disposable Tourniquet Cuffs	Medical Device	Recall	Class II	Hospital
12/11/2019	Aequalis Ascend Flex Stem Implants	Medical Device	Product Defect Correction	Class II	Hospital
12/11/2019	Friendly & H-Max C Cemented Femoral Stems	Medical Device	Hazard Alert	Class II	Hospital
12/11/2019	LIGAMAX – 5mm Endoscopic Multiple Clip Applier	Medical Device	Recall	Class II	Hospital
8/11/2019	Dual-Tab Electrodes	Medical Device	Recall	Class II	Hospital
8/11/2019	EZ Glide Aortic Cannula	Medical Device	Recall	Class I	Hospital
8/11/2019	HMTS 142D Plasma Sterilisers	Medical Device	Product Defect Correction	Class II	Hospital
8/11/2019	STAR Total Ankle Replacements	Medical Device	Hazard Alert	Class II	Hospital
8/11/2019	Thromborel S assay. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
7/11/2019	Anaesthetic Circuit	Medical Device	Product Defect Correction	Class II	Hospital
7/11/2019	iChemVELOCITY Urine Chemistry System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
7/11/2019	Oxylog 3000 Transport Ventilators	Medical Device	Product Defect Correction	Class II	Hospital
7/11/2019	Unity Knee Cutting Block	Medical Device	Recall	Class III	Hospital

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6/11/2019	Accu-Chek blood glucose meters. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Consumer
6/11/2019	Disposable Pressure Transducer System	Medical Device	Recall	Class II	Hospital
6/11/2019	iQ200 Series Urine Microscopy Analyser and iChemVELOCITY Urine Chemistry System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
4/11/2019	HeartStart XL+ Defibrillator/Monitors manufactured prior to 1 May 2017	Medical Device	Product Defect Correction	Class I	Hospital
4/11/2019	MAVIDON LemonPrep 4oz (114g) Tubes in Diagnosys Espion Ophthalmic Electrophysiology Systems	Medical Device	Recall	Class II	Hospital
4/11/2019	Philips HeartStart XL+ Defibrillator/Monitor	Medical Device	Product Defect Correction	Class I	Hospital
4/11/2019	XEN 45 Glaucoma Treatment System - Glaucoma Shunt	Medical Device	Hazard Alert	Class I	Hospital
1/11/2019	Atellica IM Testosterone II 100 and 500 Test Kits. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
1/11/2019	Elecsys Troponin T hs for use on the cobas e 801 analytical unit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
1/11/2019	Genius 2 and Genius 3 Tympanic Thermometers	Medical Device	Product Defect Correction	Class II	Hospital
1/11/2019	QUADROX-iD Paediatric with BIOLINE Coating	Medical Device	Recall	Class I	Hospital
31/10/2019	3mensio Workstation (Vascular and Structural Heart module)	Medical Device	Product Defect Correction	Class III	Wholesale
31/10/2019	Emerge Monorail PTCA Dilation Catheters & NC Emerge Monorail PTCA Dilation Catheters	Medical Device	Recall	Class II	Hospital
31/10/2019	Guedel Airways	Medical Device	Recall	Class II	Hospital
31/10/2019	Skin Prep Pads	Medical Device	Recall	Class II	Hospital
30/10/2019	Alinity m System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
30/10/2019	LimiTorr Volume Limiting External CSF Drainage and Monitoring Systems	Medical Device	Recall	Class II	Hospital
30/10/2019	Single Use Macintosh 3 Laryngoscope Blades	Medical Device	Recall	Class II	Hospital

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30/10/2019	Syramed µSP6000 Syringe Drivers and Volumed µVP7000 Large Volume Infusion pumps	Medical Device	Product Defect Correction	Class II	Retail
30/10/2019	Various Chemotherapy Compounded Drugs	Medicine	Recall	Class II	Hospital
29/10/2019	Caruso's Super Collagen Builder	Medicine	Recall	Class III	Retail
29/10/2019	Dako Autostainer Syringe Tray. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
29/10/2019	Haemonetics 125ml and 225ml Centrifuge Bowl	Medical Device	Product Defect Correction	Class II	Hospital
29/10/2019	Mitomycin 2 mg Injection (pack of 10 vials)	Medicine	Recall	Class II	Hospital
28/10/2019	Alinity c Carbon Dioxide Reagent Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
28/10/2019	Arrow MAC Two-Lumen Central Venous Access Kit	Medical Device	Product Defect Alert	Class III	Hospital
28/10/2019	BACT/ALERT VIRTUO A & B Units. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
25/10/2019	Artiset Blood Tubing System	Medical Device	Recall	Class II	Hospital
25/10/2019	Eurosilicone Implants	Medical Device	Hazard Alert	Class I	Hospital
25/10/2019	Sublime Line, Microthane & 4Two Line, Single Lumen, Micro Polyurethane, Silicone gel filled Mammary Implants	Medical Device	Hazard Alert	Class I	Hospital
25/10/2019	Textured Nagor GFX, CoGel and Impleo Mammary Implants	Medical Device	Hazard Alert	Class I	Hospital
24/10/2019	CUSA Clarity Operator's Manual associated with CUSA Clarity Console	Medical Device	Product Defect Correction	Class II	Hospital
24/10/2019	F18-FDG	Medicine	Product Defect Correction	Class III	Hospital
24/10/2019	Max-Core Disposable Core Biopsy Instruments	Medical Device	Recall	Class II	Hospital
24/10/2019	ORTHO BioVue System Cassettes. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
24/10/2019	PP2039 Anaerobic agar plates. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
24/10/2019	Tandem t:slim X2 Insulin Pump - A/C Power Adapter	Medical Device	Product Defect Correction	Class II	Consumer
23/10/2019	Amico Go-Lift Carry Bars	Medical Device	Product Defect Correction	Class II	Hospital
23/10/2019	Ellipse Heavy Duty Bariatric Rollator	Medical Device	Product Defect Correction	Class II	Consumer

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23/10/2019	Magic Mobility - Power Wheelchair	Medical Device	Product Defect Correction	Class II	Consumer
23/10/2019	Radiometer ABL800 analysers measuring cRea (ABL827, ABL837). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
23/10/2019	Sharesource Adequest	Medical Device	Product Defect Correction	Class II	Hospital
23/10/2019	SynchroMed II Implantable Infusion Pumps	Medical Device	Hazard Alert	Class I	Hospital
22/10/2019	Advanix Pancreatic Stent	Medical Device	Recall	Class II	Hospital
22/10/2019	Atellica Solution - Atellica IM Active-B12. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
22/10/2019	InTouch Critical Care Bed	Medical Device	Product Defect Correction	Class II	Hospital
22/10/2019	Torcon NB Advantage Angiographic Catheter	Medical Device	Recall	Class II	Hospital
22/10/2019	VIDAS 3 (software versions 1.2 and higher). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class I	Hospital
21/10/2019	AeroForm Tissue Expander System	Medical Device	Hazard Alert	Class I	Hospital
21/10/2019	Amico GoLift Carry Bar	Medical Device	Product Defect Correction	Class II	Consumer
21/10/2019	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
21/10/2019	Giraffe Incubator, Giraffe OmniBed, Giraffe Incubator Carestation, and Giraffe OmniBed Carestation	Medical Device	Product Defect Correction	Class II	Hospital
18/10/2019	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
18/10/2019	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
18/10/2019	Mobile X-ray System FDR-Go Plus	Medical Device	Product Defect Correction	Class II	Hospital
18/10/2019	VENTANA HE 600 system. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
17/10/2019	Akron Tilt Table	Medical Device	Product Defect Correction	Class II	Hospital
17/10/2019	Arrow EZ-IO Intraosseous Vascular Access Needle Sets	Medical Device	Product Defect Correction	Class II	Hospital
17/10/2019	Medicina Oral Tip and ENFit Home Use Low Dose Syringes	Medical Device	Recall	Class II	Retail
17/10/2019	Patient Data Manager	Medical Device	Product Defect Correction	Class II	Hospital
17/10/2019	Roche CARDIAC Pipette 150 µL cobas h 232 POC system. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
17/10/2019	Surface Temperature Probe	Medical Device	Recall	Class II	Hospital
17/10/2019	WECK Auto Endo5 Automatic Hem-o-lok Clip Appliers	Medical Device	Recall	Class II	Hospital
16/10/2019	RadiForce RX360 and GX560 Monitors	Medical Device	Product Defect Correction	Class II	Hospital
15/10/2019	Ausran (150mg and 300mg tablets), Chemists' Own Ranitidine and Chemists' Own Ranitidine Forte	Medicine	Recall	Class II	Retail
15/10/2019	Embryology Heated Plate within the RI Witness	Medical Device	Product Defect Correction	Class II	Hospital
15/10/2019	GSS67H Steriliser (software version earlier than 2.0.1)	Medical Device	Product Defect Correction	Class II	Hospital
15/10/2019	UniCel DxH Slidemaker Stainer (DxH SMS) & UniCel DxH Slidemaker Stainer II (DxH SMS II). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
14/10/2019	Panther Fusion Extraction Reagent-S. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
14/10/2019	SOMATOM go.Top with software syngo CT VA20A_SP2 and with active "Guide&GO" license	Medical Device	Product Defect Correction	Class II	Hospital
11/10/2019	BACT/ALERT VIRTUO system A & B units. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
11/10/2019	Various SOMATOM Systems with software syngo CT VB20 or syngo CT VB10	Medical Device	Product Defect Correction	Class II	Hospital
11/10/2019	VeriSeq NIPT Sample Prep Kits. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
10/10/2019	HandyVac	Medical Device	Recall	Class II	Hospital
10/10/2019	Various Soul Pattinson Manufacturing (SPM) Ranitidine Tablets	Medicine	Recall	Class II	Retail
10/10/2019	Xpert Xpress Flu/RSV Assay. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
9/10/2019	Epidural Positioning Device (EPD)	Medical Device	Product Defect Correction	Class II	Hospital
9/10/2019	Monaco version 5.40, 5.50 or 5.51	Medical Device	Product Defect Correction	Class I	Hospital
8/10/2019	Cautery Tip Cleaner	Medical Device	Product Defect Correction	Class II	Hospital
8/10/2019	Homocysteine. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
8/10/2019	Systems Manager software version 12.0.1 with PCU versions 9.X.	Medical Device	Product Defect Correction	Class I	Hospital
4/10/2019	Liquid Cardiac Control. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
4/10/2019	Philips V60 and V80 Ventilators	Medical Device	Product Defect Correction	Class II	Hospital
4/10/2019	Prismaflex Control Units with software versions 7.20 and below	Medical Device	Product Defect Correction	Class I	Hospital
4/10/2019	TJF / JF Duodenoscope	Medical Device	Product Defect Correction	Class II	Hospital
3/10/2019	AERO-AL Revision Housing	Medical Device	Product Defect Correction	Class II	Hospital
3/10/2019	CARESCAPE Respiratory Modules	Medical Device	Recall	Class I	Hospital
3/10/2019	Coles & Medix Heartburn & Acid Indigestion ranitidine (as hydrochloride) tablets 14s pack	Medicine	Recall	Class II	Retail
3/10/2019	Spacelabs Healthcare Inc. Xhibit Central	Medical Device	Product Defect Correction	Class II	Hospital
2/10/2019	Cipla Ranitidine Tablets	Medicine	Recall	Class II	Retail
2/10/2019	Generic Health Ranitidine Tablets	Medicine	Recall	Class II	Retail
2/10/2019	Symbion Ranitidine Tablets	Medicine	Recall	Class II	Retail
1/10/2019	iChemVELOCITY Urine Chemistry Strips. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
1/10/2019	Intellijoint HIP System - (Apple MacBook)	Medical Device	Product Defect Correction	Class II	Hospital
1/10/2019	Ranitidine 150mg and 300mg (Rani 2)	Medicine	Recall	Class II	Retail
1/10/2019	TherMax, Blood Warmer Unit, ROW	Medical Device	Product Defect Correction	Class II	Hospital
1/10/2019	ZANTAC Ranitidine	Medicine	Recall	Class II	Retail
30/09/2019	Apotex Ranitidine Tablets	Medicine	Recall	Class II	Retail
30/09/2019	Cornea	Biological	Hazard Alert	Class II	Hospital
30/09/2019	Forte Family Gamma Cameras	Medical Device	Product Defect Correction	Class I	Hospital
30/09/2019	Steam Steriliser - HS5510 EC1	Medical Device	Product Defect Correction	Class III	Hospital
27/09/2019	Aquilex Fluid Control System (AQL-100CBS)	Medical Device	Product Defect Correction	Class II	Hospital
26/09/2019	Caesarea Medical Electronics T34 Syringe Pumps	Medical Device	Product Defect Correction	Class II	Hospital
26/09/2019	DTX Safedraw Kits and Meritans DTXPlus Devices	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
26/09/2019	Exactamix Empty EVA Bags	Medical Device	Recall	Class I	Hospital
26/09/2019	F18-FDG	Medicine	Recall	Class II	Hospital
26/09/2019	IACS and Stand Alone M540 Monitor, s/w version VG4.1.1 & VG4.0.3 and lower	Medical Device	Product Defect Correction	Class II	Hospital
25/09/2019	Alinity ci Level Sensor & Accessory Kits. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
25/09/2019	Atellica CH 930 Analyser – Software versions 1.20.0 and below. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
25/09/2019	FoodPrint Software V7.5 provided with CNS301-16/4 and CNS301-4/4 FoodPrint Microarray 200+ Food IgG. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
25/09/2019	GA 5003, Anti-Gangliosid Dot. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class I	Hospital
25/09/2019	Non-Esterified Fatty Acids (NEFA). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
24/09/2019	Medisoft FeNO+	Medical Device	Product Defect Correction	Class II	Hospital
23/09/2019	AIR LIQUIDE Medical Carbon Dioxide - 16.5m3 G sized cylinder	Medicine	Recall	Class III	Hospital
23/09/2019	ATOK Shoulder Anchor	Medical Device	Hazard Alert	Class II	Hospital
23/09/2019	InterVapor System	Medical Device	Product Defect Correction	Class I	Hospital
23/09/2019	LBgard Blood Collection Tubes	Medical Device	Product Defect Correction	Class II	Hospital
20/09/2019	DCFPyL	Medicine	Recall	Class III	Hospital
20/09/2019	Philips HeartStart FRx and HS1 OnSite Automated External Defibrillators (AEDs)	Medical Device	Recall	Class I	Hospital
20/09/2019	ROSA Brain 3.0	Medical Device	Product Defect Correction	Class I	Hospital
19/09/2019	Selected Behind-the-Ear hearing aids	Medical Device	Recall	Class I	Consumer
18/09/2019	Alinity hq Analyser and Alinity hs Slide Maker Stainer Module. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
18/09/2019	DC-Screening II. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
18/09/2019	Radiometer AQUIRE Data Management System	Medical Device	Product Defect Correction	Class III	Hospital
17/09/2019	Sandoz Ranitidine	Medicine	Recall	Class II	Retail
17/09/2019	VHK and VKMO Adult/Small Adult	Medical Device	Recall	Class I	Hospital
17/09/2019	VHK and VKMO(D) Adult/Small Adult Accessories	Medical Device	Recall	Class I	Hospital
16/09/2019	Atellica UAS 800 Analyser and Atellica 1500 Automated Urinalysis System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
16/09/2019	Codan US Corporation Swan-Lock Needle-Free Connector	Medical Device	Recall	Class II	Retail
16/09/2019	GentleCool Pro Cryogen Canister	Medical Device	Recall	Class II	Retail
16/09/2019	OriGen Products TissueVault O-Wrap and accessories	Medical Device	Product Defect Correction	Class I	Hospital
16/09/2019	Shuttle Discovery with 4 Wheel Verve Stroller	Medical Device	Product Defect Correction	Class II	Consumer
13/09/2019	CereLink ICP Monitor	Medical Device	Recall	Class II	Hospital
12/09/2019	Alpha Conducting Solution used with Alpha-Stim M & AID devices	Medical Device	Recall	Class II	Consumer
12/09/2019	Seca Baby Scale	Medical Device	Product Defect Correction	Class I	Hospital
12/09/2019	Serres Suction Bag Liner	Medical Device	Product Defect Correction	Class II	Hospital
11/09/2019	ILED 7 Surgical Light Systems	Medical Device	Product Defect Correction	Class III	Hospital
11/09/2019	IMMAGE Total Immunoglobulin E (IgE) Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
11/09/2019	STRATAFIX Spiral Uni PDS Plus	Medical Device	Recall	Class III	Hospital
11/09/2019	SYNCHRON Systems Cannabinoid 100 ng (THC) & SYNCHRON Systems Cannabinoid 50 ng (THC5) Reagents. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
11/09/2019	SYNCHRON Systems Opiate 300 ng (OP) Reagent and SYNCHRON Systems Opiate 2000 ng (OP2) Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
10/09/2019	Introcan Safety IV Catheter	Medical Device	Recall	Class II	Hospital
10/09/2019	SPROTTE Lumbar with Introducer	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
9/09/2019	Achilles Express and Achilles Insight System Power Cords	Medical Device	Product Defect Correction	Class II	Hospital
9/09/2019	Dario Blood Glucose Tracker app. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Consumer
9/09/2019	Multiple ApexPro Telemetry server hardware platforms	Medical Device	Product Defect Correction	Class I	Hospital
9/09/2019	Philips S7-3t & S8-3t Transesophageal (TEE) Transducers	Medical Device	Product Defect Correction	Class II	Hospital
9/09/2019	Thermo Scientific Remel Salmonella paratyphi B-H phase 1 Flagellar antigen b Stained Suspension. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
9/09/2019	Various Convex Two-Piece Skin Barriers	Medical Device	Product Defect Correction	Class II	Consumer
6/09/2019	Prima Supravac Fingerswitch Pencils with Smoke Evacuation Tubing	Medical Device	Product Defect Correction	Class II	Hospital
6/09/2019	Triathlon Orthopaedic Devices	Medical Device	Hazard Alert	Class II	Hospital
5/09/2019	Arterial Catheter Mini Kit 20ga x 6"	Medical Device	Recall	Class II	Hospital
5/09/2019	Arthrem Joint Support Capsules	Medicine	Recall	Class II	Retail
5/09/2019	C3 CryoProbe 2.1mm sharp	Medical Device	Recall	Class II	Hospital
5/09/2019	REMISOL Advance. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
4/09/2019	Atomizer – EZ Spray	Medical Device	Recall	Class I	Hospital
4/09/2019	COBAS AmpliPrep/COBAS TaqMan HCV Quantitative Test, v2.0. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
4/09/2019	Philips Efficia Defibrillator/Monitor (DFM100)	Medical Device	Product Defect Correction	Class I	Hospital
4/09/2019	Tina-quant Soluble Transferrin Receptor. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
4/09/2019	Various Assays. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
3/09/2019	BM MX117 FIDIS Connective Profile Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
3/09/2019	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
3/09/2019	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
3/09/2019	GlideScope Core Systems	Medical Device	Product Defect Correction	Class III	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
3/09/2019	LemonPrep 114gm tubes	Medical Device	Recall	Class II	Hospital
3/09/2019	Vanguard XP-CR Tibial Tray	Medical Device	Hazard Alert	Class II	Hospital
2/09/2019	Euphora Semi-Compliant Rapid Exchange Balloon Dilatation Catheters	Medical Device	Recall	Class II	Hospital
30/08/2019	IH-1000. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
30/08/2019	JIN GUI SHEN QI WAN	Medicine	Recall	Class I	Consumer
30/08/2019	Rocket FBS Amnioscopes	Medical Device	Product Defect Correction	Class II	Hospital
30/08/2019	SEM Scanner	Medical Device	Recall	Class III	Wholesale
28/08/2019	Nutrabolics Blackout	Medicine	Recall	Class II	Retail
27/08/2019	Triathlon Femoral Distal Augments (10 and 15 mm, Size 2, Left and Right)	Medical Device	Recall	Class II	Hospital
26/08/2019	18F-Fluorodeoxy Glucose (18F-FDG) for injection	Medicine	Recall	Class I	Hospital
26/08/2019	Atellica UAS 800 Analyser and Atellica 1500 Automated Urinalysis System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
23/08/2019	BIS Vista Monitoring Systems Phase II	Medical Device	Product Defect Correction	Class II	Hospital
23/08/2019	Medisorb Cannister 0.8kg	Medical Device	Recall	Class II	Hospital
23/08/2019	Multiple Gold Cup Electrodes and Snap Electrode Leads	Medical Device	Recall	Class II	Hospital
23/08/2019	TheraBead Compress Cervical and TheraBead Compress STD	Medical Device	Product Defect Correction	Class II	Retail
21/08/2019	BD FACSLyric Flow Cytometer	Medical Device	Product Defect Correction	Class II	Hospital
21/08/2019	Concerto Shower Trolley and Basic Shower Trolley	Medical Device	Product Defect Correction	Class II	Retail
21/08/2019	Metafix stem size 4	Medical Device	Recall	Class II	Hospital
21/08/2019	VaccZyme Human Anti-Haemophilus Influenzae type b Enzyme Immunoassay Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
20/08/2019	Atellica IM 1300 Analyser & Atellica IM 1600 Analyser with Software V 1.19.0 and 1.19.2. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
19/08/2019	ONLINE TDM Vancomycin Gen. 3. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
16/08/2019	Atellica CH 930 Analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
16/08/2019	SYNCHRON Systems Benzodiazepine (BNZG) Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
16/08/2019	Weinmann Adult MEDUCORE Multifunctional Electrodes	Medical Device	Recall	Class I	Retail
15/08/2019	Economy Anaesthetic Face Mask, 22F	Medical Device	Product Defect Correction	Class II	Hospital
12/08/2019	Atellica CH 930 Analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
12/08/2019	Modulus, Modulus-R and Revision modular femoral stems	Medical Device	Product Defect Correction	Class II	Hospital
12/08/2019	Oxoid Mice STRIP MA0121 – Meropenem32. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
8/08/2019	AssayTip/AssayCup Tray. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
8/08/2019	DM DESLV5228 Demeditec Estrone free in saliva ELISA. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
8/08/2019	Heater Unit HU 35, 230 V	Medical Device	Product Defect Correction	Class I	Hospital
8/08/2019	IBL RE52681, Estrone Saliva ELISA. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
8/08/2019	Medtronic Micra Delivery System Packaged as part of Micra Transcatheter Pacing System	Medical Device	Product Defect Correction	Class II	Hospital
8/08/2019	Multiple da Vinci Xi and da Vinci X Systems	Medical Device	Product Defect Correction	Class II	Hospital
8/08/2019	Quantel Medical – Easyret Laser	Medical Device	Product Defect Correction	Class II	Hospital
7/08/2019	Artis zee and Artis Q patient table within a specific production lot	Medical Device	Product Defect Correction	Class II	Hospital
7/08/2019	CVC Procedure Packs	Medical Device	Recall	Class II	Hospital
7/08/2019	Various Haemodynamic Monitoring Kits	Medical Device	Recall	Class II	Hospital
6/08/2019	Ad-Tech Product Catalogue	Medical Device	Product Defect Correction	Class II	Hospital
6/08/2019	Hollister Urostomy bag	Medical Device	Recall	Class III	Consumer
6/08/2019	Magic mobility wheelchair - Mobility Handles	Medical Device	Recall	Class II	Consumer

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
6/08/2019	Steelco Endoscope Dryers	Medical Device	Product Defect Correction	Class II	Hospital
5/08/2019	Alginate Basis Cinnamon 25lbs and 6lbs	Medical Device	Recall	Class II	Retail
5/08/2019	PrisMax, V2, ROW	Medical Device	Product Defect Correction	Class II	Hospital
2/08/2019	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
2/08/2019	SOMATOM go.Up, SOMATOM go.All, SOMATOM go.Now and SOMATOM go.Top with injector and optional storage box	Medical Device	Product Defect Correction	Class II	Hospital
2/08/2019	Swivel Elbow Connectors	Medical Device	Recall	Class I	Hospital
31/07/2019	DP3 pump head	Medical Device	Product Defect Correction	Class I	Hospital
31/07/2019	EXTEM Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
30/07/2019	ADVIA Centaur, ADVIA Centaur XP, ADVIA Centaur XPT - Folate Assay. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
30/07/2019	EZTest H202 Biological Indicators	Medical Device	Recall	Class II	Hospital
30/07/2019	Floor Stands: FS 2-21, FS 2-25 and FS 3-45 with Hi-R NEO 900/A/A NIR	Medical Device	Product Defect Correction	Class II	Hospital
30/07/2019	Macro Textured Breast Implants & Tissue Expanders	Medical Device	Hazard Alert	Class I	Hospital
30/07/2019	MAMMOMAT Revelation VC10 with Biopsy Option	Medical Device	Product Defect Correction	Class II	Hospital
30/07/2019	Norm-O-Temp Hyperthermia System, MICRO-TEMP LT System, Blanketrol II Hyper-Hypothermia System, Blanketrol III Hyper-Hypothermia System and CoolBlue Hyper-Hypothermia System	Medical Device	Product Defect Correction	Class II	Hospital
29/07/2019	ENDONE oxycodone hydrochloride 5mg tablet blister pack	Medicine	Product Defect Correction	Class I	Consumer
29/07/2019	F18-FDG Injection	Medicine	Product Defect Alert	Class II	Hospital
29/07/2019	ICS CHARTR EP 200	Medical Device	Product Defect Correction	Class II	Hospital
29/07/2019	KaVo RONDOflex Powder 27µm 1000g to be used with the KaVo RONDOfLEX plus 360 air abrasion system	Medical Device	Recall	Class II	Retail
26/07/2019	Coombs-Control IgG 1 x 10mL. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
25/07/2019	Biograph mCT and mCT Flow systems running PETsyngo VG70A	Medical Device	Product Defect Correction	Class II	Hospital
25/07/2019	Impix-L Lumbar Spinal Fusion Cages	Medical Device	Recall	Class II	Hospital
25/07/2019	SOMATOM Definition Edge , SOMATOM Definition AS, SOMATOM Definition Flash, with syngo.CT software versions VA48A_SP5	Medical Device	Product Defect Correction	Class II	Hospital
24/07/2019	KARL STORZ C-Mac Video Laryngoscope Blades	Medical Device	Product Defect Correction	Class II	Hospital
24/07/2019	Nasal Alar SpO2 Sensor	Medical Device	Product Defect Correction	Class II	Hospital
24/07/2019	Spectra Optia Apheresis System	Medical Device	Product Defect Correction	Class II	Hospital
23/07/2019	Dimension clinical chemistry system, Ferritin (FERR) Flex Reagent Cartridge. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
23/07/2019	Elecsys Anti-CCP Assay. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
23/07/2019	Ingenuity CT, IQon Spectral CT, iCT, Brilliance 64 CT, Ingenuity TF	Medical Device	Product Defect Correction	Class I	Hospital
23/07/2019	Ortho Vision and Ortho Vision Max Analyser, software versions 5.12.3 and 5.12.4. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class I	Hospital
23/07/2019	Transwarmer Warming Infant Transport Mattress	Medical Device	Product Defect Correction	Class II	Hospital
22/07/2019	DAC Premium and DAC Premium+ (Autoclaves)	Medical Device	Product Defect Correction	Class III	Retail
22/07/2019	F18-FDG Injection (Fludeoxyglucose F18)	Medicine	Product Defect Correction	Class II	Hospital
22/07/2019	iGUIDE 2.2.0 - 2.2.2	Medical Device	Product Defect Correction	Class II	Hospital
22/07/2019	MAJ-1664 - Nurses Control Panel Arm-Long	Medical Device	Product Defect Correction	Class II	Hospital
22/07/2019	Omegapharm Thiopental Sodium Powder for Injection	Medicine	Product Defect Alert	Class III	Hospital
22/07/2019	Panetti ENT endoscopic ear instruments	Medical Device	Product Defect Correction	Class II	Hospital
22/07/2019	Radiometer ABL90FLEX blood gas analyser and Radiometer AQT90FLEX immunoassay analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
19/07/2019	Da Vinci Xi SureForm 60 Stapler Green and Black Reloads	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
18/07/2019	Azurion Interventional Fluoroscopic X-ray system with software version 1.2	Medical Device	Product Defect Correction	Class I	Hospital
18/07/2019	EV1000 clinical platform	Medical Device	Product Defect Correction	Class II	Hospital
18/07/2019	Fluorostar 7900 System	Medical Device	Product Defect Correction	Class II	Hospital
18/07/2019	HEYEX 2 image management components of SPECTRALIS PC Software	Medical Device	Product Defect Correction	Class II	Hospital
18/07/2019	Jointrep Cartilage Thermogel Kit - OLM-JR001	Medical Device	Product Defect Correction	Class III	Hospital
18/07/2019	Monaco version 5.10 or 5.11 using Elekta motorised wedges	Medical Device	Product Defect Correction	Class I	Hospital
18/07/2019	Pulsavac Plus Wound Debridement System	Medical Device	Recall	Class II	Hospital
18/07/2019	QIAsymphony SP instrument (Software 5.0.3). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
17/07/2019	IMMULITE 2000/2000 XPi - Progesterone (PRG). An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
17/07/2019	ImmunoCAP Tryptase Control. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
17/07/2019	Mircoaire SmartRelease system	Medical Device	Product Defect Correction	Class III	Hospital
17/07/2019	MULTIGENT Lithium and Alinity c Lithium Reagents. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
17/07/2019	SYNCHRON Systems Amphetamines (AMPH) Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
15/07/2019	Azurion Interventional Fluoroscopic X-ray System, with software version 1.2	Medical Device	Product Defect Correction	Class II	Hospital
12/07/2019	Calibration Serum Level 3. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
12/07/2019	GETINGE Steam Steriliser	Medical Device	Product Defect Correction	Class II	Hospital
12/07/2019	NEUTROGENA Visibly Clear Light Therapy Acne Mask and Activator	Medical Device	Recall	Class II	Consumer
10/07/2019	Individual GRIPPER Needles and PORT-A-CATH Trays containing GRIPPER Needles	Medical Device	Recall	Class II	Hospital
9/07/2019	Edwards Lifesciences IntraClude Intra-aortic Occlusion Device	Medical Device	Recall	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
9/07/2019	SOMATOM Confidence, SOMATOM Drive, SOMATOM Definition Edge, SOMATOM Definition AS, SOMATOM Definition Flash, SOMATOM Edge Plus, SOMATOM Force with software syngo CT VB10A	Medical Device	Product Defect Correction	Class II	Hospital
9/07/2019	VIP RIA (Vasoactive Intestinal Polypeptide) kits. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
8/07/2019	BD Connecta Plus3 White (3 way stopcock)	Medical Device	Recall	Class II	Hospital
8/07/2019	Morcher Capsular Tension Rings Type 13 Right, Type 13A Right and Type 13B Right	Medical Device	Recall	Class II	Hospital
8/07/2019	Phadia 1000 instrument. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
8/07/2019	TechnegasPlus Generator	Medical Device	Product Defect Correction	Class II	Hospital
5/07/2019	MAC VU360 systems	Medical Device	Product Defect Correction	Class II	Hospital
5/07/2019	Tina-quant Myoglobin Gen. 2 for use on cobas c 311 analysers and cobas c 501/502 modules. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class I	Hospital
4/07/2019	MAGEC System	Medical Device	Hazard Alert	Class II	Hospital
4/07/2019	Mako System SS2U Computer	Medical Device	Product Defect Correction	Class III	Hospital
3/07/2019	ADVIA 120/2120/2120i Diff Timepac Assays. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
2/07/2019	AQUIOS IMMUNO-TROL Low Cells. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
2/07/2019	CT Expres Day Set III	Medical Device	Recall	Class II	Hospital
2/07/2019	DRX-Ascend and Q-Rad System Overhead Tube Crane (OTC) Assembly	Medical Device	Product Defect Correction	Class II	Hospital
2/07/2019	Revolution CT Scanners	Medical Device	Product Defect Correction	Class II	Hospital
2/07/2019	Spectrum Medical Quantum Perfusion Systems	Medical Device	Product Defect Correction	Class II	Hospital
28/06/2019	iGUIDE 2.2	Medical Device	Product Defect Correction	Class II	Hospital
28/06/2019	Stainless Steel Interstitial Needles, 17 Gauge	Medical Device	Recall	Class II	Hospital
27/06/2019	Various Evolutis Femoral Rasps	Medical Device	Recall	Class III	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
24/06/2019	Various GlidePath Standard and Haemodialysis Catheters	Medical Device	Recall	Class II	Hospital
21/06/2019	Alinity ci-series System Control Module. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
21/06/2019	BD MaxZero Needleless Connector and associated Extension Sets	Medical Device	Product Defect Correction	Class II	Hospital
21/06/2019	MID-Tube, Orogastric calibration Tube	Medical Device	Recall	Class II	Hospital
20/06/2019	cobas 6800 System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
20/06/2019	Fluoron F-Octane and F-Decalin (syringe delivery format)	Medical Device	Recall	Class II	Hospital
20/06/2019	Tenor Passive Floor Lift	Medical Device	Product Defect Correction	Class III	Hospital
19/06/2019	BrightView SPECT, BrightView X, BrightView XCT	Medical Device	Product Defect Correction	Class II	Hospital
18/06/2019	ACUSON SC2000 VB20 and VB21 and the eSie Flow software (SW) license	Medical Device	Product Defect Correction	Class III	Hospital
18/06/2019	ARCHITECT Ceruloplasmin Reagent Kit and Alinity c Ceruloplasmin Reagent Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
18/06/2019	DiaClon Rh-Subgroups + K. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
18/06/2019	OVC3 16.17L A3 Refills	Medical Device	Recall	Class III	Hospital
18/06/2019	UX-2000 Fully Automated Integrated Urine Analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
17/06/2019	ACHRAb RIA kits. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
17/06/2019	ALT/GPT, Creatine Kinase and Glucose HK assays. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
17/06/2019	Comprehensive Reverse Shoulder Instrument Case – Total (Outer Case Vault Only)	Medical Device	Recall	Class II	Hospital
14/06/2019	6F Sherpa NX Active Catheters	Medical Device	Recall	Class II	Hospital
14/06/2019	ARTIS zee and AXIOM Artis systems with generator A100	Medical Device	Product Defect Correction	Class II	Hospital
14/06/2019	ZOLL AED PRO Product Family	Medical Device	Product Defect Correction	Class I	Hospital
12/06/2019	Artis zee and Artis Q systems	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
12/06/2019	Assayed Bovine Multi-Sera - Level 1. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
12/06/2019	SterilAmp SA/6 Certificate of Analysis	Medical Device	Product Defect Correction	Class III	Hospital
12/06/2019	SYNCHRON Systems Phosphorus Reagent (PHOSm). An in-vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
11/06/2019	BD Microtainer Tubes. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
7/06/2019	Senographe Pristina with Serena Systems	Medical Device	Product Defect Correction	Class II	Hospital
7/06/2019	Spectra Optia Apheresis System	Medical Device	Product Defect Correction	Class II	Hospital
5/06/2019	BD Alaris Pump Model 8100 Infusion Sets and Alaris Infusion Sets	Medical Device	Recall	Class I	Hospital
5/06/2019	Philips Incisive Computed Tomography X-Ray System	Medical Device	Product Defect Correction	Class II	Hospital
5/06/2019	Rifton Tram and E -Pacer - Standard and Low Leg	Medical Device	Product Defect Correction	Class II	Retail
5/06/2019	Sheridan Endotracheal Tubes and Connectors, 15mm	Medical Device	Product Defect Alert	Class II	Hospital
4/06/2019	Elecsys Syphilis 200 tests. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
4/06/2019	Filter-Tips, 1500 µl (1024) used with QIASymphony SP/AS Instruments. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
3/06/2019	ECG Trunk Cables and Leadwires	Medical Device	Product Defect Correction	Class I	Hospital
31/05/2019	Alinity i BNP Calibrators and Controls. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
31/05/2019	ARCHITECT BNP Calibrators and Controls. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
31/05/2019	Sensation Plus 7.5Fr 40cc Intra-Aortic Balloon Catheter with Accessories Kits	Medical Device	Recall	Class II	Hospital
31/05/2019	SenTech Membrane Changer and Insert	Medical Device	Recall	Class III	Retail
31/05/2019	UniCel DxH 800/600/900 Coulter Cellular Analysis System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class I	Hospital
30/05/2019	Codan Extension Set	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
30/05/2019	HeartStart MRx Defibrillator/Monitor	Medical Device	Product Defect Correction	Class I	Retail
29/05/2019	Human Assayed Control Level 2. An in vitro diagnostic medical advice (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
29/05/2019	HyLED Surgical Light Series 7, 8 and 9	Medical Device	Product Defect Correction	Class II	Hospital
29/05/2019	J623 Power Wheel Chairs ("Jazzy 623") fitted with Dynamic Controls Shark Power Module	Medical Device	Product Defect Correction	Class II	Consumer
28/05/2019	Alinity ci-series System Control Module. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
28/05/2019	Diluent Tubing on the CELL-DYN Emerald Analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
28/05/2019	Multiple ARCHITECT Assays. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
28/05/2019	Various Adjustable Crutches	Medical Device	Recall	Class III	Retail
24/05/2019	Covidien Endo GIA Articulating Reloads with Tri-Staple Technology	Medical Device	Recall	Class II	Hospital
24/05/2019	Multiple Alinity c Assays. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
23/05/2019	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
22/05/2019	CEM-530 Specular Microscope	Medical Device	Product Defect Correction	Class II	Hospital
22/05/2019	Tilt & Recline Shower Commode: Aspire, 46cm and 53cm	Medical Device	Product Defect Correction	Class II	Consumer
22/05/2019	twinSys impactor with offset	Medical Device	Recall	Class II	Hospital
21/05/2019	Alaris System Pump module (LVP) 8100	Medical Device	Product Defect Correction	Class I	Hospital
21/05/2019	Draeger Patient Monitors; Delta/Delta XL/Kappa	Medical Device	Product Defect Correction	Class III	Hospital
21/05/2019	LVivo EF app on Vscan Extend	Medical Device	Product Defect Correction	Class II	Hospital
21/05/2019	MAGNETOM Vida and Sola with syngo MR XA11 software	Medical Device	Product Defect Correction	Class II	Hospital
21/05/2019	Radiometer ABL800 series analysers. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
20/05/2019	3M Steri-Strip Elastic Skin Closures, E4540	Medical Device	Product Defect Correction	Class III	Retail
20/05/2019	Curam Duo 400/57mg Powder For Oral Suspension, (amoxicillin/clavulanic acid) 60mL	Medicine	Recall	Class II	Consumer

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20/05/2019	Philips Incisive Computed Tomography X-Ray System	Medical Device	Product Defect Correction	Class III	Hospital
17/05/2019	GETINGE WD15 Claro – Washer Disinfector	Medical Device	Product Defect Correction	Class II	Hospital
17/05/2019	GMK UNI Femur sizes 3 & 4 - non anatomic version	Medical Device	Hazard Alert	Class II	Hospital
17/05/2019	Horizon Cardiology Hemo and McKesson Cardiology Hemo	Medical Device	Product Defect Correction	Class I	Hospital
17/05/2019	Wombat Living size 3	Medical Device	Product Defect Correction	Class II	Retail
16/05/2019	DEFIGARD Touch 7	Medical Device	Product Defect Correction	Class I	Hospital
16/05/2019	iQ Control/Focus Set. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
16/05/2019	Medicina ENFit NGP and Ryles Nasogastric Feeding Tubes	Medical Device	Product Defect Correction	Class II	Hospital
16/05/2019	Orbera Intragastric Balloon System and BIB Intragastric Balloon System	Medical Device	Product Defect Correction	Class I	Retail
16/05/2019	Philips IntelliVue Information Center iX / Patient Information Center iX IntelliBridge System	Medical Device	Product Defect Correction	Class III	Hospital
16/05/2019	Portico Solo Re-Collapsible Access System	Medical Device	Recall	Class I	Hospital
16/05/2019	Power Express Sample Processing System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
16/05/2019	Various Gastric Tubes and Catheters	Medical Device	Recall	Class I	Hospital
16/05/2019	Various oral complementary medicines containing Fallopia multiflora from Global Therapeutics	Medicine	Recall	Class I	Consumer
16/05/2019	Various Schiller Defibrillation Electrodes	Medical Device	Recall	Class I	Consumer
13/05/2019	BD PhaSeal C61 Secondary Set	Medical Device	Recall	Class I	Hospital
13/05/2019	BVI Ophthalmic Instrument Wipes and Wicks	Medical Device	Recall	Class III	Hospital
13/05/2019	Creatine Kinase on the ADVIA Chemistry Platform. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
13/05/2019	Creatine Kinase on the Atellica Chemistry Platform. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
13/05/2019	O-ARM 1000 Imaging System	Medical Device	Product Defect Correction	Class II	Hospital
10/05/2019	BILT3 and LACT2 assays for use on the Cobas Integra 400 plus analyser. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class III	Hospital

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9/05/2019	Achilles EXPIL Systems with power cords	Medical Device	Product Defect Correction	Class II	Hospital
8/05/2019	All Philips EPIQ & Affiniti Ultrasound Systems with software version 4.0	Medical Device	Product Defect Correction	Class I	Hospital
8/05/2019	ARCHITECT c Systems Mixer. An in vitro medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
8/05/2019	Medtronic HeartWare Monitor AC Adapter	Medical Device	Product Defect Correction	Class II	Hospital
6/05/2019	Atellica UAS 800 Analyser. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class III	Hospital
6/05/2019	Immunohaematology control - IH-QC1. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class I	Hospital
6/05/2019	LymphoTrack Dx PGM s/w v2.4.4 or older supplied with Product # IV91210057 & LymphoTrack Dx IGH FR1/2/3 Assay – PGM. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
6/05/2019	MAHURKAR acute catheters	Medical Device	Product Defect Correction	Class I	Hospital
6/05/2019	Matrx Digital MDM Mixer	Medical Device	Product Defect Correction	Class II	Retail
6/05/2019	Prismaflex Sets	Medical Device	Product Defect Alert	Class II	Hospital
6/05/2019	SureTyper Software v6.0.0 - STTPGRX. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
3/05/2019	IntelPACS software versions 4.11.1 and later	Medical Device	Product Defect Correction	Class III	Hospital
3/05/2019	MitraClip XTR Clip Delivery System	Medical Device	Product Defect Correction	Class I	Hospital
3/05/2019	Philips SureSigns VS3/VS4 Monitors	Medical Device	Product Defect Correction	Class I	Retail
3/05/2019	Prismaflex Devices with software version 8.10	Medical Device	Product Defect Correction	Class II	Hospital
2/05/2019	2.7 Degree Angled Sagittal Saw attachment and 2.7 Degree Straight Sagittal Saw attachment	Medical Device	Recall	Class II	Hospital
2/05/2019	IMMAGE Immunochemistry Systems Immunoglobulin M (IGM) Reagent. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
2/05/2019	IntroFlex Introducers	Medical Device	Recall	Class II	Hospital
2/05/2019	Solero Microwave Tissue Ablation (MTA) System, Generator and Applicators	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
2/05/2019	Xenform Soft Tissue Repair Matrix and Pinnacle LITE Pelvic Floor Repair Kit, Posterior	Medical Device	Recall	Class I	Hospital
1/05/2019	EnCor Breast Biopsy Probes	Medical Device	Product Defect Correction	Class II	Hospital
1/05/2019	VOLISTA light head	Medical Device	Product Defect Correction	Class II	Hospital
30/04/2019	Access Free T3, Access Total T3, Access Free T4, Access GI Monitor (GI Mon), Access Thyroglobulin (Tg), Access Thyroglobulin Antibody II (TgAbII). An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
30/04/2019	Alere NT-proBNP. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
30/04/2019	Monoject Standard Hypodermic Needle, 14 G x 1-1/2	Medical Device	Recall	Class II	Hospital
30/04/2019	SOMATOM go. systems with s/w version VA20A, VA20A_SP0 or VA20A_SP1 to VA20A_SP2	Medical Device	Product Defect Correction	Class II	Hospital
30/04/2019	Sysmex SP-50 slidemaker-stainer. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
30/04/2019	Zenith Alpha Abdominal Endovascular Graft	Medical Device	Recall	Class I	Hospital
26/04/2019	Alvarado Knee Holder Base Plate Assembly and Foot Piece & Alvarado II Base Plate and Foot Piece	Medical Device	Recall	Class II	Hospital
26/04/2019	Kwart Retro-Inject Stent Sets and Salle Intraoperative Pyeloplasty Stent Sets	Medical Device	Product Defect Correction	Class III	Hospital
26/04/2019	Technetium-99m Cardiolite	Medicine	Recall	Class II	Hospital
26/04/2019	Weleda Baby Teething Powder 60g	Medicine	Recall	Class I	Consumer
24/04/2019	3M Reston Self-Adhering Foam Pads	Medical Device	Product Defect Correction	Class II	Hospital
24/04/2019	Alinity c Cuvette Segment. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
24/04/2019	Biograph Vision 600 and Biograph Vision 600 Edge (with VG75A or B software and the PATLAK reconstruction license)	Medical Device	Product Defect Correction	Class II	Hospital
24/04/2019	Thermistor for Cooling Unit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
18/04/2019	ACDA Anticoagulant Solution	Medical Device	Recall	Class II	Hospital
18/04/2019	Carestream OnSight 3D Extremity System	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
18/04/2019	Diode Fibers used with Dornier Standard Diode and Nd:YAG Lightguides	Medical Device	Recall	Class II	Hospital
18/04/2019	Liaison XL and Liaison XL LAS with POM Stirrer Bar M. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
18/04/2019	Medwarm neonate and Medwarm neonate with Skin temp port and probe	Medical Device	Recall	Class I	Hospital
18/04/2019	Philips Intellivue MX40 Patient Worn Monitors	Medical Device	Product Defect Correction	Class I	Hospital
18/04/2019	VITEK MS Preparation Station software. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
17/04/2019	LimiTorr Volume Limiting External CSF Drainage and Monitoring Systems	Medical Device	Product Defect Correction	Class II	Hospital
17/04/2019	Various Foot and Ankle Instruments (Drill / Tap and Countersink)	Medical Device	Recall	Class II	Hospital
16/04/2019	Various ARTIS zee and ARTIS Q/Q.zen systems	Medical Device	Product Defect Correction	Class II	Hospital
15/04/2019	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
15/04/2019	RÜSCH Lasertube	Medical Device	Recall	Class II	Hospital
15/04/2019	Swan-Ganz Thermodilution Catheter Double Lumen	Medical Device	Product Defect Correction	Class II	Hospital
12/04/2019	T7 Cannulated Driver AO and T7 Driver Solid AO	Medical Device	Recall	Class II	Hospital
11/04/2019	Alinity i Processing Module. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
11/04/2019	Chromophare F 528/F 628 Surgical Lights	Medical Device	Product Defect Correction	Class II	Hospital
11/04/2019	Covidien Emprint Percutaneous Antennas with Thermosphere Technology	Medical Device	Product Defect Correction	Class I	Hospital
11/04/2019	CyberKnife M6 and CyberKnife VSI Secondary Collimation Subsystem with software version 11.x	Medical Device	Product Defect Correction	Class II	Hospital
11/04/2019	Mercury Advance V1 Control Unit	Medical Device	Recall	Class II	Hospital
11/04/2019	MobileDiagnost wDR	Medical Device	Product Defect Correction	Class II	Hospital
11/04/2019	OXOID MICE Strip MA0122 – Ceftriaxone32. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
11/04/2019	TactiSys Quartz Equipment operating on Software Version 1.7.0	Medical Device	Product Defect Correction	Class II	Hospital
10/04/2019	Pericardiocentesis Catheter Set	Medical Device	Recall	Class II	Hospital
9/04/2019	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
9/04/2019	Microbore Y-Type Extension Set and Catheter Extension Set with Clearlink - Male Luer Lock Adapter	Medical Device	Recall	Class II	Hospital
9/04/2019	Mobile OR-Table MEERA	Medical Device	Product Defect Correction	Class I	Hospital
8/04/2019	Auriga 30 Laser System	Medical Device	Product Defect Correction	Class II	Hospital
8/04/2019	CSZ Haemotherm 400CE System	Medical Device	Recall	Class I	Hospital
5/04/2019	HeartMate 3 LVAD implant	Medical Device	Recall	Class II	Hospital
5/04/2019	Visiwipe Instrument Wipe 73 x 73mm	Medical Device	Recall	Class III	Hospital
5/04/2019	Wolf 445nm	Medical Device	Product Defect Correction	Class II	Hospital
4/04/2019	Alinity hq Analyser. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
4/04/2019	Cios Spin	Medical Device	Product Defect Correction	Class II	Hospital
4/04/2019	Philips Access CT Systems	Medical Device	Product Defect Correction	Class III	Hospital
4/04/2019	RealTime HBV Control Kit and RealTime CMV Control Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
4/04/2019	Single-patient use drills for NobelReplace (Tapered Drills, Dense Bone Drills, Screw Taps), Guided Start Drills/Counterbores and Guided Counterbores for NobelReplace, Implant Retrieval Instruments and Abutment Screw Retrieval Instruments	Medical Device	Recall	Class II	Retail
3/04/2019	Custom Tubing Sets	Medical Device	Recall	Class I	Hospital
3/04/2019	Drager Infinity Acute Care System (IACS) and Infinity M540 Stand Alone Patient Monitor	Medical Device	Product Defect Correction	Class II	Hospital
3/04/2019	G-6-PDH Deficient and Normal Control. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class I	Hospital
3/04/2019	Lypocheck Specialty Immunoassay Control. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital

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3/04/2019	VariFit Sterile Single Use Adult Thigh Cuffs, Single Port, Single Bladder	Medical Device	Recall	Class II	Hospital
2/04/2019	Atellica CH 930 Analyser. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class III	Hospital
2/04/2019	Dräger Disposable VentStar Helix Dual Heated Breathing Circuit	Medical Device	Product Defect Correction	Class I	Hospital
2/04/2019	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
2/04/2019	FilmArray - Blood Culture Identification (BCID) Panel used with bioMérieux BACT/ALERT Blood Culture Bottles. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
2/04/2019	Intraluminal Staplers (ILS)	Medical Device	Product Defect Correction	Class I	Hospital
2/04/2019	MAJ-209 Suction Valve	Medical Device	Product Defect Correction	Class II	Hospital
1/04/2019	Aisys Anaesthesia Devices	Medical Device	Product Defect Correction	Class I	Hospital
1/04/2019	Hamilton C6 Ventilators	Medical Device	Product Defect Correction	Class II	Hospital
29/03/2019	Heater-Cooler 3T, 230V	Medical Device	Product Defect Correction	Class II	Hospital
29/03/2019	Mylanta Antacid Double Strength 500 mL oral liquid bottle	Medicine	Product Defect Correction	Class III	Consumer
29/03/2019	RT Elements Radiation Treatment Planning Software	Medical Device	Product Defect Correction	Class I	Hospital
29/03/2019	VITROS XT 7600 Integrated System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class I	Hospital
27/03/2019	cobas p 701 post-analytical units. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
27/03/2019	TM55 Stress Testing Treadmills	Medical Device	Product Defect Correction	Class II	Hospital
26/03/2019	Drill Mini-Trephination 2.0mm	Medical Device	Recall	Class II	Hospital
26/03/2019	Freedom EVOlyzer 2 150/8. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
26/03/2019	Miller and Fogarty Atriostomy Catheters	Medical Device	Recall	Class I	Hospital
25/03/2019	Dang Gui Yin Zi (Tangkuei & Tribulus combination)	Medicine	Recall	Class II	Consumer
25/03/2019	syngo.CT Cardiac Function and syngo.CT Cardiac Planning	Medical Device	Product Defect Correction	Class II	Hospital
22/03/2019	Cios Alpha VA20 Systems	Medical Device	Product Defect Correction	Class II	Hospital

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22/03/2019	Connection Lead SP (12V) for Infusomat Space, Infusomat Space P and Perfusor Space	Medical Device	Recall	Class II	Hospital
22/03/2019	Femoral Head, living donor - bone, morselised, frozen, irradiated	Biological	Hazard Alert	Class II	Hospital
21/03/2019	ProCell II M for use on cobas e 801 analytical unit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class I	Hospital
20/03/2019	da Vinci Xi / X Erbe Footswitch	Medical Device	Product Defect Correction	Class III	Hospital
20/03/2019	Femoral head, living donor - bone, morsellised, frozen, irradiated	Biological	Hazard Alert	Class II	Hospital
20/03/2019	Leica Biosystems Cryostat Devices. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
20/03/2019	Shui An and Yang Xue Sheng Fa Capsules	Medicine	Recall	Class II	Consumer
19/03/2019	Arthrem capsules	Medicine	Product Defect Correction	Class II	Retail
19/03/2019	F-18 FDG Injection (Fludeoxyglucose F18)	Medicine	Product Defect Correction	Class III	Hospital
19/03/2019	Giraffe Bedded Warmers and Panda iRes Warmers	Medical Device	Product Defect Correction	Class I	Hospital
19/03/2019	IMAGEnet 6 Ophthalmic Data System	Medical Device	Product Defect Correction	Class II	Retail
19/03/2019	Polished Finned 1 Piece Tibial Tray 71mm	Medical Device	Hazard Alert	Class II	Hospital
18/03/2019	A610 DBS Clinician Programmer Application	Medical Device	Product Defect Correction	Class II	Hospital
18/03/2019	Albumin BCP. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class I	Hospital
18/03/2019	Glycerol Trinitrate 300mcg Tablets 100, Martindale UK	Medicine	Recall	Class II	Retail
18/03/2019	Stephanix D2RS System	Medical Device	Product Defect Correction	Class II	Hospital
18/03/2019	VAMP Optima Blood Sampling System	Medical Device	Recall	Class II	Hospital
15/03/2019	Complementary Medicines Containing Fallopia Multiflora - Herbal International	Medicine	Recall	Class II	Consumer
15/03/2019	Mobility Plus Wheelchairs - Malte, Malte-Outdoor and Marcy	Medical Device	Product Defect Correction	Class II	Consumer
14/03/2019	ALBAClone Anti-Leb. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
14/03/2019	Alinity ci-series Software version 2.5.1. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
14/03/2019	Atellica Solution Products. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
14/03/2019	Canon XR System DRAD-3000E/W8, Radrex with Wireless FPD	Medical Device	Product Defect Correction	Class II	Hospital
14/03/2019	Infinity Acute Care System (IACS) and Infinity M540 Stand Alone Monitor	Medical Device	Product Defect Correction	Class I	Hospital
13/03/2019	enFlow Fluid Warming System	Medical Device	Recall	Class I	Hospital
13/03/2019	VICRYL Absorbable Suture	Medical Device	Recall	Class II	Hospital
12/03/2019	Lafomed Premium B Class Autoclaves	Medical Device	Product Defect Correction	Class III	Retail
12/03/2019	MultiDiagnost-Eleva, OmniDiagnost-Eleva and OmniDiagnost-Classic	Medical Device	Product Defect Correction	Class II	Hospital
12/03/2019	Speedlock Knotless Fixation Implants	Medical Device	Product Defect Correction	Class III	Hospital
8/03/2019	GlideScope Go Video Laryngoscopy System	Medical Device	Product Defect Correction	Class III	Hospital
7/03/2019	FilmArray Gastrointestinal (GI) Panel. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
7/03/2019	Genex Putty 5cc	Medical Device	Recall	Class II	Hospital
7/03/2019	Hamilton G5/S1 Ventilators	Medical Device	Product Defect Correction	Class I	Hospital
7/03/2019	Radiometer TCM5 FLEX/ BASIC Transcutaneous Monitor	Medical Device	Recall	Class I	Hospital
7/03/2019	TrueBeam Radiotherapy System with Visual Coaching Device or EDGE or VitalBeam	Medical Device	Product Defect Correction	Class II	Hospital
6/03/2019	Alinity hq Analyser and Alinity hs Slide Maker Stainer Module. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
6/03/2019	Arjo SARA 3000, Tenor and Minstrel Patient Lifts	Medical Device	Product Defect Correction	Class III	Hospital
6/03/2019	ChromID CPS/Horse Blood Agar. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
5/03/2019	Alinity c and Alinity i Analysers. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
5/03/2019	MultiDiagnost-Eleva with Flat Detector and Allura Xper	Medical Device	Product Defect Correction	Class II	Hospital
5/03/2019	Smartstitch PerfectPasser Connector	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
4/03/2019	ImmunoCAP ISAC sIgE 112. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
4/03/2019	Pulmonary Vein Ablation Catheter GOLD (PVAC GOLD)	Medical Device	Product Defect Correction	Class I	Hospital
4/03/2019	StentBoost Release 4.0, 4.1 and 4.2	Medical Device	Product Defect Correction	Class III	Hospital
1/03/2019	3.4mm Certain BellaTek Abutment, ILDAT3	Medical Device	Recall	Class II	Retail
1/03/2019	BD Phoenix AST Indicator and BD Phoenix AP AST-S Indicator Bag. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
1/03/2019	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
1/03/2019	StealthStation Cranial and Synergy Cranial Software	Medical Device	Product Defect Correction	Class II	Hospital
28/02/2019	ARIA Radiation Therapy Management	Medical Device	Product Defect Correction	Class II	Hospital
28/02/2019	Dialysis start/stop set - FMC Dialysis Fistula Pack #61	Medical Device	Recall	Class II	Hospital
28/02/2019	Edge Radiosurgery System or TrueBeam and VitalBeam Radiotherapy Systems	Medical Device	Product Defect Correction	Class III	Hospital
28/02/2019	neoBLUE blanket LED Phototherapy Systems	Medical Device	Product Defect Correction	Class II	Hospital
28/02/2019	Spine & Trauma 3D Navigation System 1.0	Medical Device	Product Defect Correction	Class II	Hospital
28/02/2019	VariSeed 9.0 or Vitesse 3.0	Medical Device	Product Defect Correction	Class II	Hospital
28/02/2019	Velocity Advanced Imaging [AI], Velocity Advanced Imaging Solutions [AIS] or VelocityGRID	Medical Device	Product Defect Correction	Class II	Hospital
28/02/2019	Velocity Advanced Imaging [AI], Velocity Advanced Imaging Solutions [AIS] or VelocityGRID	Medical Device	Product Defect Correction	Class II	Hospital
27/02/2019	Arjo Sara Plus Lift	Medical Device	Product Defect Correction	Class III	Hospital
27/02/2019	Bivona Inner Cannula Tracheostomy Tube	Medical Device	Product Defect Correction	Class II	Hospital
27/02/2019	THERA-Trainer balo / THERA-Trainer verto	Medical Device	Product Defect Correction	Class II	Hospital
26/02/2019	CELL-DYN Emerald Analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
26/02/2019	GENTECH Molybdenum(99Mo)/Technetium(99mTc) sterile Generator for production of Sodium pertechnetate (99mTc) injection multidose vial	Medicine	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
26/02/2019	Inferior Vena Cava (IVC) Filter Sets	Medical Device	Product Defect Correction	Class III	Hospital
26/02/2019	Medtronic Model 37751 Recharger, in Charging Systems used with implantable neurostimulators	Medical Device	Product Defect Correction	Class I	Hospital
22/02/2019	18Gx1-1/2IN TW Precision Glide Needles	Medical Device	Recall	Class III	Hospital
21/02/2019	Ardo Sterile Tulips Nipple Shields, Medium and Large	Medical Device	Recall	Class II	Hospital
21/02/2019	Maquet Cardiopulmonary Pre-Bypass Filters used for Customised Tubing Packs	Medical Device	Product Defect Correction	Class II	Hospital
20/02/2019	Dräger BabyLeo TN500 Incuwarmer	Medical Device	Product Defect Correction	Class III	Hospital
20/02/2019	Exactamix Empty EVA Bags	Medical Device	Recall	Class I	Hospital
19/02/2019	Citracal Plus D	Medicine	Recall	Class III	Retail
19/02/2019	Duodenovideoscope TJF-160VR	Medical Device	Product Defect Correction	Class II	Hospital
19/02/2019	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
19/02/2019	Multiple SOMATOM CT Scanners - syngo CT VB10A with Option Dual Spiral Dual Energy	Medical Device	Product Defect Correction	Class II	Hospital
19/02/2019	Obturator, short cone 7" and long cone 10"	Medical Device	Recall	Class II	Hospital
19/02/2019	Terumo Needles	Medical Device	Recall	Class II	Hospital
15/02/2019	Access Thyroglobulin Antibody II (TgAbII) Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
15/02/2019	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
14/02/2019	Bard Lifestream Balloon Expandable Vascular Covered Stent	Medical Device	Product Defect Correction	Class I	Hospital
14/02/2019	Laryseal Flexi Laryngeal Mask sizes 2 and 4	Medical Device	Recall	Class II	Hospital
14/02/2019	Mobile X-Ray System MobileDaRt Evolution Handle (MX8 Version)	Medical Device	Product Defect Correction	Class II	Hospital
13/02/2019	Alinity hq Analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
13/02/2019	BonAlive Putty MIS 5cc	Medical Device	Product Defect Correction	Class III	Hospital
13/02/2019	Volcano Philips s5i/CORE/Core Mobile systems with software v2.5 FFR/IFR	Medical Device	Product Defect Correction	Class II	Hospital
13/02/2019	Xia 3 Degen Tray and French Bender instrument	Medical Device	Product Defect Correction	Class II	Hospital

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12/02/2019	Cordis Vista Brite Tip & ADROIT Guiding Catheters	Medical Device	Recall	Class II	Hospital
12/02/2019	JURNISTA hydromorphone hydrochloride 8 mg prolonged release 14 tablet blister pack	Medicine	Product Defect Correction	Class II	Consumer
12/02/2019	Uroskop Omnia / Uroskop Omnia Max	Medical Device	Product Defect Correction	Class II	Hospital
11/02/2019	CL2 Femoral Stem, Standard Offset, Collarless, Taper 12/14 - Size 8	Medical Device	Product Defect Correction	Class III	Hospital
11/02/2019	Panda iRes Warmer with ResusView Heart Rate Feature	Medical Device	Product Defect Correction	Class II	Hospital
11/02/2019	Radimetrics CDM Software	Medical Device	Product Defect Correction	Class II	Hospital
8/02/2019	ARCHITECT and Alinity i Estradiol Reagent Kits. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
8/02/2019	Certegra Workstation 1.0, software version 4.5	Medical Device	Product Defect Correction	Class II	Hospital
8/02/2019	LIFEPAK 15 Monitor/Defibrillator & LIFEPAK 15 Monitor/Defibrillator Repair Service Kit	Medical Device	Product Defect Correction	Class I	Retail
8/02/2019	Sample Probe Cover for Aptio by Siemens, Aptio by Inpeco and FlexLab Automation Interfaces connected to ADVIA Chemistry XPT. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
8/02/2019	Various Immunoassay Controls used with Siemens Immulite 2000. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
6/02/2019	ARIA OIS for Radiation Oncology version 15.5 MR1	Medical Device	Product Defect Correction	Class II	Hospital
6/02/2019	Eclipse Treatment Planning System	Medical Device	Product Defect Correction	Class III	Hospital
4/02/2019	ACUSON NX2 / NX2 Elite and ACUSON NX3 / NX3 Elite systems	Medical Device	Product Defect Correction	Class II	Hospital
4/02/2019	Coarse Milled Bone, Femoral Head	Biological	Hazard Alert	Class II	Hospital
4/02/2019	NARDIL phenelzine 15mg (as sulfate) tablet bottle	Medicine	Recall	Class II	Wholesale
4/02/2019	Percuvance Percutaneous Shaft 29cm	Medical Device	Recall	Class II	Hospital
1/02/2019	Edwards Commander Delivery System	Medical Device	Product Defect Correction	Class II	Hospital
1/02/2019	SISS BABYCONTROL Respiration monitors	Medical Device	Product Defect Correction	Class II	Hospital

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1/02/2019	TrueBeam RadioTherapy Delivery System	Medical Device	Product Defect Correction	Class III	Hospital
1/02/2019	VariSource HDR and GammaMed	Medical Device	Product Defect Correction	Class II	Hospital
31/01/2019	Medical Grade Carbon Dioxide Cylinders, C Size	Medicine	Product Defect Correction	Class III	Hospital
31/01/2019	NutriVital Premium Magnesium Complete 100 Tablets	Medicine	Recall	Class II	Retail
31/01/2019	OVC3 (One Visit Crown) 24/25 L A2	Medical Device	Recall	Class III	Retail
31/01/2019	OVC3 Hybrid Molar refill A3 - 36.37 L	Medical Device	Recall	Class III	Retail
30/01/2019	AXIUS Blower / Mister	Medical Device	Recall	Class II	Hospital
30/01/2019	BioPlex 2200 ANA Screen Control Set. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
30/01/2019	OVC (One Visit Crown) Starter Kit Package containing OVC3 16/17s A3 refills	Medical Device	Recall	Class III	Hospital
30/01/2019	Perifix Catheter Connector	Medical Device	Product Defect Correction	Class II	Hospital
30/01/2019	STA – VWF:RCo reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
30/01/2019	UltraTemp Regular Kit and UltraTemp Rez Fast Set Kit	Medical Device	Product Defect Correction	Class II	Retail
29/01/2019	5x75mm Kii Fios Advanced Fixation Access System	Medical Device	Recall	Class II	Hospital
29/01/2019	MYXAZOLE clotrimazole 10 mg/g and hydrocortisone acetate 11.2 mg/g cream tube	Medicine	Recall	Class III	Retail
29/01/2019	Sonosite L25 Needle Guide Bracket	Medical Device	Recall	Class II	Hospital
24/01/2019	EMPOVIR cidofovir 375 mg/5 mL concentrated injection for infusion vial	Medicine	Recall	Class II	Wholesale
24/01/2019	Ingenuity CT Core 128	Medical Device	Product Defect Correction	Class III	Hospital
24/01/2019	Philips PageWriter TC Cardiographs (TC20/30/50/70)	Medical Device	Product Defect Correction	Class II	Hospital
22/01/2019	OA/RA	Medicine	Recall	Class II	Consumer
22/01/2019	Philips Efficia CM Monitors	Medical Device	Product Defect Correction	Class II	Retail
21/01/2019	Burr Oval 12 Flute 5.5mm x 13cm	Medical Device	Recall	Class II	Hospital
21/01/2019	Da Vinci S/SI Harmonic Ace Curved Shear Insert	Medical Device	Recall	Class II	Hospital

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21/01/2019	Otto Bock PUSH VALVE/MAG VALVE	Medical Device	Recall	Class II	Hospital
21/01/2019	Swan-Ganz Thermodilution Catheter	Medical Device	Recall	Class II	Hospital
18/01/2019	Edwards Lifesciences IntraClude Intra-aortic Occlusion Device	Medical Device	Product Defect Alert	Class II	Hospital
18/01/2019	Electronic Thermometer supplied in Tiny Tots First Aid Kits	Medical Device	Recall	Class I	Consumer
18/01/2019	NutriVital Premium Glucosamine 1500 Plus	Medicine	Recall	Class II	Retail
18/01/2019	VITEK 2 - Card Pouch Integrity. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
16/01/2019	Adapta Dual Chamber Pacemakers	Medical Device	Recall	Class I	Hospital
15/01/2019	ARIA Oncology Information System for Radiation Oncology, versions 15.1, 15.5 & 15.6	Medical Device	Product Defect Correction	Class II	Hospital
15/01/2019	Baha Tamper-proof Battery Door, 3pcs	Medical Device	Recall	Class I	Retail
14/01/2019	Disposable Cranial Perforator and Disposable Scalp Clips	Medical Device	Product Defect Correction	Class III	Hospital
14/01/2019	Programmer Software Update Supporting the Micra Transcatheter Pacing System	Medical Device	Product Defect Correction	Class II	Hospital
14/01/2019	XN-10 automated haematology analysers. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class III	Hospital
11/01/2019	Acusnare Polypectomy (Duck Bill Shaped) Snare	Medical Device	Recall	Class II	Hospital
11/01/2019	Tritanium PL cages	Medical Device	Product Defect Correction	Class II	Hospital
11/01/2019	UNIVERSA Soft & Firm Ureteral Stent Sets, PTFE Wire Guide, Percutaneous Entry Set & Bander Ureteral Diversion Open-End Stent Set	Medical Device	Recall	Class II	Hospital
11/01/2019	Xper Flex Cardio Patient Monitoring System	Medical Device	Product Defect Correction	Class II	Hospital
10/01/2019	RX Misano Analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
10/01/2019	Various Suction Catheters, Gastro-enteral Tubes, Intermittent Urology Catheters, Drainage Kits and sterile Urine Drainage Bags	Medical Device	Recall	Class II	Hospital
9/01/2019	Eclipse Treatment Planning System	Medical Device	Product Defect Correction	Class II	Hospital
8/01/2019	Max VPC Tray Base & Max VPC Screw Caddy Brackets	Medical Device	Product Defect Correction	Class II	Hospital

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7/01/2019	Fabian HFO, Fabian +nCPAP evolution and Fabian Therapy evolution	Medical Device	Product Defect Correction	Class II	Hospital
7/01/2019	Fabian Therapy and Fabian +nCPAP evolution	Medical Device	Product Defect Correction	Class II	Hospital
7/01/2019	Ingenuity TF PET/CT running software version 4.0.2 (4.0.0.26645)	Medical Device	Product Defect Correction	Class II	Hospital
7/01/2019	Sandoz Irbesartan 150mg film-coated tablets Blister pack 30's	Medicine	Recall	Class II	Retail
4/01/2019	FDGEN fludeoxyglucose [18F] 200MBq/mL to 6000 MBq/mL injection vial	Medicine	Product Defect Correction	Class III	Hospital
4/01/2019	FDGEN fludeoxyglucose [18F] 200MBq/mL to 6000 MBq/mL injection vial	Medicine	Product Defect Correction	Class II	Hospital
3/01/2019	Various Philips MR Systems	Medical Device	Product Defect Correction	Class II	Hospital
2/01/2019	Alinity i Processing Module. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
2/01/2019	Dräger Disposable Breathing Circuit	Medical Device	Product Defect Correction	Class I	Hospital
2/01/2019	EliA ANA Positive Control 250 and EliA ANA Positive Control 2500/5000. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
2/01/2019	Leica M525 F20 Microscope System	Medical Device	Product Defect Correction	Class II	Hospital
2/01/2019	Panocell-16 Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
2/01/2019	Revision femoral neck H60mm lateralised + Screw	Medical Device	Hazard Alert	Class II	Hospital
31/12/2018	Integra MAYFIELD Skull Clamps	Medical Device	Product Defect Correction	Class II	Hospital
24/12/2018	Various Swan-Ganz Catheters	Medical Device	Recall	Class III	Hospital
21/12/2018	BILT3, IGM-2, and LACT2 Assays. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
21/12/2018	Bronchi-cough pill (Qiguanyan Kousu Tanchuanwan)	Medicine	Recall	Class II	Consumer
21/12/2018	COBAS INTEGRA 400 plus analyser. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
21/12/2018	Interactive Precision IO Scan Adapters (3.00mmD and 3.40mmD Platforms)	Medical Device	Recall	Class III	Retail
20/12/2018	ARCHITECT B12 Reagent Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital

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20/12/2018	ARCHITECT Rubella IgM Reagent Kit. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
20/12/2018	Autostainer Slide Racks. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
20/12/2018	GETINGE XS32 Flat Screen Holder	Medical Device	Product Defect Correction	Class II	Hospital
20/12/2018	IV Pole Collar for Spectra Optia Apheresis System	Medical Device	Product Defect Correction	Class III	Hospital
20/12/2018	Trima Accel Automated Blood Collection System	Medical Device	Product Defect Correction	Class III	Hospital
20/12/2018	Xyrem (sodium oxybate) 500 mg/mL oral solution	Medicine	Product Defect Alert	Class II	Retail
18/12/2018	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
18/12/2018	GE Carescape One Monitor with an ECG USB Patient Cable or SPO2 Masimo USB Patient Cable	Medical Device	Product Defect Correction	Class II	Hospital
18/12/2018	Mako Onlay Insert Extractor	Medical Device	Recall	Class II	Hospital
18/12/2018	StealthAir Percutaneous Pin Adapter	Medical Device	Recall	Class II	Hospital
17/12/2018	Amica Generator, dual ablation system (hybrid microwave and radio frequency)	Medical Device	Recall	Class II	Hospital
17/12/2018	APO-Valsartan 40/80/160/320mg products	Medicine	Recall	Class II	Consumer
17/12/2018	Bayer Overhead Counterpoise mounting system	Medical Device	Product Defect Correction	Class II	Hospital
17/12/2018	Dimension Vista Intelligent Lab Systems using a Progard Pretreatment Pack on the onboard Millipore Water Purification Module (WPM). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
17/12/2018	Fructosamine Calibrator, Fructosamine Control 1 and Control 3. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class III	Hospital
17/12/2018	MOSAIQ Radiation Oncology version	Medical Device	Product Defect Correction	Class II	Hospital
17/12/2018	Sandoz IRBESARTAN/HCT batches	Medicine	Recall	Class II	Retail
14/12/2018	ADVIA Centaur aTG. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
14/12/2018	Atellica IM Anti-Thyroglobulin. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
14/12/2018	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital

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14/12/2018	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
14/12/2018	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
14/12/2018	Power-LOAD (Cot Fastener)	Medical Device	Product Defect Correction	Class II	Hospital
14/12/2018	Various Olympus Grasping Forceps and Biopsy Forceps	Medical Device	Product Defect Correction	Class II	Hospital
13/12/2018	Platinum ICDs and CRT-Ds Devices	Medical Device	Product Defect Correction	Class I	Hospital
13/12/2018	Stryker Visum II LED Surgical Lighting system - EDS (Equipment Delivery System) Light Suspensions, Central Axis	Medical Device	Product Defect Correction	Class II	Hospital
12/12/2018	Anatomic Tibial Base Plate for fixed bearing insert cemented, Size 4	Medical Device	Hazard Alert	Class II	Hospital
12/12/2018	Mako Vizadiscs and Vizadisc Hip Tracking Kit	Medical Device	Recall	Class II	Hospital
12/12/2018	MILRINONE-CLARIS milrinone (as lactate) 10 mg/10 mL concentrated injection ampoule	Medicine	Recall	Class III	Hospital
12/12/2018	PP2001 HBA Agar Plates. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
12/12/2018	Tropisetron MYX 2mg/mL solution for injection or infusion ampoules	Medicine	Recall	Class II	Wholesale
12/12/2018	UniCel Dxl 600 & 800 Access Immunoassay Systems & UniCel DxC 660i, 680i, 860i, 880i Synchron Access Clinical Systems. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
11/12/2018	Biograph Horizon	Medical Device	Product Defect Correction	Class II	Hospital
11/12/2018	PROXIMATE Haemorrhoidal Circular Stapler	Medical Device	Recall	Class II	Hospital
11/12/2018	Various Signa OpenSpeed, Infinity, Profile Ovation, Brivo, Optima, Creator and Explorer MIR System software	Medical Device	Product Defect Correction	Class II	Hospital
10/12/2018	Celsite Safety SST601F 6.5F SI - Access Ports	Medical Device	Recall	Class II	Hospital
10/12/2018	RayOne Trifocal RAO603F + 10.5 D ADD 3.5 Intraocular Lens	Medical Device	Recall	Class II	Hospital
10/12/2018	Steelco DS1000 washers	Medical Device	Product Defect Correction	Class II	Hospital
7/12/2018	CORAIL Female Broaches (Size 9-20)	Medical Device	Hazard Alert	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
7/12/2018	Discovery NM 530c and Ventri Nuclear Medicine system using Premium (automatic) table and with MS Windows Operating System	Medical Device	Product Defect Correction	Class II	Hospital
7/12/2018	SHOEBOX Audiometry Standard and Pro V5.1.	Medical Device	Product Defect Correction	Class III	Retail
6/12/2018	MOSAIQ Radiation Oncology version 2.64 SP9 and higher using Varian True BEAM or Varian 4D or Siemens RTT	Medical Device	Product Defect Correction	Class II	Hospital
5/12/2018	BD Burette Sets	Medical Device	Recall	Class II	Hospital
5/12/2018	Bililed Maxi+ Phototherapy Unit	Medical Device	Product Defect Correction	Class II	Hospital
4/12/2018	CARESCAPE B850 Monitors; Version MBC303	Medical Device	Product Defect Correction	Class II	Hospital
4/12/2018	HeartMate 3 Left Ventricular Assist System and Outflow Graft Clip	Medical Device	Hazard Alert	Class I	Hospital
4/12/2018	MAS Alcohol/Ammonia Control. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
3/12/2018	Cisbio - Chromogranin A (CGA-ELISA). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
3/12/2018	Digital Angiography System Trinias	Medical Device	Product Defect Correction	Class II	Hospital
3/12/2018	Forceps, Coupler – GEM4183C	Medical Device	Recall	Class II	Hospital
3/12/2018	Heater-Cooler Unit HCU 40 - Flow Sensor Malfunction	Medical Device	Product Defect Correction	Class I	Hospital
3/12/2018	TRAJENTA linagliptin 5 mg film-coated tablet blister pack	Medicine	Recall	Class III	Wholesale
28/11/2018	Alinity i Estradiol Reagent Kit & Alinity i STAT High Sensitive Troponin. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
28/11/2018	ARTIS biplane systems from specific production batch	Medical Device	Product Defect Correction	Class II	Hospital
28/11/2018	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
28/11/2018	I-View Contrast Enhanced Digital Mammography, ASY-08109	Medical Device	Product Defect Correction	Class II	Hospital
28/11/2018	O-arm 1000 Imaging System 2nd Edition - software versions 3.1.6 and earlier	Medical Device	Product Defect Correction	Class II	Hospital
28/11/2018	Sonata ti100	Medical Device	Hazard Alert	Class II	Hospital
28/11/2018	Syngo.plaza version VB30A_HF01 and previous software versions	Medical Device	Product Defect Correction	Class II	Hospital

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26/11/2018	Balloon Guide Catheters 9F	Medical Device	Recall	Class II	Hospital
26/11/2018	da Vinci Xi Surgical System Arm Sensor	Medical Device	Product Defect Correction	Class II	Hospital
23/11/2018	Medicina CG Nasogastric Tubes	Medical Device	Product Defect Correction	Class II	Hospital
23/11/2018	Medtronic HeartWare HVAD System Battery Charger	Medical Device	Product Defect Correction	Class I	Hospital
23/11/2018	Raindrop Corneal Inlay	Medical Device	Hazard Alert	Class II	Retail
22/11/2018	DILART valsartan film-coated tablet blister pack; and DILART HCT valsartan and hydrochlorothiazide film-coated tablet blister pack	Medicine	Recall	Class II	Consumer
22/11/2018	Dräger Jaundice Meter	Medical Device	Product Defect Correction	Class II	Hospital
21/11/2018	Covidien Emprint Percutaneous Antennas with Thermosphere Technology	Medical Device	Recall	Class I	Hospital
21/11/2018	Philips IntelliVue MX40	Medical Device	Product Defect Correction	Class III	Hospital
21/11/2018	Suction/Anticoagulation Assembly Lines	Medical Device	Recall	Class I	Hospital
21/11/2018	UFII Control Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
19/11/2018	Evidence Investigator software. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Retail
16/11/2018	DuraDiagnost R4 - DuraDiagnost X-ray System	Medical Device	Product Defect Correction	Class III	Hospital
16/11/2018	Foetal Scalp Blood Sampling Kit and Foetal Scalp Blood Sampling Wands	Medical Device	Product Defect Correction	Class I	Hospital
16/11/2018	IMRIS ORT100 and ORT300 Operating Room Tables	Medical Device	Product Defect Correction	Class II	Hospital
16/11/2018	PneumoClear Humidification Refill Icon Discrepancy	Medical Device	Product Defect Correction	Class II	Hospital
16/11/2018	RayStation 3.5, 4.0, 4.5, 4.7, 5, 6, 7 and 8A	Medical Device	Product Defect Correction	Class II	Hospital
15/11/2018	Brilliance CT Systems	Medical Device	Product Defect Correction	Class II	Retail
15/11/2018	CWP 800 (Central Water Plant) Systems and Clinic Panels	Medical Device	Product Defect Correction	Class III	Hospital
14/11/2018	BoneScalpel and SonaStar FS1000 Ultrasonic Surgical Systems	Medical Device	Product Defect Correction	Class II	Hospital
14/11/2018	CombiDiagnost systems with software version 1.0.0, 1.0.1 and 1.0.2	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
14/11/2018	PneumoClear Heated High-Flow Tube Set	Medical Device	Recall	Class II	Hospital
14/11/2018	Revolution CT Systems with SmartStep Option	Medical Device	Product Defect Correction	Class II	Hospital
14/11/2018	STACLOT LA (REF. 00600). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
13/11/2018	A-dec Dental Chair A-dec 311 (version A)	Medical Device	Product Defect Correction	Class III	Retail
13/11/2018	Dräger Fabius Anaesthesia Machines	Medical Device	Product Defect Correction	Class I	Hospital
13/11/2018	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
13/11/2018	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
13/11/2018	Maintenance Solution Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
13/11/2018	RX Daytona Plus. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
12/11/2018	Various Trauma Guide Wires	Medical Device	Recall	Class II	Hospital
9/11/2018	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
9/11/2018	FG107 Intravitreal Procedure Pack #1 and FG110 Intravitreal Procedure Pack #2A	Medical Device	Recall	Class II	Hospital
8/11/2018	Compress Devices and Instruments	Medical Device	Product Defect Correction	Class II	Hospital
8/11/2018	Da Vinci Si Drape and Disposable Accessory Kits	Medical Device	Recall	Class II	Hospital
8/11/2018	Eurotrol_HemoTrol Normal (Level 2) and Eurotrol_HemoTrol High (Level 3). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
8/11/2018	Philips HeartStart MRx M3538A Batteries	Medical Device	Product Defect Correction	Class I	Hospital
8/11/2018	Suboxone Film 2/0.5 buprenorphine (as hydrochloride) 2mg / naloxone (as hydrochloride dihydrate) 0.5mg soluble film sachet	Medicine	Product Defect Alert	Class II	Retail
7/11/2018	Ipsogen BCR-ABL kits. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
6/11/2018	Cetirizine 10mg tablet blister packs	Medicine	Recall	Class III	Retail
5/11/2018	FoodPrint Microarray 200+ Food IgG. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
5/11/2018	HEA Precise Type Beadchip Kit and RHD Beadchip Kit, CE. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
5/11/2018	Kodak DirectView DR 7500 System	Medical Device	Product Defect Correction	Class II	Hospital
5/11/2018	Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) systems with SQ-RX Model 1010 Pulse Generator (PG)	Medical Device	Hazard Alert	Class I	Hospital
1/11/2018	4-Way Stopcock w/MLL, Adapter DBL Male and Female LL	Medical Device	Recall	Class II	Hospital
1/11/2018	ARTIS zee Systems with x-ray tube cooling units	Medical Device	Product Defect Correction	Class II	Hospital
1/11/2018	DELFA Xpress Sample and Calibrator Racks. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
31/10/2018	Aisys anaesthesia devices	Medical Device	Product Defect Correction	Class II	Hospital
30/10/2018	BD MAX System with BD MAX Reader. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
29/10/2018	GC Fuji BULK	Medical Device	Product Defect Correction	Class III	Hospital
26/10/2018	Parietex Composite Parastomal Mesh 15cm and 20cm	Medical Device	Hazard Alert	Class II	Hospital
26/10/2018	Plex Elite 9000	Medical Device	Product Defect Correction	Class II	Retail
25/10/2018	Access hsTnI Reagent. An in-vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
25/10/2018	LoFric 40cm CH12 Nelaton Catheter	Medical Device	Product Defect Correction	Class III	Consumer
25/10/2018	VITEK 2 AST-ST01 and AST-ST03 Cards used with the VITEK 2 Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Retail
24/10/2018	Heater-Cooler 3T, 230V	Medical Device	Product Defect Correction	Class I	Hospital
23/10/2018	Corneal Allograft (right and left)	Biological	Hazard Alert	Class I	Hospital
23/10/2018	Dimension Vista Intelligent Lab Systems with Software v.3.7 or v.3.8.1. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
23/10/2018	Dimension Vista System utilising Lactate Dehydrogenase (LDI) Flex reagent cartridge. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
23/10/2018	St Jude Medical Infinity DBS (Deep Brain Stimulation) System for the 8-Channel Lead, 0.5mm spacing	Medical Device	Hazard Alert	Class II	Hospital
22/10/2018	Alaris GH and CC Syringe Pump	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
22/10/2018	Iridex TruFocus LIO Premiere Laser Indirect Ophthalmoscope	Medical Device	Product Defect Correction	Class II	Hospital
22/10/2018	Multiple products containing Natural Rubber Latex	Medical Device	Recall for Product Correction	Class II	Hospital
22/10/2018	ZEISS Laser Based Systems Cell Observer SD, DirectFRAP, Laser TIRF. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
19/10/2018	CARESCAPE R860 Inspiratory Safety Guard	Medical Device	Product Defect Correction	Class II	Hospital
19/10/2018	HeartStart FR3 Automated External Defibrillators	Medical Device	Recall	Class I	Hospital
19/10/2018	RHD BeadChip Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
18/10/2018	CyberKnife M6 Treatment Delivery System	Medical Device	Product Defect Correction	Class II	Hospital
17/10/2018	iChemVELOCITY Urine Chemistry strips - An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
17/10/2018	NUCLISENS Lysis Buffer. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
17/10/2018	RX Monaco. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Retail
16/10/2018	Alinity i Free T3 and Alinity i Total T3 Reagent Kits. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
16/10/2018	ARCHITECT Free T3 and ARCHITECT Total T3 Reagent Kits. An In vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
16/10/2018	Biograph mMR with software version syngo E11P when using BodyCOMPASS	Medical Device	Product Defect Correction	Class II	Hospital
16/10/2018	Giraffe OmniBed	Medical Device	Product Defect Correction	Class II	Hospital
16/10/2018	H3 Poly Inlay	Medical Device	Recall	Class II	Hospital
16/10/2018	Neurofolin (L-methylfolate Calcium), 15mg powder, 30 sachets	Medicine	Product Defect Alert	Class III	Retail
16/10/2018	Reverse T3 RIA. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
15/10/2018	Evidence Analyser Operator Manual (EV3584) - An in vitro diagnostic medical device.	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
12/10/2018	Lifeshield Primary Plum Set 15 Micron Filter in Sight Chamber, CLAVE Secondary Port, 0.2 Micron Filter, CLAVE Y-Site, Polyethylene Lined Tubing, Secure Lock 272cm / 23mL	Medical Device	Recall	Class II	Hospital
12/10/2018	Radiometer AQT90FLEX Immunoassay analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
12/10/2018	StrataMR Adjustment Tool Kit	Medical Device	Product Defect Correction	Class I	Hospital
12/10/2018	TEXAS Bronchoscope Tube	Medical Device	Recall	Class II	Hospital
12/10/2018	TITAN 3-D Wedge, Evans, Large, 10mm	Medical Device	Recall	Class II	Wholesale
11/10/2018	Codan Filter used with Medrad Patient Administration Sets (PAS) and Intego PET Infusion Systems	Medical Device	Recall	Class II	Hospital
11/10/2018	Elecsys FT4III assay. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
11/10/2018	Evo Excel ECG Power Outlet	Medical Device	Product Defect Correction	Class II	Hospital
10/10/2018	Medtronic MiniMed 640G Insulin Pumps with version 4.10 software	Medical Device	Product Defect Correction	Class II	Consumer
9/10/2018	All Dash 3000/4000/5000, Solar 8000M/i and Solar 9500 patient monitors	Medical Device	Product Defect Correction	Class I	Hospital
9/10/2018	CareLink 2090 and CareLink Encore 29901/29901A Programmers	Medical Device	Product Defect Correction	Class I	Hospital
9/10/2018	Multiple components of the DORO Lucent Headrest System	Medical Device	Recall	Class III	Hospital
9/10/2018	RAPIDPoint 500 Blood Gas Systems. An in-vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
8/10/2018	ARCHITECT HAVAb-IgM, HAVAb IgG Reagent and Alinity i HAVAb IgG. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
8/10/2018	Atellica IM 1300 and 1600 Analyser, Atellica CH 930 Analyser and Atellica Sample Handler Prime. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
8/10/2018	BD Nexiva Closed IV catheter Dual port 18GA 1.25 IN	Medical Device	Recall	Class II	Hospital
8/10/2018	ColoVantage Home-Faecal Immunochemical Test Kits. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Alert	Class II	Retail

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8/10/2018	DigitalDiagnost Systems with system software versions 4.1.x and 4.2.x	Medical Device	Product Defect Correction	Class II	Hospital
8/10/2018	EA 1490-1208-1G Dermatology Profile ELISA. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
8/10/2018	Various Giraffe and Panda OmniBed Carestations, Incubator Carestations and Warmers	Medical Device	Product Defect Correction	Class II	Hospital
5/10/2018	Pruitt F3-S Polyurethane Outlying Carotid Shunt	Medical Device	Recall	Class II	Hospital
4/10/2018	Biograph mCT and Biograph Horizon Systems	Medical Device	Product Defect Correction	Class II	Hospital
4/10/2018	Dimension Integrated Chemistry Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
4/10/2018	Exactamix Empty EVA Bags	Medical Device	Recall	Class I	Hospital
4/10/2018	RayStation and RayPlan	Medical Device	Product Defect Correction	Class II	Hospital
4/10/2018	Therakos Cellex Photopheresis System	Medical Device	Product Defect Correction	Class II	Hospital
4/10/2018	YUKON OCT Spinal System Polyaxial Screw Size 3.5 x 34mm	Medical Device	Hazard Alert	Class II	Hospital
3/10/2018	Buddy Disposable Sets	Medical Device	Recall	Class II	Hospital
3/10/2018	CUSA Excel (Excel+) Ultrasonic Surgical Aspirator System	Medical Device	Product Defect Correction	Class II	Hospital
3/10/2018	Femoral Head	Biological	Hazard Alert	Class III	Hospital
3/10/2018	Orthofix Drill Bits - Tin Coated - Quick Connect	Medical Device	Recall	Class II	Hospital
2/10/2018	CARDIOSAVE Hybrid IABP Intra-Aortic Balloon Pump	Medical Device	Product Defect Correction	Class II	Hospital
2/10/2018	LOGIQ E10 ultrasound systems (when used with TEE probes)	Medical Device	Product Defect Correction	Class II	Hospital
2/10/2018	Puritan Bennett 980 (PB980) Ventilator Series	Medical Device	Product Defect Correction	Class II	Hospital
28/09/2018	Femoral Head Whole, Frozen, Irradiated - L	Biological	Hazard Alert	Class II	Hospital
28/09/2018	Robosac Espiner Medical Tissue Retrieval System	Medical Device	Recall	Class II	Hospital
27/09/2018	O-arm O2 Imaging Systems	Medical Device	Product Defect Correction	Class II	Hospital
26/09/2018	25GA Vitrectomy Cutter	Medical Device	Recall	Class II	Hospital
26/09/2018	All B20/B20i/B40/B40i, and B105/B125 patient monitors	Medical Device	Product Defect Correction	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
26/09/2018	CoaguChek PT Test Systems. An in-vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
26/09/2018	HydroSet Injectable HA Bone Substitute 10cc	Medical Device	Recall	Class III	Hospital
26/09/2018	Liquid Cardiac Controls - Troponin T. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
25/09/2018	Cooper Surgical Retractor System Elastic Stays	Medical Device	Recall	Class II	Hospital
25/09/2018	X-Short anti-tip tubes on certain TiLite manual wheelchairs	Medical Device	Product Defect Correction	Class II	Consumer
24/09/2018	AFX/AFX2 Endovascular AAA System	Medical Device	Product Defect Correction	Class I	Hospital
24/09/2018	Cornea (right and left) - corneal allograft	Biological	Hazard Alert	Class II	Hospital
24/09/2018	GenesisBiosystems/LipiVage, Syringe & Cannula	Medical Device	Recall	Class II	Hospital
20/09/2018	Alinity i Processing Module. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
20/09/2018	SoKINOX NO Delivery and Monitoring System	Medical Device	Product Defect Correction	Class II	Hospital
19/09/2018	Aptio Automation System by Inpeco (Aptio2). An in-vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
18/09/2018	Altrix Precision Temperature Management System	Medical Device	Product Defect Correction	Class II	Hospital
18/09/2018	Millennium MG, Millennium MC and Millennium MYOSIGHT	Medical Device	Product Defect Correction	Class I	Hospital
18/09/2018	NET Homeopathic Remedies	Medicine	Recall	Class II	Consumer
17/09/2018	Arjo Citadel Plus Bed Frame with Powerdrive	Medical Device	Product Defect Correction	Class II	Hospital
17/09/2018	Dimension Vista Lipase (LIPL). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
17/09/2018	Intravenous Cannula Insertion Pack	Medical Device	Recall	Class II	Hospital
13/09/2018	ACCELERATOR a3600. An in-vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class I	Hospital
13/09/2018	ADVIA Chemistry Creatine Kinase (CK_L) System Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
13/09/2018	Biomet 360 Tibial Augment With Bolts	Medical Device	Hazard Alert	Class III	Hospital

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13/09/2018	BOND Slide Labeller Zebra Printer Power Supply Unit (PSU) for use with BOND-III and BOND-MAX instruments. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
13/09/2018	Dimension Lipase (LIPL) Flex reagent cartridges. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
13/09/2018	Samsung Digital X-Ray System	Medical Device	Product Defect Correction	Class II	Hospital
13/09/2018	VITROS 5600 Integrated System and VITROS 5600 Refurbished Integrated System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
12/09/2018	AK 98 – Excessive UltraFiltration (UF) in Low-Weight Patients	Medical Device	Product Defect Correction	Class II	Hospital
12/09/2018	Medsurge Calcitriol 1mcg/mL 15mL Oral Solution	Medicine	Recall	Class II	Hospital
11/09/2018	4020 - FSCA - FilmArray Blood Culture Identification - BCID Panel - An in vitro diagnostic medical device (IVD),	Medical Device	Product Defect Correction	Class II	Hospital
10/09/2018	Soluscope AER Sprint	Medical Device	Product Defect Correction	Class II	Hospital
7/09/2018	Femoral Head Allograft	Biological	Hazard Alert	Class I	Hospital
6/09/2018	ARCHITECT ICT Module. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
5/09/2018	Alere Triage NT-pro BNP Test. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
5/09/2018	Calibration Film used with the Ball-Cube II phantom - CyberKnife Treatment Delivery System	Medical Device	Recall	Class II	Hospital
5/09/2018	CentriMag Acute Circulatory Support System Motor	Medical Device	Product Defect Correction	Class II	Hospital
5/09/2018	VIROTROL HIV-1 Ag. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
4/09/2018	Various Ventana Antibody and Detection Kit Reagents. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
3/09/2018	Alere NT-proBNP for ARCHITECT Controls. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
3/09/2018	Medtronic HeartWare HVAD Controller	Medical Device	Product Defect Alert	Class I	Hospital
3/09/2018	MEDUMAT Transport Ventilator	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
31/08/2018	D-100 Haemoglobin Testing System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
31/08/2018	OVC3 36S A2 Refills	Medical Device	Recall	Class III	Retail
31/08/2018	Philips HeartStart M5072A Infant/Child SMART Pads Cartridge	Medical Device	Product Defect Alert	Class III	Retail
31/08/2018	VITEK 2 System for AST An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
30/08/2018	CyPass Micro-Stent	Medical Device	Hazard Alert	Class II	Hospital
30/08/2018	Enzymatic Creatinine, HDL Cholesterol, Lipase, Uric Acid. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
30/08/2018	Selenium Cell Defence Hard shell capsules	Medicine	Recall	Class II	Retail
30/08/2018	Tremoflo C100 Airwave Oscillometry System	Medical Device	Product Defect Correction	Class III	Hospital
30/08/2018	TrueBeam, TrueBeam STx, VitalBeam and EDGE treatment delivery systems, v2.0 and 2.5 [<2.5MR2]	Medical Device	Product Defect Correction	Class II	Hospital
28/08/2018	Jelco ViaValve safety I.V. catheter	Medical Device	Recall	Class II	Hospital
28/08/2018	Pastorex Meningitis - reagent R4 (Streptococcus pneumoniae latex - green cap bottle). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
27/08/2018	Femoral Head Allograft	Biological	Hazard Alert	Class I	Hospital
27/08/2018	Hoffmann Limb Reconstruction Frame (LRF) System Hexapod Struts	Medical Device	Recall	Class II	Hospital
23/08/2018	Purely White Skin Brightening Day Cream SPF30	Medicine	Recall	Class III	Retail
23/08/2018	SICKLEDEX 50-test and 12-test variants. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
22/08/2018	Aptio Automation and StreamLAB Automation. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class I	Hospital
22/08/2018	M300 PS, C300 PS, C350 PS, C500 PS, (PS Seating only)	Medical Device	Product Defect Correction	Class II	Consumer
20/08/2018	AlignRT Plus/OSMS system	Medical Device	Product Defect Correction	Class II	Hospital
20/08/2018	Broach Handles for rasp used in orthopaedic surgery	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
20/08/2018	CLOPINE Suspension Clozapine 50mg/mL	Medicine	Recall	Class II	Retail
20/08/2018	Hematek Wright-Giemsa Stain and Modified Wright's Stain Paks / ADVIA Autoslide Wright-Giemsa Stain and Modified Wright's Stain. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
20/08/2018	MultipleVERASENSE ZBH-PSNCRxxxx-x devices.	Medical Device	Recall	Class III	Hospital
20/08/2018	Ysio and Ysio MAX with Tube stand 3D V	Medical Device	Product Defect Correction	Class II	Hospital
17/08/2018	Alinity ci-series System Control Module (SCM) software version 2.5.0. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
17/08/2018	Capnostream 20 and Capnostream 20p Bedside Patient Monitors	Medical Device	Product Defect Correction	Class II	Hospital
17/08/2018	Cerner Dosage Calculator used via PowerOrders or Pharmacy Medication Manager	Medical Device	Product Defect Correction	Class II	Hospital
17/08/2018	DX-D 600 Digital Radiography Systems	Medical Device	Product Defect Correction	Class II	Hospital
17/08/2018	Enterprise Imaging for Radiology	Medical Device	Product Defect Correction	Class II	Hospital
17/08/2018	Organ Care System (OCS) Heart system - OCS Heart Console	Medical Device	Product Defect Correction	Class II	Hospital
16/08/2018	UniCel DxH 800 and UniCel DxH 600 Coulter Cellular Analysis Systems. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class I	Hospital
16/08/2018	Xpert Xpress Flu/RSV assay. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
15/08/2018	Alcon or Endure LuxOR E71 Ophthalmic Microscope	Medical Device	Product Defect Correction	Class II	Hospital
15/08/2018	da Vinci Xi Stapler 45 Blue and Green Reload	Medical Device	Product Defect Correction	Class II	Hospital
15/08/2018	Olympus Bronchofiberscopes, Bronchovideoscopes, Bronchofibervideoscopes, Ultrasonic Bronchofibervideoscopes, Rhinolaryngo Videoscopes and Airway Mobilescopes	Medical Device	Product Defect Correction	Class II	Hospital
14/08/2018	Tools Database v1.288 CD	Medical Device	Product Defect Correction	Class II	Hospital
13/08/2018	Mako Vizadiscs and Vizadisc Hip Tracking Kit	Medical Device	Recall	Class II	Hospital
13/08/2018	Thermablate Endometrial Ablation System (EAS)	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
10/08/2018	Nokia Blood Pressure Monitor Plus (BPM+)	Medical Device	Product Defect Correction	Class II	Consumer
10/08/2018	Short Term Haemodialysis Catheters	Medical Device	Recall	Class II	Hospital
10/08/2018	sterEOS Image Review Workstation	Medical Device	Product Defect Correction	Class III	Hospital
9/08/2018	Deprox System	Medical Device	Product Defect Correction	Class III	Hospital
9/08/2018	Femoral Head	Biological	Hazard Alert	Class II	Hospital
9/08/2018	Matrx Digital MDM Mixer	Medical Device	Product Defect Correction	Class II	Retail
9/08/2018	Spatz3 Adjustable Gastric Balloon System	Medical Device	Product Defect Correction	Class II	Hospital
8/08/2018	ADVIA Centaur CKMB Calibrator Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
8/08/2018	Bard Arctic Sun 5000	Medical Device	Product Defect Correction	Class II	Hospital
8/08/2018	Hoffmann LRF Hexapod Software	Medical Device	Product Defect Correction	Class II	Hospital
8/08/2018	MOSAIQ Medical Oncology version 2.64 SP3 and higher	Medical Device	Product Defect Correction	Class II	Hospital
8/08/2018	Various in vitro fertilisation (IVF) and assisted reproduction technologies (ART) products	Medical Device	Recall	Class II	Retail
7/08/2018	Bone, morsellised, frozen, irradiated - L	Biological	Hazard Alert	Class II	Hospital
3/08/2018	Deltastream Heater-Cooler Unit	Medical Device	Product Defect Correction	Class I	Hospital
2/08/2018	Maquet Heater-Cooler Unit HCU 40	Medical Device	Product Defect Correction	Class I	Hospital
2/08/2018	SureSigns VS & VM Monitors	Medical Device	Product Defect Correction	Class II	Hospital
2/08/2018	Various Allura Xper Systems delivered with an actuator for the FlexVision Monitor Ceiling Suspension between 2003 - May 2011	Medical Device	Product Defect Correction	Class II	Hospital
1/08/2018	ARTIS Q and ARTIS pheno with a specific production lot of Detector Cooling Units	Medical Device	Product Defect Correction	Class II	Hospital
1/08/2018	Dräger Ceiling Supply Unit; AGILA and Movita Lift Pendants	Medical Device	Product Defect Correction	Class II	Hospital
31/07/2018	Alaris Syringe Pumps	Medical Device	Product Defect Correction	Class I	Hospital
31/07/2018	ARCHITECT c4000, c8000, c16000 Processing Modules. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
31/07/2018	ARCHITECT EBV VCA IgM Reagent Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
31/07/2018	Durex Real Feel Non Latex Condoms	Medical Device	Recall	Class II	Consumer
30/07/2018	BIS Vista Monitoring Systems	Medical Device	Product Defect Correction	Class II	Hospital
30/07/2018	V-PRO 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilisation Systems	Medical Device	Product Defect Correction	Class II	Hospital
27/07/2018	4008 Bloodlines	Medical Device	Recall	Class I	Hospital
27/07/2018	Corail AMT Neck Trials Surgical Instruments	Medical Device	Product Defect Correction	Class III	Hospital
27/07/2018	The Binding Site Human IgM kit for use on the SPAPLUS. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
26/07/2018	Carestation 620/650/650c A1, Carestation 620/650/650c A2, Carestation 30 and 9100c NXT Anaesthesia Systems	Medical Device	Product Defect Correction	Class I	Hospital
26/07/2018	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
26/07/2018	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
26/07/2018	MyLab Alpha in combination with probe models IH 6-18 and IL 4-13	Medical Device	Product Defect Correction	Class II	Hospital
26/07/2018	PP2030 Mannitol Salt Agar Plates. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
26/07/2018	RAPIDPoint 405 / 500 Systems and RAPIDLab 1245 / 1265 Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
25/07/2018	O-Two Equinox Relieve and Equinox Advantage Analgesic Gas Delivery Systems	Medical Device	Product Defect Correction	Class II	Hospital
25/07/2018	Various Vascutek Gelatin Sealed Grafts	Medical Device	Product Defect Correction	Class III	Hospital
24/07/2018	ARCHITECT Creatine Kinase. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
24/07/2018	da Vinci Xi and X Surgeon Consoles	Medical Device	Product Defect Correction	Class II	Hospital
20/07/2018	LINEZOLID MYX linezolid 600 mg/300 mL injection infusion bag	Medicine	Recall	Class I	Hospital
20/07/2018	Technetium-99m Makro-Albumon and Technitium-99m Nanoscan	Medicine	Recall	Class I	Retail

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
19/07/2018	IH-Com Fullversion & IH-Com for Reader. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class I	Hospital
17/07/2018	CFX96-IVD Optical Reaction Module. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
16/07/2018	Minicon BS15. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
16/07/2018	Richard Wolf TEM Tube Set	Medical Device	Recall	Class II	Hospital
13/07/2018	Atellica Solution products running on Atellica Solution System Software V 1.13 and lower	Medical Device	Product Defect Correction	Class II	Hospital
12/07/2018	MAYFIELD Infinity XR2 Radiolucent Base Unit	Medical Device	Product Defect Correction	Class II	Hospital
10/07/2018	BACT/ALERT VIRTUO System. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
10/07/2018	NovoPen Echo	Medical Device	Recall	Class II	Consumer
10/07/2018	Pentax Duodenoscope	Medical Device	Product Defect Correction	Class II	Hospital
10/07/2018	RayStation and RayPlan	Medical Device	Product Defect Correction	Class I	Hospital
9/07/2018	Charcot Osteotome Chisels	Medical Device	Recall	Class II	Hospital
9/07/2018	cobas p 612 pre-analytical system (LCP1). An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
9/07/2018	Perifix Catheter Connector	Medical Device	Product Defect Correction	Class II	Hospital
9/07/2018	Platinum Implantable Cardiac Defibrillator (ICD) and Resynchronisation Therapy Defibrillator (CRT-D)	Medical Device	Recall	Class I	Hospital
9/07/2018	Radiometer ABL800 blood gas analysers with software versions 6.14 through to Version 6.18. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
6/07/2018	GETINGE EDS8 (Endoscope Drying and Storage Cabinet) Compressor	Medical Device	Product Defect Correction	Class II	Hospital
6/07/2018	Radiometer ABL800 FLEX series blood gas analysers with Crea module. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
5/07/2018	5008 PAED Therapy System	Medical Device	Product Defect Correction	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
5/07/2018	Percepta CRT-P MRI SureScan (W1TR04) and Percepta Quad CRT-P MRI SureScan (W4TR04)	Medical Device	Hazard Alert	Class I	Hospital
5/07/2018	Premicath Neonatal PICC with Stylet	Medical Device	Product Defect Correction	Class II	Hospital
4/07/2018	Guardian Connect Mobile App	Medical Device	Product Defect Correction	Class II	Consumer
3/07/2018	Nutriline and Nutriline Twinflo Peripherally inserted central catheters (PICC)	Medical Device	Product Defect Correction	Class II	Hospital
3/07/2018	Pulmonary Conduit, Cryopreserved	Biological	Hazard Alert	Class I	Hospital
2/07/2018	10mm 0Deg Infrared Telescope and 10mm 30Deg Infrared Telescope	Medical Device	Product Defect Correction	Class II	Hospital
2/07/2018	Aidacare FL250 Bed, Single and King Single	Medical Device	Product Defect Correction	Class III	Consumer
2/07/2018	EnTrust VR/DR/AT ICDs	Medical Device	Hazard Alert	Class I	Hospital
2/07/2018	Journey BCS Knee System - Femoral Components	Medical Device	Hazard Alert	Class II	Hospital
2/07/2018	Leksell GammaPlan 11.1	Medical Device	Product Defect Correction	Class II	Hospital
2/07/2018	Patient Support (NC989001087431) for X-Ray System	Medical Device	Product Defect Correction	Class II	Retail
29/06/2018	CARDIOSAVE Hybrid IABP Intra-Aortic Balloon Pump	Medical Device	Product Defect Correction	Class I	Hospital
29/06/2018	EZ1 Advanced XL instrument. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
29/06/2018	Femoral Head Allograft - Fine Milled Bone	Biological	Hazard Alert	Class II	Hospital
29/06/2018	VITROS Chemistry Products Na+ Slides. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
27/06/2018	GETINGE WD15 Claro - Washer Disinfector	Medical Device	Product Defect Correction	Class II	Retail
27/06/2018	Natus Medical EEG Machines using Neuroworks v8.5 software	Medical Device	Product Defect Correction	Class II	Hospital
26/06/2018	ARTIS Q, ARTIS pheno systems and X-ray generator	Medical Device	Product Defect Correction	Class II	Hospital
26/06/2018	Chorionic Villus Biopsy Needle Set	Medical Device	Recall	Class III	Retail
25/06/2018	Allura Xper with FlexVision large screen monitor	Medical Device	Product Defect Correction	Class II	Hospital
25/06/2018	PhaSeal Secondary Set (C61)	Medical Device	Recall	Class II	Retail
22/06/2018	Tritanium PL 6mm	Medical Device	Recall	Class III	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
21/06/2018	Zippie Zone Wheelchair	Medical Device	Product Defect Correction	Class II	Consumer
20/06/2018	Allura Xper	Medical Device	Product Defect Correction	Class II	Hospital
20/06/2018	AMBU Ultraseal II Anaesthetic Mask	Medical Device	Recall	Class II	Hospital
20/06/2018	CARESCAPE B450, B650 and B850 Monitors (Bx50)	Medical Device	Product Defect Correction	Class I	Retail
20/06/2018	NxStage Express Fluid Warmer	Medical Device	Product Defect Correction	Class II	Hospital
20/06/2018	Safil Sutures	Medical Device	Recall	Class II	Hospital
20/06/2018	Synapse Cardiovascular (CV) Software	Medical Device	Product Defect Correction	Class II	Hospital
20/06/2018	T34 Ambulatory Syringe Pumps	Medical Device	Product Defect Correction	Class II	Hospital
19/06/2018	Alaris Infusion pump administration sets	Medical Device	Product Defect Correction	Class II	Hospital
19/06/2018	Discovery MR750w	Medical Device	Product Defect Correction	Class II	Hospital
19/06/2018	Earmoulds in use with children under 36 months	Medical Device	Product Defect Correction	Class II	Retail
19/06/2018	Mako RIO System Irrigation Clip (partial knee application only)	Medical Device	Recall	Class II	Hospital
19/06/2018	NeoMed Enteral Feeding Tubes with EO Connectors	Medical Device	Recall	Class II	Hospital
19/06/2018	RayStation and RayPlan	Medical Device	Product Defect Correction	Class II	Hospital
19/06/2018	Symmetry Surgical/Olsen – Single Use Electrocautery Forceps/Pencils/Cords	Medical Device	Product Defect Correction	Class II	Retail
19/06/2018	Visionaire Lightweight Alignment Rod	Medical Device	Recall	Class III	Hospital
18/06/2018	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
18/06/2018	GE Healthcare MRI Systems	Medical Device	Product Defect Correction	Class II	Retail
18/06/2018	In-Line Blood Set with Filter	Medical Device	Recall	Class I	Hospital
18/06/2018	QuikFlap Neuro Implants	Medical Device	Recall	Class II	Hospital
15/06/2018	Dermatome AN	Medical Device	Recall	Class II	Hospital
15/06/2018	qUAntify Control / qUAntify Plus Control. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class III	Hospital
14/06/2018	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
14/06/2018	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
14/06/2018	MobileDiagnost wDR	Medical Device	Product Defect Correction	Class III	Hospital
14/06/2018	MRSASelect II agar. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
8/06/2018	Samsung Digital X-Ray System GC80	Medical Device	Product Defect Correction	Class II	Retail
7/06/2018	FLOSEAL Special Applicator Tips	Medical Device	Recall	Class II	Hospital
7/06/2018	microTargeting Depth Stop Adapter	Medical Device	Recall	Class II	Hospital
6/06/2018	Covidien Endo GIA Articulating Reloads with Tri-Staple Technology	Medical Device	Recall	Class I	Hospital
6/06/2018	Segmental System Proximal Femoral Component 38mm Offset	Medical Device	Hazard Alert	Class II	Hospital
5/06/2018	Biograph, Symbia T and Symbia Intevo SPECT/CT systems	Medical Device	Product Defect Correction	Class II	Retail
5/06/2018	Emergency Room Examination Table	Medical Device	Product Defect Correction	Class II	Retail
5/06/2018	M320 Microscope Systems	Medical Device	Product Defect Correction	Class II	Hospital
5/06/2018	Philips Xper Flex Cardio Patient Monitoring Systems	Medical Device	Product Defect Correction	Class II	Hospital
5/06/2018	StraightShot Microdebrider Blades	Medical Device	Recall	Class II	Hospital
5/06/2018	Valpam 5mg, 50 tablets	Medicine	Product Defect Alert	Class II	Consumer
4/06/2018	DBL METRONIDAZOLE INTRAVENOUS INFUSION metronidazole 500mg/100mL solution for injection bag	Medicine	Recall	Class I	Hospital
1/06/2018	HeartMate 3 Left Ventricular Assist System	Medical Device	Hazard Alert	Class I	Hospital
1/06/2018	HF-Resection Electrode	Medical Device	Product Defect Correction	Class III	Hospital
1/06/2018	N Latex CDT. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
31/05/2018	ARTIS pheno systems	Medical Device	Product Defect Correction	Class II	Hospital
31/05/2018	Endoscan Brush Purple	Medical Device	Recall	Class III	Hospital
31/05/2018	Fortify, Fortify Assura, Quadra Assura, Quadra Assura MP, Unify, Unify Assura, Unify Quadra, Promote Quadra and Ellipse ICD & CRT-D Devices	Medical Device	Hazard Alert	Class II	Hospital
31/05/2018	Randox Liquid Assayed Specific Protein Controls. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital

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31/05/2018	VOLISTA STANOP, TRIPOD, ACCESS and QUICKLOCK Light heads	Medical Device	Product Defect Correction	Class II	Hospital
30/05/2018	EZ1 DSP Virus Kit (48). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
30/05/2018	Infacol Wind Drops Oral Liquid Bottle 30mL	Medicine	Recall	Class III	Retail
29/05/2018	Corneo-scleral Disc	Biological	Recall	Class II	Hospital
29/05/2018	LFIT Anatomic CoCr V40 Femoral Head	Medical Device	Hazard Alert	Class II	Hospital
29/05/2018	MAS chemTRAK – H Level 1 Control. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class III	Hospital
29/05/2018	ZINBRYTA daclizumab 150 mg/mL solution for injection pre-filled pen	Medicine	Recall	Class I	Retail
29/05/2018	ZYTIGA abiraterone acetate 250 mg tablet bottle	Medicine	Recall	Class I	Sponsor
25/05/2018	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
25/05/2018	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
24/05/2018	Conveyor unit (CV-50) of Sysmex XN-9000 automated haematology analysers. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class III	Hospital
24/05/2018	Paratherm Heater Cooler Unit	Medical Device	Product Defect Correction	Class I	Hospital
24/05/2018	Radiometer ABL90 Flex blood gas analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class I	Hospital
23/05/2018	Drager Fabius Anaesthesia Machine - Fabius Tiro	Medical Device	Product Defect Correction	Class II	Hospital
23/05/2018	Various ZNN & M/DN Guide Wires	Medical Device	Recall	Class II	Hospital
23/05/2018	VITROS Chemistry Products PHYT Slides. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
22/05/2018	Akron Tilt Table couches	Medical Device	Product Defect Correction	Class II	Hospital
22/05/2018	HexaPOD evo RT System with HexaPOD evo Module	Medical Device	Product Defect Correction	Class I	Hospital
22/05/2018	Thermo Scientific Remel R30855101 - Salmonella paratyphi A-H Stained Suspension. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
21/05/2018	IntelliVue MX40 with software revisions B.05, B.06 and B.06.5X	Medical Device	Product Defect Correction	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
21/05/2018	Tapered Screw-Vent Implants with 0.5 mm Machined Collar, MTX Surface and Microgrooves	Medical Device	Recall	Class II	Retail
18/05/2018	Arcomed Volumeset Set for Pump Type Volumeset µVP 5005/7000 PVC and Gravity Use	Medical Device	Product Defect Correction	Class II	Hospital
18/05/2018	ARTIS pheno systems	Medical Device	Product Defect Correction	Class II	Hospital
18/05/2018	OmniDiagnost-Eleva and OmniDiagnost-Classic	Medical Device	Product Defect Correction	Class II	Retail
18/05/2018	Powered Wheelchairs	Medical Device	Product Defect Correction	Class III	Consumer
17/05/2018	Askina Gel 15g	Medical Device	Recall	Class II	Hospital
17/05/2018	da Vinci Xi EndoWrist Stapler Release Kit (SRK)	Medical Device	Recall	Class II	Hospital
17/05/2018	Generation 1 Jasper Vektor	Medical Device	Recall	Class III	Retail
17/05/2018	Hydrochloric Acid 6 Molar 30mL Containers. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
17/05/2018	Liquichek Urine Chemistry Control Level 2 and Liquichek Urine Chemistry Control MiniPak (contains Level 2). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
17/05/2018	SAM XT Extremity Tourniquets (SAM XT) - Military (SAM-XT M) and Civilian (SAM-XT-C) Products	Medical Device	Recall	Class II	Retail
16/05/2018	GE Healthcare Revolution EVO & Optima CT Systems	Medical Device	Product Defect Correction	Class I	Retail
16/05/2018	MIA FORA NGS HLA Server and Software versions 3.0 and 3.1. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
16/05/2018	Prismaflex Control Units	Medical Device	Product Defect Correction	Class II	Hospital
16/05/2018	RayStation 6 (RayPlan 2) and RayStation 7 (RayPlan 7)	Medical Device	Product Defect Correction	Class II	Hospital
15/05/2018	HeartWare Ventricular Assist System	Medical Device	Hazard Alert	Class I	Hospital
15/05/2018	Medtronic Clip Gun Magazine, Raney Clip Gun 5pk	Medical Device	Recall	Class I	Hospital
14/05/2018	cobas MPX test. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
14/05/2018	MIA FORA NGS FLEX 11 HLA Typing Kit. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class III	Hospital
14/05/2018	RCI HA ACL Screw	Medical Device	Recall	Class III	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
11/05/2018	Femoral Head	Biological	Hazard Alert	Class II	Hospital
11/05/2018	Femoral Head	Biological	Hazard Alert	Class II	Hospital
9/05/2018	Arterial Cannulae and Customised Tubing Packs including the 3/8" Vent plug 70000.8256	Medical Device	Recall	Class I	Hospital
9/05/2018	Combur10 Test UX when measured on Urisys 1100. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
8/05/2018	ARTIS zee/Q systems with Large Display	Medical Device	Product Defect Correction	Class II	Hospital
7/05/2018	Accu-Chek Inform II Test. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
7/05/2018	HARMONIC ACE + Shears with Adaptive Tissue Technology	Medical Device	Recall	Class I	Hospital
3/05/2018	Covidien Endo GI Articulating Loading Units	Medical Device	Recall	Class I	Hospital
3/05/2018	Dimension and Dimension Vista Gentamicin (GENT) Flex reagent cartridge. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
3/05/2018	O-Two Equinox Relieve and Equinox Advantage Analgesic Gas Delivery Systems	Medical Device	Product Defect Correction	Class II	Hospital
2/05/2018	Arcomed Volumed µVP7000 Infusion Pump	Medical Device	Product Defect Correction	Class II	Hospital
2/05/2018	HeartStart FRx, HeartStart Home, and Heartstart OnSite	Medical Device	Product Defect Correction	Class I	Retail
2/05/2018	Horse Blood Agar. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
2/05/2018	OXOID AST DISC CT0159B – Oxacillin OX1. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
1/05/2018	Corneo-scleral disc	Biological	Recall	Class II	Hospital
1/05/2018	Dräger Carina Ventilator	Medical Device	Product Defect Correction	Class I	Hospital
1/05/2018	SOMATOM go.Up and SOMATOM go.Now	Medical Device	Product Defect Correction	Class II	Retail
1/05/2018	Vivid and LOGIQ Ultrasound Systems	Medical Device	Product Defect Correction	Class II	Retail
30/04/2018	The ARROWg+ard Blue PLUS antimicrobial catheter	Medical Device	Recall	Class II	Hospital
27/04/2018	CLARUS 500 with Software versions: 1.0.0, 1.0.1 and 1.0.2	Medical Device	Product Defect Correction	Class II	Retail
27/04/2018	Taylor Spatial Frame Identification Band Kit	Medical Device	Recall	Class III	Hospital
27/04/2018	Visera Elite II Video System	Medical Device	Product Defect Correction	Class III	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
26/04/2018	Nitinol Staples	Medical Device	Recall	Class II	Wholesale
24/04/2018	DiaClon ABO/D+ Reverse Grouping for Patients. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class III	Hospital
24/04/2018	Dräger Jaundice Meters	Medical Device	Product Defect Correction	Class II	Hospital
24/04/2018	Halyard Closed Suction Kits with Flex Connector	Medical Device	Product Defect Alert	Class I	Hospital
24/04/2018	Medicina Nasogastric Tubes	Medical Device	Product Defect Correction	Class II	Hospital
24/04/2018	OrthoScan Mini C-Arm X-Ray Systems	Medical Device	Product Defect Correction	Class II	Hospital
24/04/2018	Portex Thoracic Catheter and Connecting Tube	Medical Device	Recall	Class II	Hospital
23/04/2018	Aequalis Humeral Nail Drill Bit	Medical Device	Recall	Class II	Wholesale
23/04/2018	Alere Afinion ACR Control. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
23/04/2018	FUJIFILM General X-ray System FDR Smart f series	Medical Device	Product Defect Correction	Class II	Hospital
23/04/2018	MultiDiagnost Eleva and MultiDiagnost Eleva with Flat Detector	Medical Device	Product Defect Correction	Class II	Hospital
23/04/2018	Philips Intera 0.5T/1.0T/ 1.5T, Achieva 1.5T, Multiva 1.5T and Ingenia CX 1.5T	Medical Device	Product Defect Correction	Class I	Hospital
20/04/2018	Covidien EEA Haemorrhoid and Prolapse Stapler Set with DST Series Technology - 3.5mm staple and 4.8mm staple devices	Medical Device	Recall	Class II	Hospital
20/04/2018	ID-Cards for Indirect Antiglobulin Testing associated with Reagent Red Blood Cells. An in vitro diagnostic medical device (IVD).	Medical Device	Product Defect Correction	Class II	Hospital
20/04/2018	Scalpel in Lifemed Procedure Packs	Medical Device	Product Defect Correction	Class II	Hospital
20/04/2018	Trumpf Table Top Spinal System (T3SYSTEM)	Medical Device	Product Defect Correction	Class II	Hospital
19/04/2018	FDGEN fludeoxyglucose [18F] 200MBq/mL to 6000 MBq/mL injection vial	Medicine	Product Defect Correction	Class II	Hospital
19/04/2018	FilmArray Blood Culture Identification (BCID) Panel when used with BD BACTEC Blood Culture Bottles. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
19/04/2018	Instructions For Use (IFU) - Sonopet Ultrasonic Products	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
18/04/2018	Classic Series Reusable Active Cord	Medical Device	Recall	Class II	Hospital
18/04/2018	Sciatic Nerve Retractors	Medical Device	Recall	Class II	Hospital
16/04/2018	Monoclonal Mouse Anti-Human Leukaemia, Hairy Cell Clone DBA.44. An in vitro diagnostic medical device.	Medical Device	Recall	Class II	Hospital
13/04/2018	ADVIA 120/2120/2120i Haematology Systems DIFF TIMEPAC Perox 1 Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
13/04/2018	Corneoscleral Button	Biological	Hazard Alert	Class II	Hospital
13/04/2018	Discovery IGS 730	Medical Device	Product Defect Correction	Class II	Hospital
13/04/2018	Fischer Cone Biopsy Excisor	Medical Device	Recall	Class III	Hospital
13/04/2018	Radiometer TCM5 FLEX/ BASIC Transcutaneous Monitor	Medical Device	Product Defect Correction	Class I	Hospital
13/04/2018	Radiometer TCM5FLEX/BASIC	Medical Device	Product Defect Correction	Class III	Hospital
12/04/2018	IntraClude Intra-aortic Occlusion Device	Medical Device	Product Defect Alert	Class I	Hospital
12/04/2018	Philips Ingenuity Core (728321)	Medical Device	Product Defect Correction	Class II	Hospital
11/04/2018	EliA Intrinsic Factor Well. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
11/04/2018	Pulmonary Conduit, Cryopreserved	Biological	Hazard Alert	Class II	Hospital
10/04/2018	Hudson RCI One-Way Valve with Capped Monitoring Port	Medical Device	Recall	Class I	Hospital
9/04/2018	Power-LOAD (Cot Fastener)	Medical Device	Product Defect Correction	Class II	Hospital
6/04/2018	ADVIA Chemistry Systems - Urea Nitrogen (UN). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
6/04/2018	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
6/04/2018	G5 Mobile Receiver	Medical Device	Recall	Class II	Retail
6/04/2018	Pulmonary Valve, Cryopreserved	Biological	Hazard Alert	Class II	Hospital
5/04/2018	5mm ENDOPATH XCEL Trocars with Optiview Technology	Medical Device	Recall	Class II	Hospital
4/04/2018	Cobas e 801 Analytical Unit. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
4/04/2018	Immucor MATCH IT! DNA Software version 3.29.0 (released 30 Jan 2018) for use with Allele Database used with LIFECODES HLA-B SSO Typing Kits. In vitro diagnostic medical devices.	Medical Device	Product Defect Correction	Class III	Hospital
3/04/2018	Mako Onlay Insert Extractor (part of the Restoris MCK (Multi Compartmental Knee) Unicondylar System)	Medical Device	Recall	Class II	Hospital
3/04/2018	OXOID AST DISC CT1412B – Cefpirome CPO30ug 5x 50 discs. An in vitro diagnostic medical device.	Medical Device	Recall	Class II	Hospital
29/03/2018	F & P SleepStyle CPAP Device	Medical Device	Product Defect Correction	Class III	Retail
29/03/2018	Femoral Head	Biological	Hazard Alert	Class II	Hospital
29/03/2018	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
29/03/2018	Femoral Head Allograft	Biological	Hazard Alert	Class II	Hospital
29/03/2018	Randox Lipase Reagents for use on RX instruments. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
28/03/2018	4008 HD Bloodlines	Medical Device	Product Defect Alert	Class I	Hospital
28/03/2018	RPK-01 Luer Connector	Medical Device	Recall	Class I	Hospital
28/03/2018	Spot Vision Screener 100 with software version up to and including 3.0.01.07	Medical Device	Product Defect Correction	Class II	Hospital
28/03/2018	StoneBreaker Pneumatic Lithotripter and associated accessories	Medical Device	Recall	Class I	Hospital
27/03/2018	Cornea (left and right)	Biological	Hazard Alert	Class II	Hospital
27/03/2018	Dimension Vista CTNI Sample Diluent and Multi 2 Sample Diluent. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
27/03/2018	Femoral Head	Biological	Hazard Alert	Class II	Hospital
27/03/2018	Femoral Head	Biological	Hazard Alert	Class II	Hospital
27/03/2018	Femoral Head	Biological	Hazard Alert	Class II	Hospital
27/03/2018	Femoral Head	Biological	Hazard Alert	Class II	Hospital
27/03/2018	Getinge VOLISTA StandOP and TRIPOD surgical lights	Medical Device	Product Defect Correction	Class II	Hospital
27/03/2018	PTS Panels CHOL+GLU test strips. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
27/03/2018	Pulmonary Conduit Patch	Biological	Hazard Alert	Class II	Hospital
27/03/2018	Sun Specialist SPF40 High Protection Cream	Medicine	Recall	Class III	Retail

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
27/03/2018	Ultrafilter U9000 for use with AK96 and AK98 v1 dialysis machines	Medical Device	Product Defect Correction	Class I	Hospital
26/03/2018	ACUSON SC2000 ultrasound with 5.0 software (VB20A, VB20B, or VB20C) and the ECG (physio) hardware and Auxiliary (AUX IN/OUT) cable	Medical Device	Product Defect Correction	Class II	Hospital
26/03/2018	Cornea (left and right)	Biological	Hazard Alert	Class II	Hospital
26/03/2018	Entroy Pool Lifter	Medical Device	Product Defect Correction	Class II	Retail
26/03/2018	Infinity MCable Mainstream Sensor, Revision 16 only (used with Acute Care System (IACS) Monitoring Solution; and the Infinity M540 Stand-Alone Patient Monitor)	Medical Device	Product Defect Correction	Class II	Hospital
26/03/2018	NAT Testing for ocular, musculoskeletal and skin grafts	Biological	Hazard Alert	Class II	Hospital
22/03/2018	iQ200 Series Urine Microscopy Analysers	Medical Device	Product Defect Correction	Class I	Hospital
22/03/2018	Zoledronic Acid	Medicine	Recall for Product Correction	Class II	Hospital
21/03/2018	Getinge Steriliser	Medical Device	Product Defect Correction	Class II	Hospital
21/03/2018	IH-1000 with software version 04.07.02. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class I	Hospital
21/03/2018	IMRIS ORT100 and ORT300 Operating Room Tables	Medical Device	Product Defect Correction	Class II	Hospital
21/03/2018	Penumbra System Aspiration Pump - Pump Max, PMX220	Medical Device	Product Defect Correction	Class III	Hospital
21/03/2018	Universal Arm Support	Medical Device	Product Defect Correction	Class II	Hospital
20/03/2018	Covidien LigaSure Exact Dissector Nano-Coated 20.6mm-21cm	Medical Device	Recall	Class II	Hospital
20/03/2018	NON REBREATHE MASK	Medical Device	Recall	Class II	Hospital
20/03/2018	Thermo Scientific Remel Neisseria meningitidis Poly A-D 2mL and Neisseria meningitidis Group D 2mL. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
19/03/2018	HemoCue WBC Diff analysers and WBC Diff Microcuvettes. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
15/03/2018	Ingenuity TF PET/CT System with Addonics Mass Storage Device (MSD)	Medical Device	Product Defect Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
15/03/2018	Pine O Cleen Disinfectant	Medical Device	Recall	Class II	Retail
14/03/2018	EBI OsteoGen Implantable Bone Growth Stimulator	Medical Device	Hazard Alert	Class II	Hospital
14/03/2018	Labetalol Hydrochloride Injection	Medicine	Recall	Class I	Hospital
14/03/2018	OM040R - Doyen-Collin Mouth Gag 120mm	Medical Device	Product Defect Correction	Class III	Retail
14/03/2018	Philips CT couches used on Brilliance CT Big Bore, Brilliance CT Big Bore Oncology, Brilliance iCT, Brilliance iCT SP, Ingenuity Core, Ingenuity Core128, Ingenuity CT, Ingenuity Flex systems	Medical Device	Product Defect Correction	Class II	Hospital
13/03/2018	3M Surgical Clipper	Medical Device	Product Defect Correction	Class II	Hospital
13/03/2018	ADT1018 and ADT1018-50 Flow QC Tubing – haemodialysis blood tubing Set	Medical Device	Recall	Class I	Hospital
13/03/2018	Capio Suture Capturing Devices (SLIM, Standard, Open Access, RP)	Medical Device	Product Defect Correction	Class II	Hospital
13/03/2018	da Vinci X Patient Side Cart Arm Controller Joint Circuit Boards	Medical Device	Product Defect Correction	Class II	Hospital
13/03/2018	Drager Infinity Acute Care System (IACS) Monitoring Solution with s/w VG2.2 to VG6.0 & the Infinity M540 Stand-Alone Patient Monitor s/w from VG2.2 to VG6.0	Medical Device	Product Defect Correction	Class I	Hospital
13/03/2018	Haemoband PLUS	Medical Device	Product Defect Correction	Class III	Hospital
13/03/2018	Labetalol Hydrochloride Injection	Medicine	Recall	Class I	Hospital
9/03/2018	Servo Ventilators	Medical Device	Product Defect Correction	Class I	Hospital
8/03/2018	Versate Monofilament Mesh, 50x50 cm	Medical Device	Product Defect Correction	Class II	Hospital
7/03/2018	IMRIS ORT100 and ORT300 Operating Room Tables	Medical Device	Product Defect Correction	Class II	Hospital
6/03/2018	Lynparza (olaparib) capsules 50mg	Medicine	Recall	Class III	Retail
6/03/2018	Rite Aid Mini Digital Temple Touch Thermometer	Medical Device	Recall	Class I	Consumer
5/03/2018	HACTIV Calcar reamers	Medical Device	Recall	Class II	Hospital
2/03/2018	MindFrame Capture LP	Medical Device	Recall	Class I	Hospital
28/02/2018	Arjo Quick Connect Scale used with Maxi Sky 2	Medical Device	Product Defect Correction	Class II	Consumer
27/02/2018	Dräger Fabius Anaesthesia Machines	Medical Device	Product Defect Alert	Class I	Hospital

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27/02/2018	ED-530TK Duodenoscope	Medical Device	Product Defect Correction	Class I	Hospital
27/02/2018	Natus NicoletOne 32Ch Ambulatory EEG Record System	Medical Device	Product Defect Correction	Class II	Hospital
27/02/2018	Siemens Somatom Emotion, Sensation, Perspective & Scope CT Systems with s/w versions VB42B, VC10A, VC20A, VC20B, VC28A, VC30A, VC30B & VC40A	Medical Device	Product Defect Correction	Class II	Hospital
27/02/2018	SureSigns VSi, VS2+ products	Medical Device	Product Defect Correction	Class III	Hospital
26/02/2018	Cook Aspiration Unit	Medical Device	Product Defect Correction	Class II	Retail
26/02/2018	Injection Pipette	Medical Device	Recall	Class III	Retail
26/02/2018	Triathlon TS Tibial Augments Sizes 3 and 6	Medical Device	Hazard Alert	Class II	Hospital
23/02/2018	Kaisers KAGS1800 bandage scissor	Medical Device	Recall	Class III	Hospital
23/02/2018	Medfusion Syringe Pump Model Series 3500	Medical Device	Product Defect Correction	Class I	Hospital
23/02/2018	RayStation and RayPlan	Medical Device	Product Defect Correction	Class I	Hospital
23/02/2018	Sorg Jump Alpha, Jump Beta and Vector Wheelchairs	Medical Device	Product Defect Correction	Class II	Consumer
23/02/2018	U-100 Insulin Syringe 0.5mL 27G and 29G	Medical Device	Recall	Class II	Hospital
23/02/2018	Use of Tristel Trio Wipes System with GE TEE probe	Medical Device	Product Defect Correction	Class II	Hospital
22/02/2018	Femoral Head	Biological	Hazard Alert	Class II	Hospital
21/02/2018	Enterprise 8000 Electrical Bed	Medical Device	Product Defect Correction	Class III	Consumer
21/02/2018	Invivo DynaCAD Breast and Prostate with software versions 3.4 and 3.5	Medical Device	Product Defect Correction	Class II	Hospital
21/02/2018	LUCAS 2 Chest Compression System	Medical Device	Product Defect Correction	Class I	Hospital
20/02/2018	ACM W/FEM NOZZLE/PRESS (PK6) and INRPLS HP W/HIGH FLOW TIP	Medical Device	Recall	Class II	Hospital
20/02/2018	ARGENE Adenovirus R-gene and Parechovirus R- Gene Control Kits. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Alert	Class III	Hospital
20/02/2018	Faulding Vitamin B12	Medicine	Recall	Class III	Wholesale
19/02/2018	AQUIOS CL Flow Cytometry System. An in vitro medical device.	Medical Device	Product Defect Correction	Class I	Hospital

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19/02/2018	Futuro Quick Strap Ankle Support	Medical Device	Recall	Class II	Retail
19/02/2018	Single Use Instruments including Scissors, Forceps, and Suckers	Medical Device	Product Defect Correction	Class III	Hospital
14/02/2018	balanSys UNI convex PE inlay x/6, x/7, x/9	Medical Device	Hazard Alert	Class II	Hospital
14/02/2018	BIOCAL Temperature Controller	Medical Device	Recall	Class I	Hospital
14/02/2018	HeartStart MRx and FR3	Medical Device	Product Defect Correction	Class II	Hospital
13/02/2018	Automated 2500 Family Systems	Medical Device	Product Defect Correction	Class III	Hospital
13/02/2018	Elements Obturation Unit with Buchanan Heat Pluggers	Medical Device	Product Defect Correction	Class I	Retail
13/02/2018	VIDAS and mini VIDAS systems. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
12/02/2018	CareFusion Vyntus Body with Option Diffusion	Medical Device	Product Defect Correction	Class II	Hospital
12/02/2018	Enterprise and Citadel Range Beds	Medical Device	Product Defect Correction	Class II	Consumer
12/02/2018	ExacTrac Patient Positioning System with software versions 6.0, 6.1, 6.2, 6.5	Medical Device	Product Defect Correction	Class II	Hospital
12/02/2018	Hypothermia Caps, Mittens and Slippers	Medical Device	Recall	Class II	Hospital
12/02/2018	Indigo carmine - Oral Solution - 20mg/5ml	Medicine	Product Defect Correction	Class II	Hospital
12/02/2018	ProGrade Rel.1x Systems	Medical Device	Product Defect Correction	Class III	Hospital
12/02/2018	TRUST FENMOL paracetamol 500mg ibuprofen 200mg tablet blister pack	Medicine	Recall	Class III	Retail
8/02/2018	Biograph Horizon with VJ20A Software	Medical Device	Product Defect Correction	Class II	Hospital
7/02/2018	Cortisol Saliva ELISA. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
7/02/2018	Foetal Haemoglobin Monoclonal Antibody (HBF-1), FITC. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
7/02/2018	Maquet PowerLED, HLED 700 SF and Volista 600SF Surgical Lighting Systems	Medical Device	Product Defect Correction	Class II	Hospital
7/02/2018	Small Pedicle Probe ELL-IN 02 23-N	Medical Device	Recall	Class II	Wholesale
7/02/2018	syngo Workflow MLR	Medical Device	Product Defect Correction	Class II	Hospital
7/02/2018	Zenith Branch Iliac Endovascular Graft (ZBIS) - Patient Card	Medical Device	Product Defect Correction	Class III	Hospital

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6/02/2018	3M Bair Hugger Full Access Underbody Blanket	Medical Device	Recall	Class II	Hospital
6/02/2018	ACUSON SC2000 ultrasound systems with software versions VB10A, VB10B, VB10D, VB10E that have PRIME and eSie PISA software licenses	Medical Device	Product Defect Correction	Class I	Hospital
6/02/2018	Automate 2550 and 1250 Aliquotter Tip Present Sensor. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class I	Hospital
6/02/2018	Biograph mMR with software version syngo E11P	Medical Device	Product Defect Correction	Class II	Hospital
5/02/2018	Dimension Vista Calcium (CA) Flex reagent cartridge. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
5/02/2018	Mako RIO System Ethernet to Fiber Optic Converter	Medical Device	Product Defect Correction	Class III	Hospital
5/02/2018	Radiometer TCM5 FLEX / BASIC Transcutaneous Monitor	Medical Device	Product Defect Correction	Class I	Hospital
5/02/2018	Signature Ceramic Femoral Head	Medical Device	Recall	Class II	Wholesale
5/02/2018	Unomedical ConvaTec Frazier Suction Handle (included in Foot Pack Health and Lower Extremity Procedure Packs)	Medical Device	Product Defect Alert	Class II	Hospital
2/02/2018	Phadia AB Product EliA anti-TSH-R Well. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
2/02/2018	Valleylab FT10 energy platform	Medical Device	Recall for Product Correction	Class II	Hospital
1/02/2018	Biatain Ag Cavity Filler	Medical Device	Recall	Class II	Wholesale
31/01/2018	Femoral Head	Biological	Hazard Alert	Class III	Hospital
31/01/2018	Femoral Head	Biological	Hazard Alert	Class III	Hospital
31/01/2018	O-Arm 1000 Imaging System (3rd Edition)	Medical Device	Product Defect Correction	Class II	Hospital
30/01/2018	Brilliance Big Bore Oncology CT, Brilliance Big Bore Radiology CT with software version 4.2.0	Medical Device	Product Defect Correction	Class I	Hospital
30/01/2018	Custom Made Implant Systems with Minimally Invasive Grower (MIG) component	Medical Device	Hazard Alert	Class II	Hospital
30/01/2018	ETEST Polymyxin B (PO1024) blister packaging. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class I	Hospital
29/01/2018	Double Row Footplates, TL-HEX Sterile	Medical Device	Recall	Class II	Hospital

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29/01/2018	SwishTapered Implant 4.1mmD x12mmL SBM Dual Blast; 4.8mmD Platform	Medical Device	Recall	Class II	Retail
25/01/2018	BD Phoenix Gram Negative Panels containing colistin.	Medical Device	Product Defect Correction	Class II	Hospital
25/01/2018	RCI HA ACL Screw	Medical Device	Recall	Class III	Hospital
24/01/2018	Frazier suction handle	Medical Device	Product Defect Alert	Class II	Hospital
24/01/2018	TruVidia Wireless Receiver	Medical Device	Product Defect Correction	Class II	Hospital
22/01/2018	ADVIA Centaur Cyclosporine, DHEA-SO ₄ , Folate and HbC IgM Assays. An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
22/01/2018	Calmurid Cream tube 100g	Medicine	Recall	Class III	Wholesale
22/01/2018	therascreen PyroMark Gold Q24 Reagents and Pyro Buffers. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
19/01/2018	Allura Xper Systems with an attached 7th or 8th monitor	Medical Device	Product Defect Correction	Class II	Hospital
19/01/2018	APO-METFORMIN XR 1000 metformin hydrochloride 1000 mg modified release tablet blister pack 60 tablets	Medicine	Recall	Class II	Consumer
19/01/2018	Artis One in conjunction with table	Medical Device	Product Defect Correction	Class II	Hospital
18/01/2018	ADVIA Centaur CP, XP, and XPT Systems with use of BNP and TSH3-Ultra	Medical Device	Product Defect Correction	Class II	Hospital
18/01/2018	Panther and Panther Fusion Systems with 19-in monitor	Medical Device	Product Defect Correction	Class II	Hospital
17/01/2018	Moog Infusion System Administration Sets	Medical Device	Recall	Class I	Hospital
16/01/2018	AFFINITY NT Cardiotomy Venous Reservoirs stand-alone uncoated and coated models.	Medical Device	Recall	Class II	Hospital
16/01/2018	BVM (Bag-Valve-Mask) Manual Resuscitation Systems	Medical Device	Recall	Class I	Hospital
16/01/2018	FC 500 Series Flow Cytometers (new, reconditioned or refurbished). An in vitro diagnostic medical device (IVD)	Medical Device	Product Defect Correction	Class II	Hospital
16/01/2018	LiNA Gold Loop	Medical Device	Recall	Class II	Sponsor
16/01/2018	MAQUET VOLISTA central handle on StanOP, TRIPOD and ACCESS Cupolas	Medical Device	Product Defect Correction	Class II	Hospital

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16/01/2018	Vacurette Minicollect Complete 1ml Sodium Citrate 3.2%. An in vitro diagnostic medical device.	Medical Device	Recall	Class II	Hospital
16/01/2018	VIRAZOLE (Ribavirin Solution for Injection 0.1g/mL), 5 x 12 mL vials	Medicine	Recall	Class I	Hospital
16/01/2018	W & H Foot Control - S-N1/S-N2	Medical Device	Recall	Class II	Retail
15/01/2018	BrightView, BrightView X, BrightView XCT, Precedence 6, Precedence 16	Medical Device	Product Defect Correction	Class II	Hospital
15/01/2018	Vadi Heater	Medical Device	Recall	Class II	Hospital
12/01/2018	CARESCAPE Central Station (CSCS) software version 2.0.2	Medical Device	Recall for Product Correction	Class I	Hospital
12/01/2018	Hematoxylin II and Horseradish Peroxidase Reagents - An in vitro medical diagnostic device (IVD)	Medical Device	Recall	Class II	Hospital
12/01/2018	Radiolucent Spine Surgery Frame	Medical Device	Recall for Product Correction	Class II	Hospital
12/01/2018	Runyes Autoclave	Medical Device	Recall for Product Correction	Class II	Retail
12/01/2018	Xpert HIV-I Viral Load. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
11/01/2018	Nellix EndoVascular Aneurysm Sealing System	Medical Device	Recall for Product Correction	Class I	Hospital
10/01/2018	NAJA Spinal Ligament Systems for Spinal Stabilisation	Medical Device	Recall	Class II	Hospital
9/01/2018	Phadia ImmunoCAP Allergen c5, Ampicilloyl and ImmunoCAP Allergen c6, Amoxicilloyl	Medical Device	Recall	Class II	Hospital
9/01/2018	SIGMA HP PFJ Cemented Trochlear Implants	Medical Device	Hazard Alert	Class II	Hospital
5/01/2018	DBL METRONIDAZOLE INTRAVENOUS INFUSION metronidazole 500mg/100mL solution for injection bag	Medicine	Recall	Class II	Hospital
5/01/2018	Philips IntelliVue Information Center (PIIC) iX	Medical Device	Recall for Product Correction	Class II	Hospital
5/01/2018	Salter Labs Oxygen Cannulas	Medical Device	Recall	Class II	Hospital
4/01/2018	da Vinci Xi Surgical System P6b Software	Medical Device	Recall for Product Correction	Class III	Hospital

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4/01/2018	Synchron Enzyme Validator. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
4/01/2018	Tibial Implants	Medical Device	Recall	Class II	Hospital
22/12/2017	ClearSight Heart Reference Sensor	Medical Device	Recall	Class II	Hospital
22/12/2017	DuraClone B27 Reagent Kit - an in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
22/12/2017	Haemoglobin A1c (HbA1c) Reagent. An in vitro medical device.	Medical Device	Recall for Product Correction	Class II	Hospital
22/12/2017	Lifepak 20e Defibrillator/Monitor	Medical Device	Recall for Product Correction	Class II	Hospital
22/12/2017	Prelude SNAP Splittable Sheath Introducer	Medical Device	Recall	Class II	Hospital
22/12/2017	SynchroMed II Implantable Drug Infusion Pump	Medical Device	Recall for Product Correction	Class II	Hospital
21/12/2017	Ingenuity TF PET/CT running software version 4.0.2 (4.0.0.26645)	Medical Device	Recall for Product Correction	Class II	Hospital
21/12/2017	Restorelle DirectFix Anterior, Restorelle DirectFix Posterior and Altis Single Incision Sling	Medical Device	Recall	Class I	Hospital
20/12/2017	DePuy Synthes Confidence Kit Spinal Cement System	Medical Device	Recall	Class II	Hospital
20/12/2017	Ready-Prep %CDT by HPLC using the CDM software version MVC133091. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
20/12/2017	Valitude CRT-P, Resonate, Momentum & Autogen CRT-Ds, Visionist CRT-P & Dynagen CRT-D	Medical Device	Recall for Product Correction	Class I	Hospital
20/12/2017	Valitude CRT-P, Visionist CRT-P, Accolade Pacemakers and Proponent Pacemakers	Medical Device	Hazard Alert	Class I	Hospital
19/12/2017	CARBAGLU carglumic acid 200 mg dispersible tablets tube	Medicine	Recall for Product Correction	Class III	Hospital
19/12/2017	CARESCAPE R860 ventilators with software version 10SP05	Medical Device	Recall for Product Correction	Class I	Hospital
19/12/2017	CELL-DYN Emerald 22 Analyser with software version v3.0.0. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital

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19/12/2017	ETEST Teicoplanin 256 (TP) SPB and Foam packaging. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
19/12/2017	Flexible Uretero-Reno Videoscope & Flexible Uretero-Reno Fiberscope	Medical Device	Recall	Class II	Hospital
19/12/2017	Medtronic Clip Gun Scalp Clip System	Medical Device	Recall	Class I	Hospital
19/12/2017	PEDEA ibuprofen 10 mg/2 mL solution for intravenous infusion 2 mL glass ampoule	Medicine	Recall for Product Correction	Class III	Hospital
19/12/2017	Philips Intellivue Patient Monitor X3	Medical Device	Recall for Product Correction	Class II	Hospital
19/12/2017	Signia Power Handle	Medical Device	Recall for Product Correction	Class II	Hospital
19/12/2017	SynCardia Freedom Driver System (a component of the SynCardia temporary Total Artificial Heart System)	Medical Device	Recall for Product Correction	Class II	Hospital
18/12/2017	Architect c4000, c8000, c16000 Cuvette Segment. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
18/12/2017	ARCHITECT DHEA-S Reagents. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
18/12/2017	Equinox Advantage	Medical Device	Recall for Product Correction	Class II	Hospital
18/12/2017	IMMULITE/IMMULITE 1000 IMMULITE 2000/IMMULITE 2000 XPi Assays. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
18/12/2017	Nv Guider Catheter 90cm	Medical Device	Recall	Class II	Hospital
18/12/2017	Rotating IV Pole, used with Giraffe OmniBed Carestation, Giraffe Incubator Carestation Giraffe OmniBed, Giraffe Warmer, Panda Warmer, Giraffe Incubator, Care Plus Incubator, IWS, and Giraffe Shuttle.	Medical Device	Recall for Product Correction	Class II	Hospital
15/12/2017	Uphold LITE with Capio SLIM and Solyx Single Incision Sling System	Medical Device	Recall	Class I	Hospital
14/12/2017	Artis systems with Artis tables	Medical Device	Recall for Product Correction	Class II	Hospital
14/12/2017	Vacurette Minicollect Complete 1mL Sodium Citrate 3.2%.	Medical Device	Recall	Class II	Hospital
13/12/2017	C- Series lifts	Medical Device	Recall	Class II	Consumer

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
13/12/2017	Transseptal Needle	Medical Device	Recall	Class I	Hospital
12/12/2017	MCK Tibial Baseplate-RM/LL-SZ 2 and MCK Tibial Baseplate-RM/LL-SZ 7	Medical Device	Recall	Class II	Hospital
12/12/2017	Spaplus Weekly wash Protocol and Bottles. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
12/12/2017	Volcano Imaging Systems and Core Mobile Imaging Systems	Medical Device	Recall for Product Correction	Class II	Hospital
12/12/2017	Volcano s5i, CORE, CORE Mobile Systems with software version V3.5	Medical Device	Recall for Product Correction	Class II	Hospital
11/12/2017	C-Series Lifts	Medical Device	Recall	Class II	Consumer
11/12/2017	Malecot Nephrostomy Catheter Set	Medical Device	Recall	Class I	Hospital
11/12/2017	TomoTherapy High Performance Patient Couch	Medical Device	Recall for Product Correction	Class II	Hospital
8/12/2017	Hercules Patient Lifter	Medical Device	Recall for Product Correction	Class II	Consumer
8/12/2017	Pipet Tips used with AutoDG System. An in vitro diagnostic medical device	Medical Device	Recall for Product Correction	Class III	Hospital
6/12/2017	AQUIOS CL Flow Cytometry System, software versions 2.0, 2.0.1, 2.1. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
6/12/2017	MIA FORA NGS HLA FLEX 11 KIT (24 tests). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
6/12/2017	Monoclonal Mouse Anti-Human CDX2, Clone DAK-CDX2. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
5/12/2017	Airsep Impulse Elite Oxygen Conserving Device	Medical Device	Recall	Class II	Hospital
5/12/2017	Apex Knee System	Medical Device	Recall	Class III	Hospital
5/12/2017	Intro-Flex Automatic Hemostasis Valve Introducer	Medical Device	Recall	Class II	Hospital
4/12/2017	Balt Cristal Balloons	Medical Device	Recall	Class I	Hospital
4/12/2017	Brainlab Navigation System Spine & Trauma 3D	Medical Device	Recall	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
4/12/2017	Brilliance iCT (Model 728306), Brilliance iCT SP (Model 728311) and IQon Spectral CT (Model 728332) Scanner systems	Medical Device	Recall for Product Correction	Class III	Hospital
4/12/2017	Digital Accelerators with iViewGT or XVI	Medical Device	Recall for Product Correction	Class I	Hospital
4/12/2017	Phadia Prime with software up to and including version 2.1.4 . An in vitro diagnostic device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
30/11/2017	PRICELINE PHARMACY PERIOD PAIN RELIEF naproxen sodium 275mg tablet blister pack	Medicine	Recall	Class III	Retail
29/11/2017	Cordis S.M.A.R.T. Flex Vascular Stent System	Medical Device	Recall	Class II	Hospital
29/11/2017	Various Vital-Port Vascular Access Systems	Medical Device	Recall	Class I	Hospital
27/11/2017	BiPAP A 40 Ventilatory Support System	Medical Device	Recall for Product Correction	Class III	Hospital
27/11/2017	CADD Legacy 1, Model 6400 Ambulatory Infusion Pump	Medical Device	Recall for Product Correction	Class III	Hospital
27/11/2017	IntelePACS with software versions 4-3-1 and up	Medical Device	Recall for Product Correction	Class II	Hospital
27/11/2017	Thermo Scientific Remel Shigella sonnei (Phases 1 & 2) Agglutinating Serum. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
24/11/2017	Allen Medical Bow Frame	Medical Device	Recall for Product Correction	Class II	Hospital
23/11/2017	RayStation and RayPlan	Medical Device	Recall for Product Correction	Class II	Hospital
23/11/2017	RE51021 / MuSK-Ab ELISA	Medical Device	Recall	Class III	Hospital
23/11/2017	SURGICAL GOWN UL HP L	Medical Device	Recall	Class II	Hospital
22/11/2017	Global Cup Poly Liner, Neutral prostheses	Medical Device	Hazard Alert	Class II	Hospital
22/11/2017	Integrity R1.2 and Integrity R3.2 systems with a Precise Treatment Table for ATM license option	Medical Device	Recall for Product Correction	Class II	Hospital
22/11/2017	Rechargeable Li-Ion Batteries with incorrect firmware used in Puritan Bennett 980 Ventilators	Medical Device	Recall for Product Correction	Class II	Hospital
21/11/2017	LIPITOR atorvastatin 80mg (as calcium) tablet blister pack	Medicine	Recall	Class III	Retail

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
20/11/2017	Fujifilm Synapse PACS software version 4.0, 4.1, 4.2, 4.3 (a picture archiving and communication system)	Medical Device	Recall for Product Correction	Class II	Hospital
20/11/2017	Pentacam AXL, with software versions 1.21r01, 1.21r03, 1.21r11 and 1.21r13	Medical Device	Recall for Product Correction	Class II	Hospital
20/11/2017	Spectra System/Legacy Guided Surgery Handle Kit Inserts	Medical Device	Recall	Class II	Retail
20/11/2017	Tango Reflex - Lasers, Ophthalmic Model LT5106-T	Medical Device	Recall for Product Correction	Class II	Hospital
17/11/2017	Bard ArcticSun ArticGel Pads	Medical Device	Recall for Product Correction	Class II	Hospital
17/11/2017	Epiclone Anti-M Blood Grouping Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
17/11/2017	Epiclone Anti-M Blood Grouping Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
16/11/2017	iChemVELOCITY Urine Chemistry Strips. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
16/11/2017	iQ200 Series Urine Microscopy Analyzer with Barcode Reader Model NFT-2100	Medical Device	Recall for Product Correction	Class II	Hospital
16/11/2017	Remisol Advance Software Versions 1.6-1.9, Architect Driver	Medical Device	Recall for Product Correction	Class II	Hospital
15/11/2017	Foetal Haemoglobin Monoclonal Antibody (HBF-1). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
15/11/2017	Multicare and Multicare LE Electrically operated Hospital Beds	Medical Device	Product Defect Correction	Class II	Hospital
15/11/2017	ProTrack Microcatheter	Medical Device	Recall	Class II	Hospital
15/11/2017	Signature Orthopaedics Logival 20 degree Hooded XLPE Liner	Medical Device	Hazard Alert	Class III	Hospital
15/11/2017	TunnelLoc Tibial Fixation Devices (used during anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) reconstruction)	Medical Device	Hazard Alert	Class II	Hospital
14/11/2017	MAQUET HLX 2004-5 DF, HLX 3004-5 DF and XTEN DF cupolas Surgical Lighting System	Medical Device	Recall for Product Correction	Class II	Hospital
13/11/2017	CP5 control panels and HLM bubble sensors and EP packs manufactured prior to 10 February, 2017	Medical Device	Recall for Product Correction	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
13/11/2017	i-STAT 1 Analyser Software with i-STAT Total â-hCG Cartridge with software version JAMS 143/CLEW A34. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
13/11/2017	METS Principal Shaft	Medical Device	Hazard Alert	Class II	Hospital
13/11/2017	Percuvance Percutaneous Surgical System	Medical Device	Recall	Class I	Hospital
13/11/2017	Thermofisher Remel Bactipstaph Latex Kits	Medical Device	Recall	Class II	Hospital
10/11/2017	Accent / Anthem, Accent MRI / Accent ST, Assurity / Allure and Assurity MRI devices	Medical Device	Recall for Product Correction	Class II	Hospital
10/11/2017	APO-Perindopril Arginine 2.5mg, AUST R: 184808	Medicine	Recall	Class III	Consumer
8/11/2017	Disposable Reuter Tip-Deflecting Wire Guide	Medical Device	Recall	Class II	Hospital
8/11/2017	DxH 500 Open-Vial Haematology System, with software version 1.0.2 and 1.1. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
8/11/2017	LIFEPAK EXPRESS AED, LIFEPAK CR Plus AED, LIFEPAK 1000 defibrillator, or LIFEPAK 500 Biphasic AED with a pink connector	Medical Device	Recall	Class I	Retail
8/11/2017	Metaraminol Syringes	Medicine	Recall	Class III	Hospital
8/11/2017	Philips Brilliance 64, Ingenuity Core128 and Ingenuity CT with software version 4.1.6	Medical Device	Recall for Product Correction	Class II	Hospital
8/11/2017	SOMATOM Definition AS, Definition, Definition Edge, Definition Flash and SOMATOM Force	Medical Device	Recall for Product Correction	Class I	Hospital
7/11/2017	Eluvia 150mm and Innova 200mm Stent Systems	Medical Device	Recall	Class I	Hospital
7/11/2017	Preloaded hydrophobic intraocular lenses	Medical Device	Recall	Class II	Hospital
7/11/2017	Various Optetrak Devices - Spine Stiffener Screw and Constrained Condylar (CC) Tibial Insert when used in conjunction with Offset Tibial Tray	Medical Device	Recall for Product Correction	Class II	Hospital
7/11/2017	V-PRO 60 Low Temperature Sterilisation System with VAPROX HC Sterilant	Medical Device	Recall for Product Correction	Class II	Hospital
6/11/2017	Compella Air Surfaces Bed System (220 - 240 V, 50 Hz), used in conjunction with International 220 - 240 V, 50 Hz Controllers	Medical Device	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
6/11/2017	Compounded Medications within CADD Medication Non-flow stop Cassette Reservoirs	Medical Device	Recall	Class II	Hospital
6/11/2017	Haemoglobin A1c (HbA1c) Flex reagent cartridge used with Dimension Vista with software version 3.6.2 or higher. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
6/11/2017	SENSATION PLUS 8Fr. 50cc Intra-Aortic Balloon Catheter with Insertion Kit & STATLOCK	Medical Device	Recall	Class II	Hospital
6/11/2017	VITEK 2 Gram-Positive (GP) Identification (ID) Test Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
3/11/2017	Acetabular Cup Introducer (32mm)	Medical Device	Recall	Class II	Hospital
3/11/2017	Alaris System Pump module (LVP), Mechanism Sub-assembly and Kit Assembly	Medical Device	Recall for Product Correction	Class I	Hospital
3/11/2017	Doro Sterile Disposable Skull Pins	Medical Device	Recall	Class I	Hospital
2/11/2017	Midazolam APOTEX midazolam 5mg/1 mL solution for injection ampoule	Medicine	Recall	Class I	Retail
1/11/2017	RHD2.5 Hex Driver, 2.5mm with GemLock Retention, contained within TSVKIT Surgical Kit	Medical Device	Recall	Class II	Retail
1/11/2017	Various Acuvue for Astigmatism Contact Lenses	Medical Device	Recall	Class III	Retail
31/10/2017	Copernic2L and Eclipse2L Occlusion Balloon Catheters	Medical Device	Recall for Product Correction	Class II	Hospital
31/10/2017	FLEX Monoclonal Rabbit Anti-Human Estrogen Receptor Clone EP1, Ready-to-use. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class I	Hospital
30/10/2017	Drystar DT 2 C Hardcopy Film 14" x 17"	Medical Device	Recall for Product Correction	Class II	Hospital
30/10/2017	Leica Proveo 8 Ophthalmic Microscope System	Medical Device	Recall for Product Correction	Class II	Hospital
30/10/2017	rHead Radial Head and Uni-Elbow System	Medical Device	Recall	Class II	Hospital
30/10/2017	Veletri Consumables Kit with non Flow-Stop CADD Medication Cassette Reservoirs	Medical Device	Recall	Class II	Hospital
27/10/2017	Sorin Group perfusion system – Heater Cooler 1T devices	Medical Device	Recall	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
27/10/2017	Sorin Group perfusion system – Heater Cooler 3T devices	Medical Device	Recall for Product Correction	Class I	Hospital
25/10/2017	Access BR Monitor used with the Access family of Immunoassay systems. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
25/10/2017	Plum 360 Infusion System	Medical Device	Recall for Product Correction	Class II	Hospital
25/10/2017	WECK Auto Endo5 Automatic Hem-o-lok Clip Applicators	Medical Device	Recall	Class II	Hospital
24/10/2017	3.0T GE 6-Channel Phased Array Flex Coil	Medical Device	Recall for Product Correction	Class II	Hospital
24/10/2017	Dialysis Treatment Therapy Pack 105	Medical Device	Recall	Class II	Hospital
24/10/2017	MIA FORA NGS Software v3.27.0. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
24/10/2017	Various Dimension and Dimension Vista LOCI Assays. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
23/10/2017	AUSTRALIAN RADIOISOTOPES Sodium Iodide (I-131) 50 - 6000MBq Therapy Capsule vial	Medicine	Recall	Class III	Hospital
23/10/2017	Curlin 6000 Painsmart IOD Infusion Pump Power Adapter Accessory	Medical Device	Recall for Product Correction	Class II	Hospital
23/10/2017	Hospira labelled MedNet Medication Management Suite – with Plum 360 Infusion System	Medical Device	Recall for Product Correction	Class I	Hospital
23/10/2017	Thoracic Pedicle Feeler	Medical Device	Recall	Class II	Hospital
20/10/2017	Tracoe Twist Tracheostomy Tube	Medical Device	Recall	Class II	Hospital
18/10/2017	FlexCath Advance Steerable Sheath	Medical Device	Recall for Product Correction	Class I	Hospital
18/10/2017	Liko Multirall 200 overhead lift and S65 Carriage	Medical Device	Recall for Product Correction	Class II	Hospital
18/10/2017	Oxford Dipper Hoist	Medical Device	Recall for Product Correction	Class II	Retail
18/10/2017	Oxford Dipper pool hoist	Medical Device	Recall for Product Correction	Class II	Retail

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
18/10/2017	Philips Network Firewall 867098 (Cisco ASA 5506 Firewall) used with the Philips IntelliVue Information Center iX or Classic Information Center	Medical Device	Recall	Class II	Hospital
18/10/2017	Radiometer TCM5 FLEX / BASIC Transcutaneous Monitor	Medical Device	Recall for Product Correction	Class I	Hospital
17/10/2017	Beater-Positioner-Aligner	Medical Device	Recall	Class II	Hospital
17/10/2017	Catheter Mount	Medical Device	Recall	Class II	Hospital
17/10/2017	Ingenuity TF PET/CT System with software version 4.0.3.26129	Medical Device	Recall for Product Correction	Class III	Hospital
17/10/2017	Non-Flow-Stop CADD Medication Cassette Reservoirs 50 and 100mL	Medical Device	Recall	Class I	Hospital
16/10/2017	AQUIOS CL Flow Cytometry System. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
16/10/2017	CareLink iPro Therapy Management Software MMT-7340	Medical Device	Recall for Product Correction	Class II	Hospital
16/10/2017	Pentax ED-3490TK Video Duodenoscope	Medical Device	Recall for Product Correction	Class II	Hospital
16/10/2017	Radiometer ABL800 series with FLEXQ module. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
13/10/2017	Ceiling Unit CU5001/3 and CU 3-21/23	Medical Device	Recall for Product Correction	Class II	Hospital
13/10/2017	ERGO version 1.7.3 and higher and using a Multileaf Collimator (MLC) device for planning	Medical Device	Recall for Product Correction	Class I	Hospital
12/10/2017	Gentamicin / Gentamicin & Citrate, Syringes, Bags and Eye Drops	Medicine	Recall	Class II	Hospital
11/10/2017	All Carestation 620, 650 and 650c Anaesthesia systems	Medical Device	Recall for Product Correction	Class I	Hospital
11/10/2017	Corpus Powered Wheelchairs	Medical Device	Recall for Product Correction	Class II	Consumer
11/10/2017	DIMETAPP COUGH COLD & FLU DAYTIME/NIGHTTIME LIQUID CAPS capsule blister pack	Medicine	Recall	Class II	Retail
11/10/2017	Integra CUSA Clarity Footswitch packaged with CUSA Clarity Console C7000	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
9/10/2017	Abut Gold Friction-Fit	Medical Device	Recall	Class II	Retail
9/10/2017	Conformable GORE TAG Thoracic Endoprosthesis	Medical Device	Recall for Product Correction	Class I	Hospital
9/10/2017	Midazolam 5mg/5mL ampoules	Medicine	Recall	Class I	Retail
9/10/2017	O-arm O2 Surgical Imaging System	Medical Device	Recall for Product Correction	Class II	Hospital
9/10/2017	Pilling Knife Handles	Medical Device	Recall	Class II	Hospital
9/10/2017	Prick-Test Diagnostic Rye Flour B16	Medicine	Recall	Class II	Hospital
9/10/2017	Sodium Iodide (I-131) Therapy Capsule	Medicine	Recall	Class II	Hospital
9/10/2017	SureSigns VSi, VS2+	Medical Device	Recall for Product Correction	Class III	Hospital
9/10/2017	Various Safeset and Transpac Blood Pressure Transducer Sets	Medical Device	Recall	Class II	Hospital
9/10/2017	Xpert EV Assay. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
6/10/2017	Gentamicin Injection BP 80 mg in 2 mL Steriluer, 10 and 50 packs	Medicine	Recall	Class I	Consumer
5/10/2017	Fluorocell PLT reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
4/10/2017	Infinity Dual Hemo MCable Pod used with the Infinity Acute Care System (IACS) Monitoring Solution	Medical Device	Recall for Product Correction	Class I	Hospital
4/10/2017	Various Disposable Catheter Mounts	Medical Device	Recall	Class I	Hospital
3/10/2017	Bard Max-Core Disposable Core Biopsy Instrument	Medical Device	Recall	Class I	Hospital
3/10/2017	SOMATOM go.Up and SOMATOM go. Now	Medical Device	Recall for Product Correction	Class II	Hospital
29/09/2017	AIRO Mobile CT Scanner	Medical Device	Recall for Product Correction	Class I	Hospital
28/09/2017	Hamilton Medical C3 Ventilator	Medical Device	Recall for Product Correction	Class II	Hospital
28/09/2017	IntelePACS InteleViewer with software version 3-5-1 to 4-15-1	Medical Device	Recall for Product Correction	Class II	Hospital
27/09/2017	Artis systems with wireless footswitch	Medical Device	Recall for Product Correction	Class II	Hospital

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27/09/2017	GastriSail Gastric Positioning System	Medical Device	Recall	Class II	Hospital
27/09/2017	Mobile Detector Holder Trolley (9890-010-88152)	Medical Device	Recall for Product Correction	Class II	Hospital
27/09/2017	Progressa Bed System	Medical Device	Recall for Product Correction	Class II	Hospital
26/09/2017	9025RHTR ABG Sampling Kit	Medical Device	Recall	Class II	Hospital
26/09/2017	Brilliance iCT/iCP SP, CT 64, Ingenuity CT/Core/Core 128 with software version 4.1.6	Medical Device	Recall for Product Correction	Class II	Hospital
21/09/2017	Auriga XL 4007 Laser System	Medical Device	Recall for Product Correction	Class II	Hospital
21/09/2017	DELTA XTEND Reverse Shoulder System Modular Centered and Eccentric Epiphysis Implants	Medical Device	Recall	Class II	Hospital
21/09/2017	ReNew Reusable Tips (Scissors, Graspers and Dissectors)	Medical Device	Recall	Class II	Hospital
20/09/2017	Surflink Media and Surflink Media 2	Medical Device	Recall for Product Correction	Class III	Consumer
19/09/2017	Auriga XL 4007 Laser System	Medical Device	Recall for Product Correction	Class II	Hospital
18/09/2017	Lucrin Depot Paediatric acetate 30mg for injection, prefilled dual chamber syringe	Medicine	Recall	Class II	Consumer
18/09/2017	Thermocool Smarttouch SF Bi-Directional Navigation Catheter	Medical Device	Recall	Class II	Hospital
15/09/2017	Freedom Healthcare Quad Walkers	Medical Device	Recall for Product Correction	Class II	Consumer
15/09/2017	NM Implantable Pulse Generator within the Infinity and Proclaim device families	Medical Device	Recall for Product Correction	Class II	Hospital
14/09/2017	Radiometer AQT90FLEX Immunoassay analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
13/09/2017	Artis zee and Artis Q systems with software version VD11C	Medical Device	Recall for Product Correction	Class II	Hospital
13/09/2017	CoaguChek HS Plus/Pro System. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
13/09/2017	DiaMed Q.C. System. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
13/09/2017	Lax Sachets	Medicine	Recall	Class II	Consumer

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13/09/2017	Lentis Foldable Intraocular Lenses (IOL)	Medical Device	Recall	Class II	Hospital
13/09/2017	MetaVision ICU version 6.0x - 6.9x	Medical Device	Recall for Product Correction	Class II	Hospital
13/09/2017	Oxoid AST Disc - Ceftazidime CAZ10. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
11/09/2017	Lifecodes HLA-DRB1 SSO Typing Kit and HLA-DQA1/B1 Typing Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
11/09/2017	Medtronic MiniMed Infusion Sets	Medical Device	Recall	Class II	Consumer
11/09/2017	Various Disposable Catheter Mounts	Medical Device	Recall	Class II	Hospital
11/09/2017	Various Sage Oral Care Products	Medical Device	Recall	Class II	Hospital
7/09/2017	Philips IntelliVue Patient Monitors ECG 12-lead option #C12	Medical Device	Recall for Product Correction	Class II	Hospital
6/09/2017	Allura Xper R9 and Azurion R1.1 systems with the QA Basic Measurement tool	Medical Device	Recall for Product Correction	Class II	Hospital
6/09/2017	Cystoscopy Bridges	Medical Device	Recall	Class II	Hospital
6/09/2017	Graseby 3300 Pump and Graseby 3000 Series Accessories	Medical Device	Recall for Product Correction	Class II	Hospital
6/09/2017	Plastic Cannula – 11 gauge	Medical Device	Recall	Class II	Hospital
6/09/2017	TM0268 GC Sugar Set. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
4/09/2017	Slit Lamp	Medical Device	Recall for Product Correction	Class III	Hospital
4/09/2017	VisuMax	Medical Device	Recall for Product Correction	Class III	Hospital
31/08/2017	Iris Hi Lo Bed	Medical Device	Recall for Product Correction	Class II	Hospital
30/08/2017	Affirm Lateral Arm Upright Biopsy Accessory	Medical Device	Recall for Product Correction	Class II	Hospital
30/08/2017	Ausganica Soothing Herbs Toothpaste	Medicine	Recall	Class III	Consumer
30/08/2017	Epiclone Anti N BGR - Immunohaematology Reagent. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital

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30/08/2017	Phadia 1000 Instrument. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
30/08/2017	VITROS Chemistry Products PHYT Slides. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
29/08/2017	Artis one system with DP Transceiver below version 03	Medical Device	Recall for Product Correction	Class II	Hospital
29/08/2017	HeartWare HVAD Controllers and Heartware 1435 DC Adapters	Medical Device	Recall	Class II	Hospital
29/08/2017	Leica M525 F40 Surgical Microscopes	Medical Device	Recall for Product Correction	Class II	Hospital
29/08/2017	Mako THA Application User Guides	Medical Device	Recall for Product Correction	Class II	Hospital
29/08/2017	Various Tissu-Trans Products	Medical Device	Recall	Class II	Hospital
29/08/2017	VITROS Immunodiagnostic Products Signal Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
29/08/2017	WATO EX-65 and A-Series (A5/A7) anaesthesia machines	Medical Device	Recall for Product Correction	Class II	Hospital
28/08/2017	Artis zee biplane and Artis Q biplane systems	Medical Device	Recall for Product Correction	Class III	Hospital
28/08/2017	cobas 8000 core unit with software versions 5.01 and later. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
28/08/2017	Essure Permanent Birth Control	Medical Device	Hazard Alert	Class II	Hospital
28/08/2017	Fortify, Fortify Assura, Quadra Assura, Quadra Assura MP, Unify, Unify Assura and Unify Quadra devices	Medical Device	Hazard Alert	Class II	Hospital
23/08/2017	AQUIOS CL Flow Cytometry System. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
23/08/2017	Kii Abdominal Troacar	Medical Device	Recall	Class II	Hospital
23/08/2017	Remel Wellcolex Colour Shigella Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
23/08/2017	Solitaire Platinum Revascularisation Device	Medical Device	Recall for Product Correction	Class III	Hospital

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23/08/2017	Streptex Rapid Latex Agglutination Test. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
23/08/2017	Sysmex CS-5100 Analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
22/08/2017	FemoSeal Vascular Closure System	Medical Device	Recall	Class I	Hospital
22/08/2017	Pfizer (Perth) Pty Limited LIGNOCAINE 2% GEL syringe	Medicine	Recall for Product Correction	Class III	Hospital
21/08/2017	Immunoassay Premium and Premium Plus controls when used with ACTH assays. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
17/08/2017	Oh Baby! Natural Formula capsules, JO LMax Extra tablets and RUFF Natural Formula 10,000mg capsules	Medicine	Recall	Class II	Consumer
17/08/2017	Platinum Implantable Cardiac Defibrillators (ICDs) and Cardiac Resynchronisation Therapy Defibrillators (CRT-Ds)	Medical Device	Hazard Alert	Class III	Hospital
16/08/2017	A.T.S. 2200 and A.T.S. 4000 Tourniquet Systems	Medical Device	Recall for Product Correction	Class III	Hospital
16/08/2017	Oncentra Brachy using versions 4.5, 4.5.1 and 4.5.2	Medical Device	Recall for Product Correction	Class II	Hospital
16/08/2017	Philips Brilliance iCT	Medical Device	Recall for Product Correction	Class II	Hospital
16/08/2017	Rechargeable Lithium Ion Battery used in Beneview T1 Patient Monitors	Medical Device	Recall for Product Correction	Class II	Hospital
15/08/2017	Abbott RealTime HIV-1 Assay. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
15/08/2017	Disposable Expandable Adult 22mmID Expandable Anaesthetic Circuits	Medical Device	Recall	Class II	Hospital
14/08/2017	Nicolet Elite Doppler Probe 2 MHz and 3 MHz Obstetric, 5 MHz Vascular	Medical Device	Recall for Product Correction	Class II	Hospital
11/08/2017	Heparin 5000 IU/5mL injection 50 pack and Lignocaine 50mg/5mL x 50	Medicine	Recall	Class I	Consumer
10/08/2017	Covidien Emprint Percutaneous Antennas with Thermosphere Technology	Medical Device	Recall	Class I	Hospital
10/08/2017	Janus and Janus G3 Automated Workstation	Medical Device	Recall for Product Correction	Class III	Hospital

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10/08/2017	Medtronic MyCareLink Remote Monitors	Medical Device	Recall for Product Correction	Class II	Hospital
10/08/2017	nanOss Bioactive 10cc Bone Void Filler	Medical Device	Recall	Class III	Hospital
10/08/2017	Vanguard Open Box Posterior Stabilised Femoral Components	Medical Device	Hazard Alert	Class II	Hospital
10/08/2017	VITROS Performance Verifier II. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
10/08/2017	Vygon Umbilical Catheters	Medical Device	Recall	Class II	Hospital
9/08/2017	balanSys RP Tibial Plateau TiNbN cem	Medical Device	Recall	Class II	Hospital
9/08/2017	D-Rad Titanium 2.4mm x 10mm Locking Screw T7 Self-Tapping	Medical Device	Recall	Class II	Hospital
9/08/2017	Rigid Arm Supports	Medical Device	Recall	Class I	Hospital
8/08/2017	Fujifilm MS Swivel Arm	Medical Device	Recall for Product Correction	Class II	Hospital
8/08/2017	illumigene Malaria Kit. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class III	Hospital
8/08/2017	PLEGIOX Cardioplegia Heat Exchanger	Medical Device	Recall for Product Correction	Class I	Hospital
7/08/2017	70mL Centrifuge Bowl	Medical Device	Recall	Class II	Hospital
7/08/2017	AIRO Mobile CT Scanner	Medical Device	Recall for Product Correction	Class II	Hospital
7/08/2017	ARROW Pressure Injectable PICC Kit	Medical Device	Recall	Class III	Hospital
7/08/2017	Gentian Cystatin C Calibrator Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
7/08/2017	Human IgM kit for use on SPAPLUS	Medical Device	Recall for Product Correction	Class II	Hospital
7/08/2017	Maquet/Datascope Intra-Aortic Balloon Pump (IABP)	Medical Device	Recall for Product Correction	Class II	Hospital
7/08/2017	Metamucil Natural Granular Original with Sugar (48 doses)	Medicine	Recall	Class III	Retail
7/08/2017	Polarstem Cardan for 21000438	Medical Device	Recall	Class II	Hospital
3/08/2017	S7XTRA Concentrate 5 Litre bottles	Medical Device	Recall	Class II	Hospital
3/08/2017	VITEK MS Clinical Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
2/08/2017	ImmunoCAP Allergen f205, Herring. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
2/08/2017	Pentax Ultrasound Video Bronchoscope	Medical Device	Recall for Product Correction	Class II	Hospital
1/08/2017	Ultrasound Upper GI Video Scopes	Medical Device	Recall for Product Correction	Class II	Hospital
27/07/2017	ProBP 2400 Digital Blood Pressure Device	Medical Device	Recall	Class II	Hospital
27/07/2017	Ultrasonic Mixer cover (USM) 3. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
26/07/2017	Various Trauma and Extremity Instruments (drill bits, screw taps and saw blades)	Medical Device	Recall	Class II	Hospital
25/07/2017	Fujifilm Digital Mammography System	Medical Device	Recall for Product Correction	Class II	Hospital
25/07/2017	Heater Unit HU 35	Medical Device	Recall for Product Correction	Class I	Hospital
24/07/2017	Maquet Heater-Cooler Unit HCU 40	Medical Device	Recall for Product Correction	Class I	Hospital
21/07/2017	Philips Sync Cables and Philips ECG Out Cables	Medical Device	Recall	Class II	Hospital
20/07/2017	Allura Xper FD20 R8.2	Medical Device	Recall for Product Correction	Class III	Hospital
20/07/2017	CareScape Patient Data Module (PDM) with software v2.6	Medical Device	Recall for Product Correction	Class II	Hospital
20/07/2017	Essure Permanent Birth Control System	Medical Device	Recall for Product Correction	Class II	Hospital
20/07/2017	Mueller Hinton E Agar (MHE)	Medical Device	Recall	Class II	Hospital
20/07/2017	Various Microgenics Applications Sheets. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
19/07/2017	ARCTIC SUN 5000 Temperature Management System (220-240 V Australia)	Medical Device	Recall for Product Correction	Class II	Hospital
19/07/2017	Astral 100 and 150 ventilators	Medical Device	Recall for Product Correction	Class I	Consumer
19/07/2017	JTS Drive Unit	Medical Device	Recall	Class II	Hospital
19/07/2017	Thin and Radial Osteotome Blades	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
18/07/2017	Medtronic Spinous Process Clamps	Medical Device	Recall for Product Correction	Class I	Hospital
14/07/2017	Aequalis Ascend Flex Shoulder System PTC Humeral Stems	Medical Device	Recall	Class II	Hospital
14/07/2017	Euphora Semi-Compliant Rapid Exchange Balloon Dilatation Catheter	Medical Device	Recall	Class I	Hospital
14/07/2017	HF-Resection Electrodes	Medical Device	Recall for Product Correction	Class I	Hospital
12/07/2017	E.T.O.I.L.E system – E.TO.I.L.E extension table (leg holder used in total hip arthroplasty)	Medical Device	Recall	Class II	Hospital
12/07/2017	Multiple AxiEM ENT Suction Instruments	Medical Device	Recall	Class I	Hospital
12/07/2017	SoKINOX NO (Nitric Oxide) Delivery and Monitoring System	Medical Device	Recall for Product Correction	Class II	Hospital
12/07/2017	Synchron Systems Salicylate Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
11/07/2017	Alere HIV Combo. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
11/07/2017	Fusion Pushing Catheter	Medical Device	Recall	Class III	Hospital
11/07/2017	Heron Toilet and Bath Chair	Medical Device	Recall for Product Correction	Class II	Hospital
11/07/2017	HomeChoice Pro Automated PD Cycler and HomeChoice Claria APD System	Medical Device	Recall for Product Correction	Class I	Hospital
11/07/2017	Mako Internal cPCI Card Cage	Medical Device	Recall for Product Correction	Class II	Hospital
11/07/2017	Nitinol RF Reusable Electrodes	Medical Device	Recall for Product Correction	Class I	Hospital
11/07/2017	syngo Workflow MLR using Portal Radiologist	Medical Device	Recall for Product Correction	Class I	Hospital
11/07/2017	Various Immunochemistry modules. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
7/07/2017	cobas e 411 analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
7/07/2017	DigitalDiagnost Release 3.1.x	Medical Device	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
6/07/2017	ADVIA Chemistry Products - Ammonia, Salicylate and Alanine Amino transferase Assays. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
6/07/2017	Dimension Clinical Chemistry System and Dimension Vista System. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
5/07/2017	BVM (Bag-Valve-Mask) Manual Resuscitation Systems	Medical Device	Recall	Class I	Hospital
5/07/2017	Emblem and SQ-RX Subcutaneous-Implantable Cardiac Defibrillators (S-ICDs)	Medical Device	Recall for Product Correction	Class I	Hospital
4/07/2017	Maquet/Datascope Intra-Aortic Balloon Pump (IABP)	Medical Device	Recall for Product Correction	Class I	Hospital
4/07/2017	MOSAIQ and Treating on linear accelerators with the RATM license	Medical Device	Recall for Product Correction	Class II	Hospital
3/07/2017	Haemophilus Test medium (HTM). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
29/06/2017	Sysmex XN-450, XN-550 & other XN-L series Automated Haematology Analysers. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
28/06/2017	Zenith Alpha Thoracic Endovascular Graft	Medical Device	Recall	Class I	Hospital
27/06/2017	Bard ArcticSun ArticGel Pads	Medical Device	Recall for Product Correction	Class III	Hospital
27/06/2017	Codan Extension Set with T Connector	Medical Device	Recall	Class II	Hospital
27/06/2017	Comprehensive Nano Humeral Component PPS	Medical Device	Recall for Product Correction	Class II	Hospital
27/06/2017	Coulter LH and HmX Analysers. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
27/06/2017	Recapper for the AutoMate 2500 Family. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
27/06/2017	Sealing Caps (A0282 and A0313) used with compatible endoscopy instruments	Medical Device	Recall	Class II	Hospital
27/06/2017	Trauma Guide Wires, 70cm	Medical Device	Recall	Class II	Hospital
26/06/2017	ArjoHuntleigh Flowtron ACS900 Active Compression System	Medical Device	Recall for Product Correction	Class I	Hospital

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26/06/2017	Pivot, Pivot Hygiene, Pivot Hammock and Tony Pringle clip style sling with the keyhole clip fastening	Medical Device	Recall	Class II	Consumer
26/06/2017	Pre-Transfusion Blood Testing System PK7300 Automated Microplate System. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
26/06/2017	Promed High Concentration Oxygen Masks, Elongated (under chin), Adult Med Concentration	Medical Device	Recall	Class II	Hospital
26/06/2017	Unomedical High Concentration Oxygen Masks	Medical Device	Recall	Class I	Hospital
23/06/2017	Artis Systems in conjunction with Artis Table	Medical Device	Recall for Product Correction	Class I	Hospital
23/06/2017	BacT/ALERT BPN Culture Bottles. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
23/06/2017	BK Virus R-gene Real-time Detection and Quantification Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
23/06/2017	Hospira Plum 360 Infusion System	Medical Device	Recall for Product Correction	Class I	Hospital
23/06/2017	Kleihauer	Medical Device	Recall	Class III	Hospital
22/06/2017	iGUIDE software 2.2	Medical Device	Recall for Product Correction	Class I	Hospital
22/06/2017	Medtronic DLP Adapters and Pressure Display Sets	Medical Device	Recall	Class I	Hospital
22/06/2017	MOSAIQ Medical Oncology with software version 2.50.05 and higher	Medical Device	Recall for Product Correction	Class II	Hospital
22/06/2017	Sysmex CA-600 series with built-in barcode reader. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
22/06/2017	Unicel DxH Slidemaker Stainer Coulter Cellular Analysis System. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
21/06/2017	Accu2ipMTA Applicator	Medical Device	Recall	Class II	Hospital
21/06/2017	Encore 26 Inflation Device Single Pack	Medical Device	Recall	Class II	Hospital
20/06/2017	BVM (Bag-Valve-Mask) Manual Resuscitation Systems	Medical Device	Recall	Class I	Hospital
19/06/2017	Nordic Neuro Lab Headphones used with Siemens MRI systems	Medical Device	Recall for Product Correction	Class II	Hospital

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14/06/2017	HeartMate 3 Left Ventricular Assist System (LVAS)	Medical Device	Hazard Alert	Class II	Hospital
14/06/2017	Multiplate Analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
14/06/2017	Valproic Acid and Antibiotic TDM Multi-Calibrator. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
14/06/2017	Various Microgenics Application Sheets. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
13/06/2017	Caliber Inflation Device	Medical Device	Recall	Class II	Hospital
13/06/2017	Flocare Gastrotomy Tubes (G-tube) ENFit connector	Medical Device	Recall for Product Correction	Class II	Consumer
13/06/2017	GC80 Diagnostic X-Ray system	Medical Device	Recall for Product Correction	Class II	Hospital
9/06/2017	Amlodipine Sandoz 5mg tablets	Medicine	Recall	Class II	Consumer
9/06/2017	Calibrator 30 (2 pack) used with ADVIA Centaur Enhanced Estradiol (eE2) on the ADVIA Centaur, Centaur XP and Centaur XPT systems. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
9/06/2017	Rosa One 3.1	Medical Device	Recall for Product Correction	Class I	Hospital
9/06/2017	Valpam 5, 5mg tablets	Medicine	Recall	Class I	Consumer
8/06/2017	cobas omni MGP Reagent when used with cobas MPX assay. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
8/06/2017	Infinity Acute Care Monitoring System (IACS) used with Kontron C500 Cockpit	Medical Device	Recall for Product Correction	Class I	Hospital
8/06/2017	r ex-tem reagent.	Medical Device	Recall	Class II	Hospital
8/06/2017	Shimadzu Ceiling Type X-ray Tube Support	Medical Device	Recall for Product Correction	Class II	Hospital
7/06/2017	Radiometer ABL90 Series analysers with software version 3.2 or below. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
6/06/2017	Ankle Arthrodesis Nail 611AFN	Medical Device	Recall for Product Correction	Class II	Wholesale
6/06/2017	Philips IntelliVue MX40 Wearable Patient Monitors manufactured prior to the 6th of July 2015	Medical Device	Recall	Class I	Hospital

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5/06/2017	MULTIGENT Creatinine (Enzymatic) assay. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
5/06/2017	Organ Care System (OCS) Heart system - OCS Heart Console	Medical Device	Recall for Product Correction	Class II	Hospital
5/06/2017	Phenocell B 0.8% and 3% and Abtectcell III 0.8%RhD. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
2/06/2017	Alcon LuxOR LX3 Microscope Floor Stand	Medical Device	Recall for Product Correction	Class II	Hospital
2/06/2017	MiniMed 640G Insulin Infusion Pump	Medical Device	Recall for Product Correction	Class I	Consumer
1/06/2017	Access Total T3, Access Thyroglobulin, Access Free T4, Access GI Monitor Immunoassays. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
1/06/2017	DRX Revolution Mobile X-Ray System	Medical Device	Recall for Product Correction	Class II	Hospital
1/06/2017	DuraDiagnost Release 1.0, 2.0, 3.0 X-Ray systems	Medical Device	Recall for Product Correction	Class I	Hospital
1/06/2017	OptiLite Multi-Use Holmium Laser Fibers	Medical Device	Recall	Class II	Hospital
1/06/2017	PrepPlus & PrepPlus 2. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
31/05/2017	Stemetil 5mg Tablets	Medicine	Recall	Class II	Consumer
30/05/2017	Cook Multi-Use Holmium Laser Fibers	Medical Device	Recall for Product Correction	Class II	Hospital
30/05/2017	DxH 500 Haematology Analyser, with software version 1.0.2. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
30/05/2017	F-18 FDG Injection	Medicine	Recall for Product Correction	Class III	Hospital
30/05/2017	Laser Guide, Endotherapy, single use - TXMF600BFS Fibres, when using pullback device	Medical Device	Recall	Class I	Hospital
30/05/2017	VueOptic Visualisation Source & Flexor Vue Deflecting Endoscopic System	Medical Device	Recall for Product Correction	Class II	Hospital
29/05/2017	Randox Liquid Cardiac Controls when used with CKMB and Myoglobin assays. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital

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29/05/2017	Various Terumo Introducer Kits	Medical Device	Recall	Class II	Hospital
26/05/2017	Blooms The Chemist (BTC) Paracetamol Codeine tablets, BTC Rosuvastatin 10mg tablets and APOTEX-Pantoprazole 20mg and 40mg tablets	Medicine	Recall	Class II	Consumer
26/05/2017	N Protein Standard SL and N/T Protein Controls SL when used with N Antiserum to Human Ceruloplasmin. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
26/05/2017	PROT 1 CAL and PROT 1 CON when used with Dimension Vista CER Flex Reagent Cartridge. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
26/05/2017	ROSA Brain and ROSA One Surgical Robots	Medical Device	Recall for Product Correction	Class I	Hospital
26/05/2017	Valium 5mg tablets	Medicine	Recall	Class I	Consumer
25/05/2017	ALBAclone Advanced Partial RhD Typing Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
24/05/2017	V-Lyte Dilution Check & V-Lyte Integrated Multisensor Technology (IMT). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
23/05/2017	Endo Peanut 5mm Device	Medical Device	Recall	Class II	Hospital
23/05/2017	Philips V60 non-invasive ventilator	Medical Device	Recall for Product Correction	Class I	Hospital
22/05/2017	Dynabeads HLA Class II and Dynabeads HLA Cell Prep II. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
19/05/2017	1322 3M Comply Lead Free Steam Indicator Tapes & 1355 3M Comply Lead Free Steam Indicator Tapes for Disposable Wraps	Medical Device	Recall	Class III	Hospital
19/05/2017	Kii abdominal trocars	Medical Device	Recall	Class II	Hospital
19/05/2017	OEC Elite systems	Medical Device	Recall for Product Correction	Class II	Hospital
19/05/2017	Philips IntelliVue Neuromuscular Transmission (NMT) Patient Cables	Medical Device	Recall	Class II	Hospital
18/05/2017	Carestation 620, 650 and 650c A1 Anaesthesia devices	Medical Device	Recall for Product Correction	Class I	Hospital

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18/05/2017	DigitalDiagnost Release 3.1.x	Medical Device	Recall for Product Correction	Class III	Hospital
18/05/2017	Sysmex XN-10 and XN-20 Automated Haematology Analysers. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
17/05/2017	AbbVie Percutaneous Endoscopic Gastronomy and Jejunal tubing kits (AbbVie PEG and AbbVie J)	Medical Device	Recall for Product Correction	Class III	Hospital
17/05/2017	LABType DNA Typing Tests (for transplant compatibility analysis). An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
16/05/2017	Miele washer-disinfectors when connected to an in-house network	Medical Device	Recall for Product Correction	Class II	Hospital
16/05/2017	Spectra Optia Apheresis Systems	Medical Device	Recall for Product Correction	Class II	Hospital
16/05/2017	Trauma Implants - intramedullary nails	Medical Device	Recall	Class II	Hospital
16/05/2017	UniCel DxH 800 Coulter Cellular Analysis System and UniCel DxH 600 Coulter Cellular Analysis System	Medical Device	Recall for Product Correction	Class I	Hospital
15/05/2017	cobas 4800 HPV Amplification/Detection Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
15/05/2017	Synchron Systems Microalbumin (MA) Reagent	Medical Device	Recall	Class II	Hospital
12/05/2017	Carina Mobile Lifts	Medical Device	Recall for Product Correction	Class II	Consumer
12/05/2017	Microcatheter SONIC 1.5F	Medical Device	Recall	Class II	Hospital
12/05/2017	Ultrasound Probe Cover (Telescopic folded with gel); and	Medical Device	Recall	Class I	Hospital
10/05/2017	Asserachrom Von Willebrand Factor (VWF):Collagen (CB). An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
10/05/2017	Ovatio, Paradym, Paradym RF and Intensia Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronisation Therapy Defibrillators (CRT-Ds)	Medical Device	Recall for Product Correction	Class II	Hospital
9/05/2017	Acor and Integrale primary femoral stem with modular neck	Medical Device	Recall for Product Correction	Class II	Hospital

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9/05/2017	Endoscopic Curved Needle Driver, LapSac Introducer and LapSac Introducer Set	Medical Device	Recall	Class II	Hospital
9/05/2017	Polysorb Braided Absorbable Suture and EndoStitch Loading Unit with Polysorb Suture	Medical Device	Recall	Class II	Hospital
9/05/2017	Wingman35 Crossing Catheters	Medical Device	Recall	Class I	Hospital
8/05/2017	Cook Pereyra-Raz Ligature Carrier, Stamey Needle and Clarke-Reich Laparoscopic Knot Pusher	Medical Device	Recall	Class II	Hospital
8/05/2017	ETEST ETP32 (Ertapenem) WW B30. An in vitro diagnostic medical device (IVD) for Antimicrobial susceptibility testing.	Medical Device	Recall for Product Correction	Class II	Hospital
8/05/2017	Medtronic SynchroMed II Pumps	Medical Device	Hazard Alert	Class I	Hospital
8/05/2017	Prosigna Breast Cancer Prognostic Gene Signature Assay. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
4/05/2017	Sysmex XN-550 Automated Haematology Analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
3/05/2017	Jackson-Pratt Perforated and Hemaduct Wound Drainage Systems	Medical Device	Recall	Class II	Hospital
2/05/2017	Abilify Maintena aripiprazole (as monohydrate) 400 mg powder and solvent for prolonged release suspension for injection	Medicine	Recall	Class II	Retail
2/05/2017	ARCHITECT Free T4 Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
2/05/2017	Meducore Easy Automatic External Defibrillator (AED) - Battery Pack	Medical Device	Recall for Product Correction	Class I	Retail
1/05/2017	Affixus Hip Fracture Nail	Medical Device	Recall	Class II	Hospital
1/05/2017	Brennen Skin Graft Mesher - 4.5 and 6.5 inch	Medical Device	Recall for Product Correction	Class II	Hospital
1/05/2017	Corpuls3 CO2 Disposable Naso-oral Adaptor Capone	Medical Device	Recall for Product Correction	Class II	Hospital
28/04/2017	Omega+ Lag Screw	Medical Device	Recall	Class II	Hospital
28/04/2017	Venture RX, OTW and CS Catheters	Medical Device	Recall	Class I	Hospital

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27/04/2017	Alaris Syringe Pumps (GH, CC, TIVA, PK and Enteral) - All Variants	Medical Device	Recall for Product Correction	Class I	Hospital
27/04/2017	Artis Dialysis Systems - 230V, 230V Physio & 230 V Physio I	Medical Device	Recall for Product Correction	Class I	Hospital
27/04/2017	Safety Clip - Hoffmann Limb Reconstruction Frame (LRF) Bone Transport	Medical Device	Recall	Class II	Hospital
26/04/2017	Architect Sex Hormone Binding Globulin (SHBG) reagents. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
26/04/2017	Healon Ophthalmic Viscosurgical Devices (OVD) 0.55mL	Medical Device	Recall	Class II	Hospital
26/04/2017	neoBLUE LED Phototherapy Lights (2nd Generation)	Medical Device	Recall	Class II	Hospital
26/04/2017	Prismaflex Control Unit (with software versions prior to 8.10)	Medical Device	Recall for Product Correction	Class I	Hospital
26/04/2017	RAPIDPoint 500 Blood Gas Analyser with V2.4 Software	Medical Device	Recall for Product Correction	Class II	Hospital
26/04/2017	Vitreectomy Cutter	Medical Device	Recall	Class II	Hospital
24/04/2017	Sensis system	Medical Device	Recall for Product Correction	Class II	Hospital
21/04/2017	Absorb Bioresorbable Vascular Scaffold (BVS) System	Medical Device	Recall	Class I	Hospital
21/04/2017	Access BR Monitor. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
21/04/2017	ADVIA Centaur / XP / XPT / CP Systems Insulin (IRI) assay. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
21/04/2017	Laser photocoagulator Easyret software version 1.03	Medical Device	Recall for Product Correction	Class I	Hospital
21/04/2017	VITEK 2 Identification / Antimicrobial Susceptibility Test Cards. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
20/04/2017	ACQUITY UPLC Sample Organisers. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
20/04/2017	AQUIOS CL Flow Cytometer utilising software versions 2.0 and 2.0.1. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
20/04/2017	iChemVELOCITY Automated Urine Chemistry Systems equipped with Colour/Clarity/Specific Gravity Module. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
20/04/2017	Mobile Digital X-Ray GM60A	Medical Device	Recall for Product Correction	Class II	Hospital
20/04/2017	Monopolar HF Resection Electrodes	Medical Device	Recall	Class II	Hospital
20/04/2017	Synchron Systems Cholesterol, Creatinine, HDL Cholesterol, Lactate, Triglyceride, Uric Acid & Salicylate Reagents. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
20/04/2017	WECK Visistat 35R Disposable Skin Stapler	Medical Device	Recall for Product Correction	Class III	Hospital
20/04/2017	Wilson Frame Tempur Pedic Pad Set	Medical Device	Recall	Class II	Hospital
19/04/2017	ACUSON S Family ultrasound systems with software versions VD10A or VD10C when using 18L6 HD transducer	Medical Device	Recall for Product Correction	Class II	Hospital
19/04/2017	EZ-Load Lens Delivery System	Medical Device	Recall	Class I	Hospital
19/04/2017	Hyland's Teething Tablets and Nighttime Teething Tablets	Medicine	Recall	Class II	Consumer
19/04/2017	neoBLUE blanket LED Phototherapy Systems	Medical Device	Recall for Product Correction	Class II	Hospital
19/04/2017	SOMATOM Force with software version VA50A	Medical Device	Recall for Product Correction	Class II	Hospital
19/04/2017	TB2000 Disposable t-piece infant resuscitation circuit with adjustable PEEP	Medical Device	Recall	Class I	Hospital
19/04/2017	Visum LED Surgical Lighting system - EDS Light Suspensions, Central Axis	Medical Device	Recall for Product Correction	Class II	Hospital
18/04/2017	SwiveLock SP Suture Anchor	Medical Device	Recall	Class II	Hospital
13/04/2017	Span-K (potassium chloride) 600mg Tablets	Medicine	Recall	Class II	Consumer
12/04/2017	Newport HT70 and HT70 Plus Ventilators	Medical Device	Recall for Product Correction	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
11/04/2017	Dimension Troponin 1 (TNI) & Dimension Vista Digoxin (DIGXN), Estradiol (E2), Ferritin (FERR), Prolactin (PRL) & Thyroid Stimulating Hormone (TSH) assays. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
10/04/2017	BodyGuard Pump IV Administration Set	Medical Device	Recall	Class II	Hospital
10/04/2017	Corpuls3 defibrillator/monitoring unit – Printer Paper	Medical Device	Recall	Class III	Hospital
10/04/2017	Secondary Set Oncology	Medical Device	Recall	Class II	Hospital
7/04/2017	N Latex Carbohydrate-deficient Transferrin (CDT). An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class III	Hospital
7/04/2017	ROHO High Profile and Mid Profile Single Compartment Cushion with Sensor Ready Technology	Medical Device	Recall	Class II	Consumer
6/04/2017	Cook Biodesign 1-Layer Tissue Graft and Cook Biodesign 4-Layer Tissue Graft	Medical Device	Recall for Product Correction	Class II	Hospital
6/04/2017	LiquiBand FIX8 Hernia Mesh Adhesive Fixation Device	Medical Device	Recall for Product Correction	Class II	Hospital
5/04/2017	ARROW PICC Kits with Peel-Away Sheath Component	Medical Device	Recall for Product Correction	Class III	Hospital
5/04/2017	Philips Allura Xper X-Ray Systems	Medical Device	Recall for Product Correction	Class II	Hospital
5/04/2017	Solus Flexible, wire-reinforced laryngeal mask airway	Medical Device	Recall	Class I	Hospital
4/04/2017	da Vinci Xi EndoWrist Stapler Release Kit (SRK)	Medical Device	Recall for Product Correction	Class II	Hospital
4/04/2017	Philips IntelliVue MX40 WLAN Patient Wearable Monitor	Medical Device	Recall for Product Correction	Class II	Hospital
3/04/2017	Monolisa HCV Ag-Ab ULTRA V2 assay. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
3/04/2017	NucliSENS Lysis Buffer. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
31/03/2017	iASSIST Validation Tool	Medical Device	Recall for Product Correction	Class II	Hospital
31/03/2017	Sample Probe Connector used with cobas modules. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
29/03/2017	Accu-Chek Connect diabetes management app – Bolus Advisor function	Medical Device	Recall for Product Correction	Class II	Hospital
29/03/2017	Multiple Zenith Alpha Thoracic Endovascular Graft Products	Medical Device	Recall for Product Correction	Class I	Hospital
28/03/2017	DBS Lead Depth Stop	Medical Device	Recall for Product Correction	Class I	Hospital
28/03/2017	Sysmex XN-Series Automated Haematology Analysers. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
27/03/2017	ADVIA Centaur BR Assay (50 and 250 tests). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
27/03/2017	cobas 8000 modular analyser series. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
27/03/2017	Philips HeartStart MRx Monitor/Defibrillator	Medical Device	Recall for Product Correction	Class I	Hospital
24/03/2017	ADVIA Centaur BR Assay (50 and 250 tests). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
24/03/2017	ROSA Brain 3.0.0 Robotic Surgical Assistant	Medical Device	Recall for Product Correction	Class I	Hospital
24/03/2017	VITEK MS Clinical Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
23/03/2017	Multiple Vivid Ultrasound Products	Medical Device	Recall for Product Correction	Class II	Hospital
22/03/2017	cobas 8100 BRF and URF with software versions 02-xx. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
22/03/2017	NC Trek Rx Coronary Dilatation System	Medical Device	Recall	Class I	Hospital
21/03/2017	EpiPen Auto Injectors	Medicine	Recall	Class I	Consumer
21/03/2017	Xpert CT/NG Assay. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
20/03/2017	Minop Invent 30 degrees Trocar D 8.3mm L 150mm	Medical Device	Recall	Class II	Hospital
20/03/2017	ONLINE TDM Gentamicin. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
17/03/2017	Access 2 Family of Immunoassay Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
17/03/2017	Covidien Curity Eye Pad, Curity Eye Pad Oval, Curity Sodium Chloride Dressing	Medical Device	Recall	Class II	Hospital
17/03/2017	VITROS Immunodiagnostic Products NT-proBNP Reagent Pack. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
16/03/2017	Brilliance Big Bore Oncology CT and Radiology CT (with software version 4.2.0)	Medical Device	Recall for Product Correction	Class II	Hospital
14/03/2017	AMM Flex Reagent Cartridge used with Dimension Clinical Chemistry System	Medical Device	Recall for Product Correction	Class II	Hospital
14/03/2017	Dimension Vista 500 Intelligent Lab System and Dimension Vista 1500 Intelligent Lab System. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
14/03/2017	FlexTherm Heater Cooler Device	Medical Device	Recall	Class II	Hospital
14/03/2017	VIDAS 3 System (used with software version 1.1.4) An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
10/03/2017	Cook Bush SL and Bush DL Ureteral Illuminating Catheters	Medical Device	Recall	Class II	Hospital
10/03/2017	EliA Sample Diluent	Medical Device	Recall	Class II	Hospital
10/03/2017	LaserEdge Knives	Medical Device	Recall	Class I	Hospital
10/03/2017	Liaison C-Peptid Assay. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
10/03/2017	Mycophenolate Sandoz (capsules) 250mg	Medicine	Recall	Class II	Retail
10/03/2017	Randox Myoglobin Assay	Medical Device	Recall for Product Correction	Class II	Hospital
10/03/2017	Thoracentesis/paracentesis kit, Illinois needle aspiration & Jamshidi needle bone marrow	Medical Device	Recall	Class II	Hospital
10/03/2017	TriForce Peripheral Crossing Set	Medical Device	Recall	Class I	Hospital
9/03/2017	multiFiltratePRO devices	Medical Device	Recall for Product Correction	Class II	Hospital
8/03/2017	Danis Procedure Pack and Danis Procedure Pack - Basic	Medical Device	Recall for Product Correction	Class II	Hospital
8/03/2017	Iodine 131	Medicine	Recall	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
8/03/2017	Wireless Foot Switch - Artis systems	Medical Device	Recall for Product Correction	Class II	Hospital
7/03/2017	LipiFlow System Activator	Medical Device	Recall for Product Correction	Class III	Hospital
7/03/2017	Sealapex Xpress	Medical Device	Recall	Class II	Retail
6/03/2017	BrightView, BrightView X and BrightView XCT with Tangential, Radius, and Roll drive assembly	Medical Device	Recall for Product Correction	Class I	Hospital
6/03/2017	VisuMax Laser	Medical Device	Recall for Product Correction	Class II	Hospital
3/03/2017	Endurant / Endurant II 23mm and 25mm Bifurcated Stent Graft Systems	Medical Device	Recall	Class I	Hospital
3/03/2017	ETEST products. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
3/03/2017	Left Double Lumen Endobronchial Tube with Parker Flex-Tip	Medical Device	Recall	Class I	Hospital
3/03/2017	Panocell-20 and Capture-R Ready-ID. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class III	Hospital
3/03/2017	VITROS Chemistry Products VANC Reagent. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
2/03/2017	Artis Q Systems with A100G generators	Medical Device	Recall for Product Correction	Class II	Hospital
2/03/2017	Elecsys Thyroid Stimulating Hormone (TSH) and Elecsys Parathyroid Hormone (PTH) (1-84) when used on the cobas e 602 module. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
2/03/2017	LIFEPAK 15 Monitor/Defibrillators with End-Tidal CO2 (EtCO2) functionality	Medical Device	Recall for Product Correction	Class II	Hospital
2/03/2017	Medtronic StrataMR Adjustable Valves & Shunts used in the management of hydrocephalus	Medical Device	Recall	Class I	Hospital
2/03/2017	Screwdriver Shaft, hexagonal, large, diameter 3.5mm, length 165mm, for Quick Coupling	Medical Device	Recall	Class II	Hospital
1/03/2017	Reflection Deadblow Mallet	Medical Device	Recall	Class II	Hospital
28/02/2017	Artiste, Oncor and Primus Digital Linear Accelerators running Control Console software version 13.0.302	Medical Device	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
28/02/2017	ConMed Hyfrecator 2000 Electrosurgical Unit and Accessory Packages containing Handpiece Sheaths	Medical Device	Recall	Class II	Hospital
28/02/2017	Getinge HS33 Sterilisers	Medical Device	Recall for Product Correction	Class II	Hospital
28/02/2017	MobiCath Bi-Directional Guiding Sheath, Small Curve	Medical Device	Recall	Class II	Hospital
28/02/2017	Turon Impaction Fixture and RSP Monoblock Impaction Fixture (found in instrument trays - FA RSP Glenoid, FA RSP Monoblock Ltd Release and FA Turon Humerakl Head 2010)	Medical Device	Recall	Class II	Hospital
28/02/2017	Various ID-Diacell Products. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
27/02/2017	Aerowound Combine Dressing ACD2040S, size 20cm x 40cm	Medical Device	Recall	Class II	Retail
27/02/2017	Liquichek Diabetes Control	Medical Device	Recall for Product Correction	Class II	Hospital
27/02/2017	Magnetic Silica MagSIL. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class I	Hospital
27/02/2017	PregSure Digital Pregnancy Test & Pregsure Pregnancy Test. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Retail
27/02/2017	V60 Respiratory Ventilator with software version 2.20	Medical Device	Recall for Product Correction	Class I	Hospital
24/02/2017	Cordis S.M.A.R.T. Flex Vascular Stent System	Medical Device	Recall	Class I	Hospital
24/02/2017	Lotus Valve System	Medical Device	Recall	Class I	Hospital
24/02/2017	Philips BrightView / BrightView X / BrightView XCT and BrightView X upgrade to XCT	Medical Device	Recall for Product Correction	Class II	Hospital
24/02/2017	Philips Ingenuity CT system	Medical Device	Recall for Product Correction	Class II	Hospital
24/02/2017	Various Polyethylene Implants	Medical Device	Recall	Class I	Hospital
23/02/2017	Ellex Prager scleral shell for Biometry and 10MHZ Biometric A Scan Probe Kit	Medical Device	Recall for Product Correction	Class I	Hospital
21/02/2017	ADVIA Chemistry Lactate Dehydrogenase (LDLP and LDPL). An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
21/02/2017	Atrium Thoracic Catheters, Sizes 8Fr & 10Fr	Medical Device	Recall for Product Correction	Class II	Hospital
21/02/2017	First Response Digital Pregnancy Test and First Response Test & Reassure. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class III	Retail
21/02/2017	ImmunoCAP Allergen fx20, Food. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class III	Hospital
17/02/2017	BioloX Forte 36mm Alumina Ceramic Head	Medical Device	Hazard Alert	Class II	Hospital
16/02/2017	Medtronic Strata II/Strata NSC Valves (including Burr Hole and Lumbar Peritoneal [LP]) used in the management of hydrocephalus	Medical Device	Hazard Alert	Class II	Hospital
16/02/2017	Radpharm PYP kit for the production of Technetium (99mTc) tin pyrophosphate powder for injection multidose vial	Medicine	Recall for Product Correction	Class II	Hospital
15/02/2017	i-STAT1 Analyser when used with i-STAT Celite Activated Clotting Time (ACT) & Kaolin ACT Cartridges. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class III	Hospital
15/02/2017	Steelco DS1000 Washer Disinfectors with an auto load/unload module attached	Medical Device	Recall for Product Correction	Class II	Hospital
14/02/2017	Artis Systems with software versions VC14, VC21, VD10, VD11 and VE10	Medical Device	Recall for Product Correction	Class II	Hospital
14/02/2017	Diffiam Sore Throat Ready to Use Iodine Gargle (povidone-iodine 10mg/mL), 200mL Bottle	Medicine	Recall	Class II	Retail
14/02/2017	Elecsys Anti-HAV assay run on the Elecsys 2010 and cobas e 411 analysers, cobas e 601/602 modules and Modular Analytics E-Module. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
14/02/2017	HYDRO LeMaitre Valvulotome Devices	Medical Device	Recall	Class II	Hospital
13/02/2017	Inhalo Medical Oxygen with Integrated Pressure Regulator/Flowmeter	Medical Device	Recall for Product Correction	Class II	Retail
13/02/2017	MiniMed 640G Insulin Infusion Pump (with software version 2.6)	Medical Device	Recall for Product Correction	Class I	Consumer
9/02/2017	ENDOEYE HD II Rigid Videoscope	Medical Device	Recall for Product Correction	Class I	Hospital

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9/02/2017	METS Modular Tumour System	Medical Device	Hazard Alert	Class II	Hospital
9/02/2017	Philips BrightView XCT and Philips BrightView X to XCT Upgrade Kit	Medical Device	Recall for Product Correction	Class III	Hospital
8/02/2017	ABC1 HLA Typing Tray included in ABC1 / ABC2 Kits. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
8/02/2017	Advantx Legacy/Legacy-D Radiographic and Fluoroscopic System	Medical Device	Recall for Product Correction	Class II	Hospital
8/02/2017	ADVIA Centaur XPT System with software versions V1.0 to V1.2. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
8/02/2017	AngioJet Ultra 5000A Console - Foot Switch	Medical Device	Recall for Product Correction	Class II	Hospital
8/02/2017	Duloxetine 30mg and 60mg capsules, RBX and Sandoz	Medicine	Recall	Class II	Retail
8/02/2017	Immulate 2000 / Immulate 2000 XPI Sex Hormone Binding Globulin (SHBG). An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
8/02/2017	StarClose SE Vascular Closure System (VCS), International Green Sheath	Medical Device	Recall	Class II	Hospital
7/02/2017	Brainlab Offset Cup Impactor Universal (blue handle)	Medical Device	Recall for Product Correction	Class II	Hospital
6/02/2017	Drager V Series Ventilator with the Optional PS500 External Power Supply Unit installed	Medical Device	Recall for Product Correction	Class I	Hospital
6/02/2017	E.T.O.I.L.E sytem extension table (leg holder)	Medical Device	Recall for Product Correction	Class II	Hospital
3/02/2017	AnastoClip AC Closure System	Medical Device	Recall	Class III	Hospital
3/02/2017	ARTISTE, ONCOR and PRIMUS Digital Linear Accelerators	Medical Device	Recall for Product Correction	Class II	Hospital
3/02/2017	Figulla Flex II ASD, Figulla Flex II PFO and Occlutech PDA Occluder Cardiac Occluders	Medical Device	Recall for Product Correction	Class II	Hospital
3/02/2017	iChemVELOCITY Automated Urine Chemistry Systems. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
3/02/2017	Uronav, Transperineal option - Stepper with Stand	Medical Device	Recall for Product Correction	Class III	Hospital

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2/02/2017	Meropenem Kabi 500mg and 1g (Powder for injection) vials	Medicine	Recall for Product Correction	Class II	Hospital
1/02/2017	ETEST XM256 (Cefuroxime) Foam and SPB. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
1/02/2017	Lysercell WDF 2 x 4L used on Sysmex XN-Series Automated Haematology Analysers. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
1/02/2017	Valleylab Laparoscopic Handset, Four-Function	Medical Device	Recall	Class I	Hospital
31/01/2017	Diego Elite Tubeset, Standard and Declog	Medical Device	Recall	Class II	Hospital
31/01/2017	Glucose-6-Phosphate Dehydrogenase. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
31/01/2017	LIFEPAK 1000 Defibrillators	Medical Device	Recall for Product Correction	Class I	Retail
30/01/2017	Alaris System Pump module (LVP) 8100 and Air-In-Line (AIL) Sensor Kits	Medical Device	Recall for Product Correction	Class II	Hospital
30/01/2017	Boostrix, Havrix, Twinrix, Typherix, Varilrix Vaccines	Medicine	Recall	Class II	Retail
30/01/2017	OER-AW Endoscope Reprocessor	Medical Device	Recall for Product Correction	Class III	Hospital
27/01/2017	Acecide Test Strips	Medical Device	Recall	Class II	Hospital
27/01/2017	Alaris Syringe Module Model 8110	Medical Device	Recall for Product Correction	Class II	Hospital
27/01/2017	NX workstation with NX 3.0.8950 image processing software	Medical Device	Recall for Product Correction	Class II	Hospital
25/01/2017	BK Virus R-gene kit when used on SmartCycler 2.0 platform. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
25/01/2017	Magnetic Silica MagSIL. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
25/01/2017	Radiometer ABL800 Series Analysers (used with software version 3.1 MR5). An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
25/01/2017	RaySearch RayStation 4.5, 4.7, 5, and 6	Medical Device	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
25/01/2017	SynchroMed II Infusion System and Model 8870 Software Application Card used in the 8840 N'Vision Clinician Programmer	Medical Device	Recall for Product Correction	Class I	Hospital
25/01/2017	Sysmex XN-9000 Automated Haematology System. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
24/01/2017	Clements Suction Regulators	Medical Device	Recall for Product Correction	Class II	Hospital
24/01/2017	DRX Revolution Mobile X-Ray System	Medical Device	Recall for Product Correction	Class II	Hospital
24/01/2017	IRT Screening Assay used for screening newborns for cystic fibrosis. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
24/01/2017	Radiometer ABL90 Series Analysers (used with software version 3.1 MR5). An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
23/01/2017	Innovance D-Dimer assay run on Sysmex CS Systems. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
23/01/2017	LIFEPAK 15 Monitor/Defibrillator	Medical Device	Recall for Product Correction	Class II	Hospital
20/01/2017	Li-Ion Battery used with the Cardiosave Hybrid/Rescue Intra-aortic Balloon Pump (IABP)	Medical Device	Recall for Product Correction	Class II	Hospital
20/01/2017	Xpert BCR-ABL Monitor assay (used for monitoring patients being treated for chronic myelogenous leukaemia). An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
19/01/2017	Model 3200 programmer for Emblem, Emblem MRI and SQ-Rx Subcutaneous-Implantable Cardiac Defibrillators (S-ICDs)	Medical Device	Recall for Product Correction	Class I	Hospital
18/01/2017	Calibrator A used with ADVIA Centaur FT4 (free thyroxine) assay on the ADVIA Centaur, Centaur XP, Centaur XPT Systems. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
18/01/2017	ISOMed Arterial Embolectomy Catheters – Single Lumen (2F & 3F)	Medical Device	Recall for Product Correction	Class II	Hospital
18/01/2017	Vanguard Open Box Femoral Components	Medical Device	Hazard Alert	Class II	Hospital
17/01/2017	Comprehensive Reverse Shoulder Tray	Medical Device	Hazard Alert	Class II	Hospital

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17/01/2017	Mammomat Inspiration System with software version VB30 and Biopsy functionality	Medical Device	Recall for Product Correction	Class II	Hospital
13/01/2017	Covidien Devon Light Glove (included in multiple Procedure Packs)	Medical Device	Recall for Product Correction	Class II	Hospital
12/01/2017	Biolo World Slimming Capsules	Medicine	Recall	Class II	Consumer
12/01/2017	Cryptococcal Antigen Lateral Flow Assay (CrAg LFA). An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
12/01/2017	Roth Net Standard Polyp Retriever U-711151	Medical Device	Recall	Class III	Hospital
11/01/2017	MEDPOR Facial and Oculoplastic Sizer Sets and TLS Drain System	Medical Device	Recall	Class II	Hospital
11/01/2017	Pak Lx Assay	Medical Device	Recall for Product Correction	Class II	Hospital
10/01/2017	ADVIA Centaur, Dimension Vista & Immulite Systems	Medical Device	Recall for Product Correction	Class I	Hospital
10/01/2017	Monaco (with the use of Elekta Motorised Wedges)	Medical Device	Recall for Product Correction	Class II	Hospital
9/01/2017	ARROW OnControl Bone Marrow Biopsy System Tray	Medical Device	Recall	Class II	Hospital
6/01/2017	Transpac 4 Disposable Pressure Transducer Monitoring Kit	Medical Device	Recall	Class II	Hospital
5/01/2017	Accu-Chek Connect diabetes management app	Medical Device	Recall for Product Correction	Class II	Consumer
5/01/2017	Covidien Devon Light Glove	Medical Device	Recall	Class II	Hospital
5/01/2017	Plum 360 Infusion Pump, software version 15.02	Medical Device	Recall for Product Correction	Class II	Hospital
4/01/2017	Dimension Clinical Chemistry System and Dimension Vista System. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
4/01/2017	VITROS Chemistry Products Na+ Slides. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
3/01/2017	BioFlo PICC with ENDEXO and PASV Valve Technology with Nitinol Guidewire - Catheterisation kit, central venous	Medical Device	Recall	Class II	Hospital
23/12/2016	Biograph mCT and Biograph mCT Flow	Medical Device	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
23/12/2016	Chinese Sports Injuries Pill (Zhong Guo Die Da Wan)	Medicine	Recall	Class II	Consumer
23/12/2016	Glucose GLUC-PAP. An in-vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
23/12/2016	iPlan RT, iPlan RT Dose and BrainSCAN	Medical Device	Recall for Product Correction	Class I	Hospital
23/12/2016	Mirena levonorgestrel 52 mg intrauterine drug delivery system	Medicine	Recall for Product Correction	Class I	Retail
23/12/2016	Nellcor RS10 SpO2 Forehead Sensor	Medical Device	Recall	Class II	Hospital
23/12/2016	Trauma RIA (Reamer/Irrigator/Aspirator) System	Medical Device	Recall	Class II	Hospital
23/12/2016	UniCel DxH 600 & 800 Coulter Cellular Analysis Systems. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
22/12/2016	Arsenal Set-Screw, a sub-component of the Arsenal Spinal Fixation System	Medical Device	Hazard Alert	Class II	Hospital
22/12/2016	Imager II Angiographic Catheter	Medical Device	Recall for Product Correction	Class II	Hospital
22/12/2016	Imager II Angiographic Catheters	Medical Device	Recall	Class II	Hospital
22/12/2016	Oncentra External Beam (formerly known as Oncentra MasterPlan during release of v3.x)	Medical Device	Recall for Product Correction	Class II	Hospital
22/12/2016	SMF and MDF Modular Neck Hip Prosthesis	Medical Device	Hazard Alert	Class II	Hospital
21/12/2016	Dimension Vista V-LYTE Integrated Multisensor (used for measuring Na ⁺ /K ⁺ /Cl ⁻). An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
20/12/2016	Artis zee, Artis Q and Artis Q.zen systems with software version VD11B	Medical Device	Recall for Product Correction	Class I	Hospital
20/12/2016	Greatbatch Medical Offset Reamer Handle	Medical Device	Recall for Product Correction	Class II	Hospital
20/12/2016	sleep.safe Set, sleep.safe Set Plus and sleep.safe Set Paed	Medical Device	Recall	Class I	Consumer
16/12/2016	Smart Site Add-on Bag Access Device	Medical Device	Recall	Class II	Hospital
16/12/2016	Vinyl examination/treatment glove, non-powdered	Medical Device	Recall	Class II	Retail

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
15/12/2016	DePuy Synthes Impactor for PFNA Blade	Medical Device	Recall	Class II	Hospital
15/12/2016	Medical Mattresses and Mattress Covers	Medical Device	Recall	Class II	Hospital
15/12/2016	PreciControl Varia when used with Elecsys Parathyroid Hormone (PTH) assay on the cobas e 411 analyser. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
14/12/2016	Artiset HD SN HC Bloodlines (blood tubing system used for haemodialysis with Artis system)	Medical Device	Recall for Product Correction	Class I	Hospital
14/12/2016	Dräger Oxylog Transport Ventilators - Oxylog 3000 and Oxylog 3000plus	Medical Device	Recall for Product Correction	Class I	Hospital
14/12/2016	Merge eFilm Workstation/eFilm Lite versions 2.1, 2.1.2, 3.0, 3.1, 3.3.5, 3.4, 4.0, 4.0.1, 4.0.2, 4.0.3 and 4.1	Medical Device	Recall for Product Correction	Class II	Hospital
14/12/2016	VITROS Chemistry Products UPRO Slides for measurement of protein in urine (using VITROS 250/350/5,1 FS/4600 and 5600 Systems). An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
13/12/2016	Amplia MRI CRT-D SureScan and Claria MRI CRT-D SureScan	Medical Device	Hazard Alert	Class I	Hospital
13/12/2016	Bard StatLock Catheter Stabilisation Device	Medical Device	Recall for Product Correction	Class II	Hospital
13/12/2016	Cancellous Bone Screws 16mm, 20mm, 25mm, 30mm, 35mm, 45mm, 50mm	Medical Device	Recall	Class III	Hospital
13/12/2016	Conmed GS2000 - 50L Abdominal Insufflator	Medical Device	Recall for Product Correction	Class I	Hospital
13/12/2016	HICO - Variotherm 550 Hypothermia/Hyperthermia Unit	Medical Device	Recall for Product Correction	Class II	Hospital
13/12/2016	LQT6283LB In-line leucoreduction system for red cell concentrates with LCRD2 Leucoflex soft filter	Medical Device	Recall for Product Correction	Class II	Hospital
13/12/2016	Reagent Red Blood Cells 0.8% Resolve Panel C. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class I	Hospital
13/12/2016	UniCel DxC Synchron Wash Concentrate II when used with Thermo-Fisher Lithium reagent (Ref A19611). An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
12/12/2016	Alaris System Point of Care Unit (PC unit)	Medical Device	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
12/12/2016	Algerbrush II and Algerbrush II Accessories	Medical Device	Recall for Product Correction	Class I	Hospital
12/12/2016	ID-DC Screening II. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
12/12/2016	Philips Ingenia 1.5T and Ingenia 3.0T MR systems with Ingenia MR-OR solution	Medical Device	Recall for Product Correction	Class II	Hospital
9/12/2016	Philips MX 16-slice CT systems featured with Lung Nodule Analysis	Medical Device	Recall for Product Correction	Class I	Hospital
9/12/2016	Prestige 2, Prestilix, Prestige VH, Prestige SI, RFX/SFX, Legacy and Precision 500D, ADVANTX and Innova 2000 Systems	Medical Device	Recall for Product Correction	Class II	Hospital
8/12/2016	F-18 FDG Injection (Fludeoxyglucose 18F)	Medicine	Recall	Class III	Hospital
6/12/2016	Architect Active-B12 Reagent Kit. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
6/12/2016	Atrium Chest Drains	Medical Device	Recall for Product Correction	Class II	Hospital
6/12/2016	Quinn's Advantage Medium with Hepes (In vitro fertilisation culture medium)	Medical Device	Recall	Class II	Hospital
6/12/2016	Radiometer ABL700 and ABL800 series blood gas analysers. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
6/12/2016	TB2000 Disposable t-piece infant resuscitation circuit with adjustable PEEP	Medical Device	Recall	Class II	Hospital
5/12/2016	CentraLink Data Management Systems with software versions v13x, v14x, v15x. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
5/12/2016	Distraction Screws Packaged sterile	Medical Device	Recall	Class II	Hospital
5/12/2016	O2Vent T	Medical Device	Recall for Product Correction	Class II	Consumer
2/12/2016	balanSys UNI convex polyethylene (PE) inlay x/5 (with thickness 5)	Medical Device	Hazard Alert	Class II	Hospital
2/12/2016	CONSERVE Shell, DYNASTY Metal Liner, RIM-LOCK Metal Liner, LINEAGE Metal Liner	Medical Device	Hazard Alert	Class II	Hospital
2/12/2016	Dilantin (phenytoin sodium) 30 & 100 mg capsule bottles and Dilantin (phenytoin) Infatabs 50 mg tablet bottle	Medicine	Recall for Product Correction	Class II	Consumer

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
2/12/2016	O2Vent T	Medical Device	Recall for Product Correction	Class II	Consumer
1/12/2016	Medical Mattresses and Mattress Covers	Medical Device	Recall	Class II	Hospital
30/11/2016	Biologix Delta Ceramic Hip Components	Medical Device	Recall for Product Correction	Class II	Hospital
30/11/2016	Homocysteine Enzymatic Assay used on Cobas Integra 400 plus/800 analysers and cobas c 501/502 & 701/702 modules. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
30/11/2016	Immulate 2000 / Immulite 2000 XPI Intact Parathyroid Hormone (iPTH) assay. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
30/11/2016	Straumann dental surgical drills	Medical Device	Recall	Class II	Hospital
29/11/2016	Deluxe First Aid Kit	Medical Device	Recall	Class II	Retail
29/11/2016	Femoral Head (R) MC	Biological	Hazard Alert	Class III	Hospital
28/11/2016	VITROS Chemistry Products PHYT Slides used on VITROS 250/350/950/5,1 FS/4600/5600 Systems. An in vitro diagnostic device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
25/11/2016	WECK Visistat 35W Skin Stapler	Medical Device	Recall	Class II	Hospital
24/11/2016	Architect Toxo IgM Assay	Medical Device	Recall for Product Correction	Class II	Hospital
24/11/2016	Fujifilm Access Point for FDR Go Flex – DR-ID 1200 AP KIT E	Medical Device	Recall for Product Correction	Class III	Hospital
24/11/2016	Laerdal Compact Suction Unit 4 (LCSU 4)	Medical Device	Recall	Class II	Consumer
24/11/2016	Nanostim Leadless Cardiac Pacemaker (LCP)	Medical Device	Hazard Alert	Class I	Hospital
24/11/2016	SynchroMed II Implantable Drug Infusion Pump	Medical Device	Hazard Alert	Class I	Hospital
23/11/2016	Optipac Bone Cement	Medical Device	Recall	Class II	Hospital
23/11/2016	Philips Brilliance 64 and Ingenuity CT/Core/Core128 with software versions 4.1.6.XX030 or 4.1.6.XX032	Medical Device	Recall for Product Correction	Class II	Hospital
23/11/2016	Quantum Blue Calprotectin Assay and Quantum Blue Calprotectin High Range	Medical Device	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
23/11/2016	ROTAIO Cervical Disc Prosthesis	Medical Device	Recall for Product Correction	Class II	Hospital
22/11/2016	3R62 Pheon Modular Knee Joint (External leg prosthesis)	Medical Device	Recall for Product Correction	Class III	Hospital
21/11/2016	Artis zee with sw versions VC21C, VD11 and Megalix Cat+ X-Ray tubes	Medical Device	Recall for Product Correction	Class II	Hospital
21/11/2016	ImmunoCAP Specific IgG/IgG4 i1 Control H when used with ImmunoCAP Allergen i1, Honey bee venom. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class III	Hospital
21/11/2016	SynReam Flexible Shaft (re-usable surgical instrument supplied as part of the SynReam medullary reaming system)	Medical Device	Recall	Class II	Hospital
21/11/2016	Xpert MRSA/SA Blood Culture Assay. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
18/11/2016	BIOLOX delta ceramic components	Medical Device	Recall for Product Correction	Class II	Hospital
18/11/2016	Kasios TCP and Kages	Medical Device	Hazard Alert	Class II	Hospital
17/11/2016	MAQUET HLS and PLS Sets with BIOLINE Coating (extracorporeal support sets)	Medical Device	Recall	Class I	Hospital
16/11/2016	ADVANCE HA Coated Titanium Tibial Bases, all sizes	Medical Device	Hazard Alert	Class II	Hospital
16/11/2016	EasySept HYDRO+ (3% hydrogen peroxide) Cleaning & Disinfecting Solution (Contact lens care kit)	Medical Device	Recall	Class II	Retail
16/11/2016	Neuro Flap Fix Kit (used for fixation of cranial bone flaps and fractures)	Medical Device	Recall	Class II	Hospital
16/11/2016	Pico 70 Arterial blood sampler (used with Radiometer Blood Gas Analysers)	Medical Device	Recall	Class I	Hospital
16/11/2016	Source Administration Sets (SAS) used with the Medrad Intego PET Infusion System	Medical Device	Recall	Class I	Hospital
16/11/2016	Supergloves Vinyl Examination Gloves, powdered & powder free	Medical Device	Recall	Class II	Retail
16/11/2016	Xhibit Central Station, software version 1.1.5	Medical Device	Recall for Product Correction	Class III	Hospital
14/11/2016	ARROW OnControl System Trays	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
14/11/2016	Du Huo Ji Sheng Tang (Tuhuo & Loranthus Combination), Chuan Xiong Cha Tiao San (Ligusticum & Tea Formula) and Dang Gui Si Ni Tang (Tangkuei & Jujube Combination)	Medicine	Recall	Class II	Consumer
14/11/2016	F-18 FDG Injection (Fludeoxyglucose F 18)	Medicine	Recall	Class II	Hospital
14/11/2016	Monaco V 5.00 and higher (Radiation therapy treatment planning system software)	Medical Device	Recall for Product Correction	Class II	Hospital
11/11/2016	Lifepak15 Monitor/Defibrillator with End-tidal CO2 Option	Medical Device	Recall for Product Correction	Class II	Hospital
10/11/2016	Artis Q systems with s/w version VD11 and Gigalix X-Ray tubes	Medical Device	Recall for Product Correction	Class II	Hospital
10/11/2016	AXIOM Artis systems with s/w version VB35E and Megalix X-Ray tubes	Medical Device	Recall for Product Correction	Class II	Hospital
10/11/2016	Brilliance iCT/iCT SP/Big Bore/6/10/16/16P/40/64 and Ingenuity CT/Core/Core128	Medical Device	Recall for Product Correction	Class II	Hospital
10/11/2016	K-Wires for T2 and Gamma Systems (Internal fixation wire)	Medical Device	Recall	Class II	Hospital
9/11/2016	Freelite Human Lambda Free kit for use on SPAPLUS	Medical Device	Recall	Class II	Hospital
9/11/2016	Offset Cup Reamer Handle	Medical Device	Recall	Class II	Hospital
9/11/2016	SOMATOM Force with software version VA50_SP2 (Computed tomography x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
8/11/2016	iMR Cabinet label of Brilliance iCT, Ingenuity CT, Ingenuity Core 128	Medical Device	Recall for Product Correction	Class III	Hospital
7/11/2016	Lumenis FemTouch Delivery System (used with AcuPulse laser system and AcuScan120 microscanner for gynecological treatments)	Medical Device	Recall for Product Correction	Class II	Hospital
7/11/2016	SynchroMed II Model 8637 Implantable Drug Infusion Pump	Medical Device	Hazard Alert	Class I	Hospital
4/11/2016	ARRIVE Braided Transseptal Sheath	Medical Device	Recall	Class I	Hospital
4/11/2016	VITROS Chemistry Products C-reactive protein (CRP) Slides	Medical Device	Recall for Product Correction	Class II	Hospital
4/11/2016	Wallis Posterior Dynamic Stabilisation System instruments and containers	Medical Device	Recall for Product Correction	Class II	Hospital
3/11/2016	AU680 chemistry analysers with software version 4.05. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital

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3/11/2016	LMA MAD Nasal Intranasal Mucosal Atomisation Device (used for intranasal drug delivery)	Medical Device	Recall	Class I	Hospital
3/11/2016	Medtronic Model 37751 Recharger, in Charging Systems used with implantable neurostimulators (INS)	Medical Device	Recall for Product Correction	Class I	Hospital
3/11/2016	Monaco V 5.11 and V 5.20 (used for radiation treatment planning)	Medical Device	Recall for Product Correction	Class II	Hospital
3/11/2016	SOMATOM Definition AS and SOMATOM Definition Flash (Computed tomography x-ray diagnostic system)	Medical Device	Recall for Product Correction	Class II	Hospital
3/11/2016	SOMATOM Definition AS and SOMATOM Definition Flash (Computed tomography x-ray diagnostic system)	Medical Device	Recall for Product Correction	Class II	Hospital
2/11/2016	Atrium Trocar Catheters, Sizes 8Fr to 32Fr	Medical Device	Recall	Class II	Hospital
2/11/2016	Nellix EndoVascular Aneurysm Sealing System	Medical Device	Hazard Alert	Class I	Hospital
2/11/2016	Radiometer TCM5 transcutaneous blood gas monitor	Medical Device	Recall for Product Correction	Class III	Hospital
1/11/2016	AK 98 Self-Care Haemodialysis machine with software versions 1.1.0 and earlier	Medical Device	Recall for Product Correction	Class I	Hospital
1/11/2016	Infinity Acute Care Monitoring System (IACS) with software version VG5.0 and Microstream (Patient monitoring system)	Medical Device	Recall for Product Correction	Class I	Hospital
1/11/2016	Spot-light Tissue Pre-treatment Kit (Antigen retrieval reagent used in cellular imaging). An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class III	Hospital
31/10/2016	Intuitive Surgical Endoscope Instrument Control System - da Vinci Xi Surgical System with P5 software	Medical Device	Recall for Product Correction	Class II	Hospital
31/10/2016	Pressure Care Medical Mattresses and Mattress Covers	Medical Device	Recall	Class II	Hospital
27/10/2016	Avance CS2, Avance, and Amingo anaesthesia devices with the optional large tray insert accessory installed	Medical Device	Recall for Product Correction	Class II	Hospital
27/10/2016	Brainlab Knee Navigation System: Femoral and Tibial Cutting Block Adapter Base	Medical Device	Recall	Class II	Hospital
26/10/2016	Atropine Injection BP atropine sulfate monohydrate 600 mcg in 1mL (sterile) Steriluer ampoules, 10 pack	Medicine	Recall	Class II	Retail

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24/10/2016	Achieva 3.0T and Ingenia 3.0T MR Systems with passive shielding in the rear wall	Medical Device	Recall for Product Correction	Class I	Hospital
24/10/2016	ARCHITECT Lactic Acid. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
21/10/2016	Active Knee Total Knee Replacement System	Medical Device	Hazard Alert	Class II	Hospital
21/10/2016	TBS iN Sight v. 3.0.1 (software installed on bone densitometers for estimating fracture risk)	Medical Device	Recall for Product Correction	Class II	Hospital
20/10/2016	Hallu-Fix Drill, Diameter 1.9mm, supplied in Hallu-Fix system instrumentation set (used for orthopaedic foot surgery)	Medical Device	Recall	Class II	Hospital
20/10/2016	Human sTfR Quantikine IVD ELISA Kit (used as indicator of iron status). An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
20/10/2016	SynReam Reaming Rod 2.5mm, L 650mm, sterile	Medical Device	Recall	Class II	Hospital
19/10/2016	Blood Pressure Monitoring Kits with Transpac IV Transducers	Medical Device	Recall	Class II	Hospital
19/10/2016	VITROS Immunodiagnostic Products Intact iPTH Reagent Packs & Calibrators (used on VITROS ECi/ECiQ/3600 Immunodiagnostic Systems, &	Medical Device	Recall	Class II	Hospital
18/10/2016	Bard Inlay Optima Ureteral Stents	Medical Device	Recall for Product Correction	Class II	Hospital
18/10/2016	Chemistry Calibrator used with ADVIA Chemistry Systems Direct Bilirubin Assay (DBIL_2). An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
18/10/2016	Perceval Sutureless Aortic Heart Valves (bioprosthetic heart valve)	Medical Device	Recall for Product Correction	Class I	Hospital
18/10/2016	VITROS Chemistry Products Calibrator Kit 25 (used on VITROS 4600/5600 Systems and with VITROS Chemistry Products dHDL Slides). An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class III	Hospital
17/10/2016	RaySearch RayStation 5 (Radiation therapy treatment planning system)	Medical Device	Recall for Product Correction	Class II	Hospital
17/10/2016	Vitamin D Total 100 Tests and Vitamin D Total 500 Tests (Used with ADVIA Centaur / ADVIA Centaur XP / ADVIA Centaur XPT Systems)	Medical Device	Recall for Product Correction	Class II	Hospital

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14/10/2016	MAGNETOM Combi Dockable Neurosurgery Table	Medical Device	Recall for Product Correction	Class I	Hospital
13/10/2016	ALBAclone Advanced Partial RhD Typing Kit. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
13/10/2016	Eyesaline Eyewash Solution, 32oz, for use with Eyesaline Wall Station (for emergency eye rinsing)	Medical Device	Recall	Class II	Consumer
13/10/2016	Total Hip Software Application 3.1 & 3.1.1 for use with 3.0 Mako system (Robotic surgical navigation system used during total hip arthroplasty)	Medical Device	Recall for Product Correction	Class II	Hospital
11/10/2016	4F Stiffened Micro-Introducer Kits (guidewire or catheter introducer)	Medical Device	Recall	Class II	Hospital
11/10/2016	Fortify, Fortify Assura, Quadra Assura, Unify, Unify Assura and Unify Quadra	Medical Device	Hazard Alert	Class I	Hospital
10/10/2016	Aptio Automation Modules. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
10/10/2016	Tina-quant Haemoglobin A1c Gen.2 used with COBAS INTEGRA 400 plus analyser, COBAS INTEGRA 800 analyser and cobas c 501/502 modules. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
7/10/2016	Alligator Retrieval Device, Xcelerator Hydrophilic Guidewire and Marathon Microcatheter (with Stylet)	Medical Device	Recall	Class I	Hospital
7/10/2016	iPlan RT Dose / iPlan RT Versions 4.5.3 and 4.5.4, when used in combination with the optional function Dose Planning for Agility Multileaf-Collimator (MLC)	Medical Device	Recall for Product Correction	Class I	Hospital
7/10/2016	Philips IntelliVue MX40 Patient Wearable Monitor s/w versions B.05.28, B.05.29 and B.05.32	Medical Device	Recall for Product Correction	Class II	Hospital
7/10/2016	Xpert HIV-1 Viral Load Assay. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
6/10/2016	Devon Light Glove (Used as a cover with a compatible surgical light handle)	Medical Device	Recall for Product Correction	Class II	Hospital
6/10/2016	Freelite Human Kappa Free Kit (use on the Beckman AU (400, 480, 640, 680, 2700, 5400) Series). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
6/10/2016	Invacare Birdie Lifters (Patient lifters)	Medical Device	Recall for Product Correction	Class II	Consumer
6/10/2016	SenoMark UltraCor MRI 14 Gauge Breast Tissue Markers (used for radiographic marking of breast biopsy sites)	Medical Device	Recall for Product Correction	Class II	Hospital
5/10/2016	Clarify Visualization System (Laparoscopic Care Kit)	Medical Device	Recall	Class II	Hospital
5/10/2016	Rack Trays used with cobas, Modular Analytics and Urisys instruments/systems. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
4/10/2016	EZ-Strip 145µm (Assisted reproduction microtool)	Medical Device	Recall	Class II	Hospital
30/09/2016	AlignRT patient positioning/tracking video camera system (when used with TrueBeam Radiotherapy Delivery System)	Medical Device	Recall for Product Correction	Class I	Hospital
30/09/2016	Arctic Sun Temperature Management System (used for regulating the temperature and circulation of water to a vest worn by the patient)	Medical Device	Recall for Product Correction	Class II	Hospital
30/09/2016	Feather Touch Vinyl Examination Gloves	Medical Device	Recall	Class II	Retail
29/09/2016	AVOXimeter 1000E Cuvettes (used for oximetry assessment during heart catheterisation procedures). An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
29/09/2016	Zero-Gravity Radiation Protection System (overhead suspended radiation protection shield)	Medical Device	Recall for Product Correction	Class II	Hospital
28/09/2016	Monaco V5.10 and V5.20 (used for radiation treatment planning)	Medical Device	Recall for Product Correction	Class II	Hospital
28/09/2016	STAR Instruments Kit, sterile packaged (used to implant Scandinavian Total Ankle Replacement System)	Medical Device	Recall	Class III	Hospital
28/09/2016	Sterile Single Use Minor Surgery Bipolar Cable, IEC-BC (Used for connecting the bipolar handpieces to the RF generator for electrosurgical procedures)	Medical Device	Recall	Class II	Retail
23/09/2016	Radiometer TCM5 Flex Monitor (non-invasive blood gas monitor)	Medical Device	Recall for Product Correction	Class II	Hospital
23/09/2016	VITROS Automation Solutions configured with a Thermo Scientific Centrifuge Module. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital

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22/09/2016	Automatic QC Cartridge tHb Level 1 (used with RAPIDPoint 400/405/500 instruments). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
22/09/2016	Chemistry 1 Calibrator (used with the Dimension Vista System). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
22/09/2016	Fludarabine Ebewe 50mg/2ml concentrated injection solution (5 vials)	Medicine	Recall	Class II	Hospital
21/09/2016	Metagenics Nasoclear Nasal Spray 30mL	Medicine	Recall	Class II	Consumer
21/09/2016	Spinocath G22 / G27 (Spinal anaesthesia kit)	Medical Device	Recall	Class I	Hospital
21/09/2016	Twin-Pass dual access catheters	Medical Device	Recall	Class II	Hospital
20/09/2016	FerriScan (software for determining liver iron concentration from MRI images)	Medical Device	Recall for Product Correction	Class III	Hospital
19/09/2016	Ingenuity CT system with software version 4.1.5	Medical Device	Recall for Product Correction	Class III	Hospital
19/09/2016	LFIT Anatomic CoCr V40 Femoral Heads (Modular components used in total hip replacement procedures)	Medical Device	Hazard Alert	Class II	Hospital
19/09/2016	MAGiC (MAGnetic resonance image Compilation) on Signa Pioneer MRI systems running application software version DV25.1	Medical Device	Recall for Product Correction	Class II	Hospital
16/09/2016	Macopharma blood bags	Medical Device	Recall for Product Correction	Class II	Hospital
16/09/2016	NIO-A device (Automatic intraosseous infusion device that provides rapid, safe and easy intravascular access through the bone marrow)	Medical Device	Recall	Class II	Hospital
15/09/2016	F-18 FDG Injection (Fludeoxyglucose F 18)	Medicine	Recall for Product Correction	Class III	Hospital
15/09/2016	Getinge ED-FLOW AER, ED-FLOW SD AER (Automated washer-disinfector for endoscopes)	Medical Device	Recall for Product Correction	Class I	Hospital
15/09/2016	MAQUET operating table accessories with Accessory Adaptor 600525A0	Medical Device	Recall for Product Correction	Class II	Hospital
14/09/2016	AQUIOS CL Flow Cytometer System	Medical Device	Recall for Product Correction	Class II	Hospital

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14/09/2016	C-series carry bars (used with C300, C450 Manual, C625 ceiling lifts/hoists)	Medical Device	Recall for Product Correction	Class II	Consumer
14/09/2016	Debriflo Ultrasonic Wound Irrigation Hand-piece	Medical Device	Recall for Product Correction	Class I	Hospital
14/09/2016	SIGNA Creator and SIGNA Explorer (MRI System)	Medical Device	Recall for Product Correction	Class II	Hospital
13/09/2016	Combur-Test and ChoiceLine 10 test kits (urine test strips). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
13/09/2016	Infant Warmer System (IWS)	Medical Device	Recall for Product Correction	Class II	Hospital
13/09/2016	Philips BV25, BV300, BV Libra, BV Endura, BV Pulsera (Fluoroscopic x-ray systems)	Medical Device	Recall for Product Correction	Class III	Hospital
13/09/2016	Radiometer ABL90FLEX and ABL90FLEX PLUS Blood Gas Analyser with software version below 3.2. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
12/09/2016	Arthrex ITD Articulating Arm 300 + 350MM	Medical Device	Recall for Product Correction	Class II	Hospital
12/09/2016	Pennine Healthcare Ryles Tubes (used for enteral feeding)	Medical Device	Recall for Product Correction	Class II	Hospital
12/09/2016	Philips Brilliance 64 and Ingenuity CT, Core, Core128 with software version 4.1.6.XX030	Medical Device	Recall for Product Correction	Class II	Hospital
12/09/2016	Plum 360 Infusion Pump, with software version 15.02	Medical Device	Recall for Product Correction	Class II	Hospital
9/09/2016	RAPIDPoint 400/405 Systems Measurement Cartridge (blood gas analysers). An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
9/09/2016	RaySearch RayStation 2.5, 3.0, 3.5, 4.0, 4.5, 4.7, 5.0 and 4.3 (InverseArc 1.0) (Radiation therapy treatment planning system)	Medical Device	Recall for Product Correction	Class II	Hospital
8/09/2016	Coxiella burnetii IFA IgG Kit	Medical Device	Recall	Class II	Hospital
8/09/2016	FIDS dsDNA Kit	Medical Device	Recall	Class II	Hospital
8/09/2016	Iron Assay performed with the Dimension & Dimension Vista Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
7/09/2016	Accu-Chek Connect Diabetes Management App for iPhone (iOS) v1.2.0(.5)	Medical Device	Recall for Product Correction	Class I	Consumer
7/09/2016	GlucaGen HypoKit (glucagon (rys) as HCl 1 mg (1 IU) powder vial with 1 mL, pre-filled solvent syringe)	Medicine	Recall	Class I	Consumer
7/09/2016	HF Cable used with ESG-400 Electrosurgical Generator (bipolar)	Medical Device	Recall for Product Correction	Class III	Hospital
7/09/2016	Pulmonary Patch	Biological	Hazard Alert	Class II	Hospital
7/09/2016	Resus-EZY Air Cushion Mask	Medical Device	Recall	Class III	Hospital
6/09/2016	Panthera S3 Wheelchair	Medical Device	Recall for Product Correction	Class II	Hospital
6/09/2016	Tandem Bipolar Hip System (hemiarthroplasty hip prosthesis)	Medical Device	Hazard Alert	Class II	Hospital
5/09/2016	IMMULITE Systems 1000 / 2000 / 2000 XPi CMV IgM Assay (used for the determination of Cytomegalovirus (CMV). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
5/09/2016	Sage Comfort impregnated cloth topical skin products	Medical Device	Recall	Class II	Consumer
2/09/2016	Alaris GP Infusion set with Back Check Valve	Medical Device	Recall	Class I	Hospital
2/09/2016	Sensitest Agar	Medical Device	Recall for Product Correction	Class II	Hospital
2/09/2016	TECNIS 1-Piece Intraocular Lens (IOL) with TECNIS iTEC Preloaded Delivery System PCB00	Medical Device	Hazard Alert	Class II	Hospital
1/09/2016	Lescol 20mg Tablets	Medicine	Recall	Class III	Retail
30/08/2016	APO-Cabergoline 500mcg Tablets	Medicine	Recall	Class II	Consumer
30/08/2016	HeartWare Ventricular Assist Device (HVAD) System	Medical Device	Hazard Alert	Class I	Hospital
29/08/2016	Hamilton Medical C3 Ventilator	Medical Device	Recall for Product Correction	Class II	Hospital
29/08/2016	Hamilton Medical MR1 Ventilator	Medical Device	Recall for Product Correction	Class II	Hospital
29/08/2016	Ventricular Catheter Accessory Kit (used for external cerebrospinal fluid (CSF) drainage)	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
26/08/2016	CONMED Concept Heatwave Electrode, 130mm x 2.3mm diameter (5 per box) (electrosurgical electrode used for ablation of soft tissue and coagulation of vessels)	Medical Device	Recall	Class I	Hospital
26/08/2016	Universal Impactor/Positioner (used to introduce and extract compatible universal window trials and acetabular cups into the prepared acetabulum during total hip arthroplasty)	Medical Device	Recall	Class II	Hospital
25/08/2016	iGUIDE with software version 2.2.0 (used with HexPOD evo RT System, used for accurate patient positioning during radiation therapy treatment)	Medical Device	Recall for Product Correction	Class II	Hospital
25/08/2016	Molift Air 205 and 300 ceiling hoist (a powered lifting device)	Medical Device	Recall for Product Correction	Class II	Consumer
25/08/2016	VITROS Chemistry Products Slide Assays - GLU, LAC, TRIG, URIC. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
24/08/2016	Dimension & Dimension Vista Urine Opiates Screen assays. In vitro diagnostic medical devices (IVDs).	Medical Device	Recall for Product Correction	Class II	Hospital
24/08/2016	Medela breastpumps detachable wall plug component of AC Power Adaptor	Medical Device	Recall	Class II	Consumer
24/08/2016	Oxoid Antimicrobial Susceptibility Testing Disc - Cefazidime CAZ10. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
24/08/2016	Viva Cardiac Resynchronisation Therapy Defibrillators (CRT-Ds) and Evera Implantable Cardioverter Defibrillator (ICDs)	Medical Device	Hazard Alert	Class I	Hospital
23/08/2016	Bard EnCor Needle Guide Insert (part of the EnCor Breast Biopsy Probe)	Medical Device	Recall for Product Correction	Class II	Hospital
23/08/2016	syngo RT Therapist 4.3.SP1 or 4.3.138 or 4.3.1_AR1 or 4.2.110 in combination with Oncology Information System (OIS), MOSAIQ	Medical Device	Recall for Product Correction	Class II	Hospital
22/08/2016	ADVIA Chemistry Triglyceride Concentrated (TRIG_c) Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
22/08/2016	da Vinci Xi EndoWrist Stapler 45 Instrument	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
22/08/2016	RAPIDPoint 400/405/500 Systems and RAPIDLab 1240/1245/1260/1265 Systems (blood gas analysers). An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
22/08/2016	Red top histology jars containing 10% Neutral Buffered Formalin Solution. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
22/08/2016	Stryker Instruments Heavy Duty Sagittal Blade 18x0.97x90mm (used to cut bone and bone related tissue in orthopaedic procedures)	Medical Device	Recall	Class II	Hospital
22/08/2016	Sysmex CS-2000i and CS-2100i systems (Automated blood coagulation analysers). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
19/08/2016	Monaco with software versions 3.1 and higher (Radiation therapy treatment planning system)	Medical Device	Recall for Product Correction	Class II	Hospital
19/08/2016	QMS Everolimus Immunoassay (used for the therapeutic monitoring of immunosuppressant drugs). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
19/08/2016	UniCel DxH 600 and DxH800 Coulter Cellular Analysis System. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
18/08/2016	Flocare Infinity Pump and Infinity Plus Pump (enteral feeding pumps)	Medical Device	Recall for Product Correction	Class II	Consumer
18/08/2016	LifePak CR Plus and LifePak Express Automatic External Defibrillators	Medical Device	Recall for Product Correction	Class I	Retail
18/08/2016	syngo RT Oncologist with software version 4.2.X or 4.3.X (image processing device that can be a component of one or more radiation therapy systems)	Medical Device	Recall for Product Correction	Class II	Hospital
17/08/2016	Digital Linear Accelerators of type Primus, ONCOR and ARTISTE running Control Console software version 12.0.25 or 13.0.65 and syngo RT Therapist running software version 4.2.110 or 4.3.SP1	Medical Device	Recall for Product Correction	Class I	Hospital
16/08/2016	Astral 100 and Astral150 Ventilators - Degraded Battery Pack	Medical Device	Recall for Product Correction	Class I	Consumer
15/08/2016	Ceiling Bracket, Arch 71 White (used for installing Liko patient lifts to wooden and concrete ceilings)	Medical Device	Recall	Class II	Wholesale

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
15/08/2016	Cemented resurfacing patellar implant, Ø 33mm and 36mm	Medical Device	Recall	Class II	Hospital
12/08/2016	BARD Toomey Irrigation Syringe 70cc with Resectoscope Tip, Catheter Tip, Luer Adapter and Cap	Medical Device	Recall	Class II	Hospital
11/08/2016	Certegra Workstation used in conjunction with Medrad Stellant CT Injection System	Medical Device	Recall	Class II	Hospital
11/08/2016	IntelePACS InteleViewer software 4-10-1 and earlier versions (Picture archiving and communication system for radiology)	Medical Device	Recall for Product Correction	Class II	Hospital
11/08/2016	Medtronic EnVeo R Delivery Catheter System (DCS)	Medical Device	Recall for Product Correction	Class I	Hospital
10/08/2016	ADVIA Centaur Systems Calibrator U (Myoglobin). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
10/08/2016	Allen Wrench 5mm in SMR supplied in instrument set (surgical instrument used during implantation of SMR anatomic and Reverse shoulder prosthesis)	Medical Device	Recall	Class II	Hospital
10/08/2016	e.cam and Symbia E systems	Medical Device	Recall for Product Correction	Class III	Hospital
10/08/2016	Renasys Transparent Film and Renasys Gauze Dressing Kits (used to dress, protect and seal wounds undergoing Negative Pressure Wound Therapy (NPWT))	Medical Device	Recall	Class II	Hospital
10/08/2016	Scorpio Patella Clamp (used to hold the patella in place during the cementing process)	Medical Device	Recall	Class II	Hospital
9/08/2016	da Vinci Xi EndoWrist Stapler	Medical Device	Recall for Product Correction	Class I	Hospital
9/08/2016	Leongatha Delivery Pack containing umbilical clamps	Medical Device	Recall for Product Correction	Class II	Hospital
9/08/2016	UniCel DxH Slidemaker Stainer Coulter Cellular Analysis System	Medical Device	Recall for Product Correction	Class I	Hospital
8/08/2016	1.5 mm HYDRO LeMaitre Valvulotome, 40 cm	Medical Device	Recall	Class II	Hospital
8/08/2016	Whipknot Soft Tissue Cinch #5 Sutures (used in assisting in the harvest, preparation, and placement of soft tissue grafts during ligament reconstructive surgery)	Medical Device	Recall	Class II	Hospital

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5/08/2016	ATEC Canister (used with ATEC vacuum-assisted breast biopsy systems)	Medical Device	Recall	Class II	Hospital
5/08/2016	BK Virus R-gene Real-time Detection and Quantification Kit (used to measure the viral load of BK virus in whole blood, plasma and urine samples). An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
5/08/2016	Ethicon Mersilene Tape (intended for use in circular suture of the cervix)	Medical Device	Recall for Product Correction	Class III	Hospital
4/08/2016	COLESTID colestipol HCl 5 g granules for oral suspension, 120 sachets	Medicine	Recall	Class III	Retail
4/08/2016	Lotus Valve System (transcatheter aortic valve implantation (TAVI) system)	Medical Device	Recall	Class I	Hospital
4/08/2016	Philips IntelliVue Patient Monitors	Medical Device	Recall for Product Correction	Class II	Hospital
3/08/2016	Alere INRatio / INRatio 2 PT/INR Monitoring System. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class I	Consumer
2/08/2016	Cell Marque Rabbit Monoclonal Antibody. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
1/08/2016	Prostate-specific antigen (PSA) Assay performed on ADVIA Centaur, Centaur XP, Centaur XPT, and Centaur CP Analysers. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
1/08/2016	Various Kits containing Anticoagulant Citrate Dextrose Solution, Solution A (ACDA) 30mL Vials (Supplied in apheresis and surgical procedure kits)	Medical Device	Recall	Class II	Hospital
29/07/2016	Absorb Bioresorbable Vascular Scaffold (BVS) System	Medical Device	Recall for Product Correction	Class II	Hospital
29/07/2016	Etest COLISTIN CO 256 WW. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
29/07/2016	Multiple Laerdal Suction Units (LSU) with NiMH Battery	Medical Device	Recall for Product Correction	Class II	Retail
28/07/2016	AXIOM Artis, Artis zee and Artis Q/Q.zen system (fluoroscopic angiographic x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
27/07/2016	Multiple Polishing Products containing Optrapol (a dental polishing system)	Medical Device	Recall	Class II	Retail

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
27/07/2016	VITROS Immunodiagnostic Products Estradiol Reagent Pack (used for the determination of estradiol in human serum). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
26/07/2016	Bisolvon Chesty Natural Kids Oral Liquid, 200mL	Medicine	Recall	Class III	Wholesale
26/07/2016	Sterrad 100NX system (Sterilisation system)	Medical Device	Recall for Product Correction	Class III	Hospital
25/07/2016	ADVIA Chemistry XPT System Software Test Definition (TDef) Version 1.0 disks. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
25/07/2016	ImmunoCAP Specific IgE Control H (used to aid the diagnosis of allergy or asthma). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
25/07/2016	NIM Standard Reinforced EMG Endotracheal Tube	Medical Device	Recall for Product Correction	Class II	Hospital
25/07/2016	Zimmer Air Dermatome II Handpiece (used during skin grafting surgeries)	Medical Device	Recall for Product Correction	Class II	Hospital
22/07/2016	Locking Screws Stardrive Ø 2.4 mm, Self-Tapping, Length 12 mm, Titanium-Alloy-Niobium Alloy (Orthopaedic bone screw)	Medical Device	Recall	Class II	Hospital
22/07/2016	Maquet Operating Table with Fixture 1002.65AO	Medical Device	Recall for Product Correction	Class I	Hospital
22/07/2016	Progressa Bed System with European (OIML) Version Scale	Medical Device	Recall for Product Correction	Class II	Hospital
22/07/2016	Steelco Washer Disinfectors (Instrument cleaner and disinfectors)	Medical Device	Recall for Product Correction	Class II	Hospital
22/07/2016	Trigen Internal Hex Captured Recon Screw Blue 6.4mm x 65mm (Internal fixation screw supplied as part of the Intramedullary Nail System)	Medical Device	Recall for Product Correction	Class II	Hospital
21/07/2016	G-scan Brio Magnetic Resonance System	Medical Device	Recall for Product Correction	Class II	Hospital
21/07/2016	Medline Procedure Packs containing ConvaTec Unomedical Brand Frazier Suction Handle	Medical Device	Recall for Product Correction	Class II	Hospital
20/07/2016	Adapter for Colibri, Electric Pen Drive and Light Adapter for Colibri and Colibri II hand piece	Medical Device	Recall	Class II	Hospital

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20/07/2016	Medtronic O-Arm O2 Surgical Imaging System (a portable, diagnostic, fluoroscopic x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
20/07/2016	MOSAIQ Medical Oncology version 2.50.05 and higher (oncology information system used to manage workflows for treatment planning and delivery)	Medical Device	Recall for Product Correction	Class II	Hospital
20/07/2016	NucliSENS easyMAG Magnetic Silica MagSIL (used with the NucliSENS easyMag nucleic acid extraction system for the automated extraction of total nucleic acids (RNA/DNA) from biological samples). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
20/07/2016	O-Arm 1000 Surgical Imaging System (Portable, diagnostic, fluoroscopic x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
20/07/2016	Tecotherm Neo (a heating/cooling system for use with infants)	Medical Device	Recall for Product Correction	Class II	Hospital
19/07/2016	LIAISON Estradiol II Gen Assay (used for the determination of estradiol in human serum). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
18/07/2016	SOMATOM Definition AS, Definition Edge and Definition Flash CT scanners with coupled contrast agent injectors in software version VA48A-SP2	Medical Device	Recall for Product Correction	Class II	Hospital
15/07/2016	MultiDiagnost Eleva and MultiDiagnost Eleva with Flat Detector (diagnostic fluoroscopic x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
14/07/2016	Exeter Non V40 Rasp with plastic handle	Medical Device	Recall	Class II	Hospital
14/07/2016	Twinfix Quick-T Knot Pusher Suture Cutters	Medical Device	Recall	Class II	Hospital
13/07/2016	Medtronic DBS Pocket Adaptor for use with Activa PC (Model 37601) and Activa RC (Model 37612) brain neuro-stimulators	Medical Device	Hazard Alert	Class I	Hospital
13/07/2016	Synthesis, Avant & Primo2x Families Adult Oxygenator Mounting Brackets (used with Sorin 3T Heater-Cooler devices)	Medical Device	Recall for Product Correction	Class II	Hospital
12/07/2016	Avenir Müller Stem 6 Lateral uncemented and Avenir Müller Stem 4 Standard uncemented	Medical Device	Hazard Alert	Class II	Hospital
12/07/2016	DuraDiagnost X-ray systems	Medical Device	Recall for Product Correction	Class II	Hospital

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12/07/2016	Frazier Suction instrument (used for precision suction in spinal or neurological surgeries)	Medical Device	Recall for Product Correction	Class II	Hospital
12/07/2016	RayStation 3.0, 3.5, 4.0, 4.5, 4.7, and 5	Medical Device	Recall for Product Correction	Class II	Hospital
12/07/2016	Savion ED Trolley (mobile stretcher)	Medical Device	Recall for Product Correction	Class II	Hospital
12/07/2016	SerenoCem Granules BCG050 (Orthopaedic bone cement)	Medical Device	Hazard Alert	Class II	Hospital
11/07/2016	Artis Systems with 19" Live Display	Medical Device	Recall for Product Correction	Class II	Hospital
11/07/2016	Covidien Valleylab Laparoscopic Wire Retractable Electrode (used in laparoscopic and thoracic surgeries for electrosurgical cutting and coagulation)	Medical Device	Recall	Class II	Hospital
11/07/2016	Sara Combilizer	Medical Device	Recall for Product Correction	Class II	Hospital
8/07/2016	Triathlon Modular Handle	Medical Device	Recall	Class II	Hospital
7/07/2016	Merge PACS with software versions 6.0MR2 and greater up to and including 6.6.2.2, 7.0 and greater up to and including 7.0.2 (picture archiving and communication system)	Medical Device	Recall for Product Correction	Class II	Hospital
7/07/2016	Quickie Q7 Manual Wheelchair	Medical Device	Recall for Product Correction	Class II	Consumer
7/07/2016	Sorenson's Buffer. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
7/07/2016	UniCel DxS Synchron Systems No Foam Reagent (used with the UniCel DxS Synchron Clinical System). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
6/07/2016	Merge CADstream, All versions (used for breast cancer or general MRI studies)	Medical Device	Recall for Product Correction	Class II	Hospital
5/07/2016	PHIL (Precipitating Hydrophobic Injectable Liquid) Non-Adhesive Liquid Embolic System	Medical Device	Recall	Class II	Hospital
4/07/2016	Guide Sleeve, yellow for Trochanteric Fixation Nail Advanced (TFNA) Proximal Femoral Nailing System	Medical Device	Recall for Product Correction	Class II	Hospital
4/07/2016	VITROS Immunodiagnostic Products HBsAg Controls. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital

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4/07/2016	Zenostar MT Color and Zenostar MT Color Impulse products	Medical Device	Recall	Class II	Retail
1/07/2016	Allura Xper R8.2 and UNIQ R1.0 X-Ray Systems (diagnostic, fluoroscopic x-ray system)	Medical Device	Recall for Product Correction	Class I	Hospital
1/07/2016	Chlorofluor Gel 30mL and 250mL bottles and 100mL pump pack	Medicine	Recall	Class II	Consumer
1/07/2016	General Laparoscopy Procedure Pack and Gynaecological Laparoscopy Procedure Pack containing CORE Suction Irrigation Handpiece (sterile)	Medical Device	Recall	Class II	Hospital
1/07/2016	REX Rehab and REX P Devices (robotic walking device which is worn on the lower limbs by mobility-impaired users to provide enhanced functional mobility for exercise and rehabilitation purposes)	Medical Device	Recall for Product Correction	Class II	Hospital
1/07/2016	Safil Quick (synthetic absorbable sterile surgical suture)	Medical Device	Recall	Class II	Hospital
1/07/2016	VASCU-GUARD Peripheral Vascular Patch, 0.8 x 8cm	Medical Device	Recall	Class I	Hospital
30/06/2016	Merge CADstream with software versions earlier than 5.2.6.	Medical Device	Recall for Product Correction	Class II	Hospital
30/06/2016	Merge iConnect Enterprise Archive (iCEA) with software versions 8.30.7 through 9.4.3, with tier 2 storage enabled	Medical Device	Recall for Product Correction	Class II	Hospital
30/06/2016	Merge iConnect Enterprise Archive (iCEA) with software versions 8.80 through 9.4.4 (a picture archiving and communications system)	Medical Device	Recall for Product Correction	Class II	Hospital
30/06/2016	Merge iConnect Enterprise Archive (iCEA) with software versions: 5.30.0 and greater up to and including 9.4.3	Medical Device	Recall for Product Correction	Class II	Hospital
30/06/2016	Merge OrthoCase with software versions 3.7.3 and earlier (a picture archiving and communications system)	Medical Device	Recall for Product Correction	Class II	Hospital
30/06/2016	Merge PACS with software versions 6.0MR2 and greater up to and including 6.6.2.2. Merge PACS versions 7.0 and greater up to and including 7.0.2	Medical Device	Recall for Product Correction	Class II	Hospital
30/06/2016	Merge PACS with software versions V6.0.2.0 MR2 and earlier (a picture archiving and communications system)	Medical Device	Recall for Product Correction	Class II	Hospital
30/06/2016	Volker LTC bed (with lateral release button for the side rails)	Medical Device	Recall for Product Correction	Class II	Consumer

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29/06/2016	Access AMH QC Kits for use with Access Family of Immunoassay Systems. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class III	Hospital
29/06/2016	James Leckey Design Mygo Stander	Medical Device	Recall for Product Correction	Class II	Consumer
29/06/2016	Merge PACS (Amicas PACS) with software versions 6.0.2.0 MR2, 6.0.3.0 MR3, 6.0.3.1 MR3 CU1 (used for medical imaging acquisition)	Medical Device	Recall for Product Correction	Class II	Hospital
29/06/2016	Merge PACS with software versions 6.5.5, 6.5.6, 6.5.7, 6.5.8, 6.5.9, 6.6, 6.6.1, 6.6.1.1, 6.6.2 (picture archiving and communication system)	Medical Device	Recall for Product Correction	Class II	Hospital
29/06/2016	Merge PACS with software versions 6.6.1, 6.6.1.1, 6.6.2, 6.6.2.1, 6.6.2.2, 7.0, 7.0.1 (picture archiving and communication system)	Medical Device	Recall for Product Correction	Class II	Hospital
29/06/2016	Stratus CS Acute Care Diagnostics System. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
27/06/2016	ADVIA Chemistry Theophylline_2 Reagent	Medical Device	Recall	Class II	Hospital
27/06/2016	cobas 6800 system - cobas MPX, 96 tests and cobas MPX, 480 tests. An in-vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class I	Hospital
27/06/2016	Torque Limiting Adapter for use in orthopaedic and trauma surgical procedures (Re-useable surgical instrument)	Medical Device	Recall	Class II	Hospital
24/06/2016	ADVIA Centaur XPT System. An in-vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
24/06/2016	Aquasil Easy Mix Putty (used for taking impressions of teeth)	Medical Device	Recall	Class III	Retail
24/06/2016	CONMED CORE Suction Irrigation Handpieces (used to perform suction and irrigation during endoscopic procedures)	Medical Device	Recall	Class II	Hospital
24/06/2016	Prodisc-C Vivo Cervical Disc Prosthesis (part of the Prodisc-C Vivo Cervical Disc Prosthesis System)	Medical Device	Recall	Class II	Hospital
24/06/2016	Temporary Transvenous Pacing Lead System Model 6416	Medical Device	Recall	Class I	Hospital
23/06/2016	da Vinci Xi 5mm-8mm Universal Cannula Seal and da Vinci Xi 12mm & Stapler Universal Cannula Seal	Medical Device	Recall for Product Correction	Class I	Hospital

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22/06/2016	Shipping cartons labelled as Frusemide-Clarix, frusemide 20 mg/2 mL, Solution for Injection contains incorrect product (Ondansetron 4mg/2mL ,UK product)	Medicine	Recall	Class III	Hospital
21/06/2016	Medrad MRXperion MR Injection System	Medical Device	Recall for Product Correction	Class II	Hospital
21/06/2016	QIAsymphony DSP DNA Mini Kits. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
20/06/2016	ACHILLON Minimally Invasive Achilles Tendon Suture System	Medical Device	Recall	Class II	Hospital
20/06/2016	Sirona Dac Universal Combination Steriliser	Medical Device	Recall for Product Correction	Class II	Retail
20/06/2016	V-PRO 1, V-PRO 1 Plus, V-PRO maX Low Temperature Sterilisation Systems	Medical Device	Recall for Product Correction	Class III	Hospital
17/06/2016	Access Free T3 Reagent Kit (used in the diagnosis and monitoring of patients with thyroid disorders). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
17/06/2016	Softpac C299 (used in preparing dialysate for haemodialysis therapies)	Medical Device	Recall	Class II	Hospital
17/06/2016	Xenform Soft Tissue Repair Matrix 8cm x 12cm	Medical Device	Recall	Class II	Hospital
16/06/2016	Dimension Creatinine (CRE2) Flex reagent cartridge (Used with Dimension clinical chemistry system). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
16/06/2016	Dimension Vista Creatinine (CRE2) Flex reagent cartridge (Used with Dimension Vista system). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
16/06/2016	GENTECH molybdenum (99Mo) / technetium (99mTc) sterile generator for production of sodium pertechnetate (99mTc) injection multidose vial	Medicine	Recall	Class II	Hospital
15/06/2016	Alaris System Infusion PC Unit	Medical Device	Recall for Product Correction	Class II	Hospital
15/06/2016	Alphadent Ceka-Preciline Dental Devices - Ceka, Revax. Preci-Ball, Preci-Horix. Preci-bar and Preci-Clip	Medical Device	Recall	Class II	Retail
15/06/2016	Dräger Babytherm Infant Warmer	Medical Device	Recall for Product Correction	Class I	Hospital

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15/06/2016	Mandible Distractor and Proximal Footplate (used to stabilise bone and lengthen for the correction of congenital deficiencies or post-traumatic defects)	Medical Device	Recall	Class II	Hospital
15/06/2016	Medtronic Midas Rex Sagittal Saws (used with the Medtronic Integrated Power Console (IPC) System)	Medical Device	Recall	Class II	Hospital
15/06/2016	SERVO-i/s ventilator systems with software version 8.00.00	Medical Device	Recall for Product Correction	Class I	Hospital
15/06/2016	Trident Constrained Liner Impactor Tips (Used for implantation of Trident Constrained Inserts during hip arthroplasty)	Medical Device	Recall	Class II	Hospital
15/06/2016	Vancomycin Assay (performed on cobas C and Modular Analytics P-Module)	Medical Device	Recall for Product Correction	Class II	Hospital
14/06/2016	BrightView X and BrightView XCT with software versions 2.5.2 and earlier, 2.5.3 and 2.5.4	Medical Device	Recall for Product Correction	Class II	Hospital
14/06/2016	MOSAIQ 2.62 and higher with the IQ Scripts license enabled (Oncology information system used to manage workflows for treatment planning and delivery)	Medical Device	Recall for Product Correction	Class II	Hospital
10/06/2016	ALT and Glucose-Stat Assays (used for the determination of ALT and Glucose). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
10/06/2016	Maxter Catheters Entral pH Indicator Strips (used to determine the pH of the stomach prior to tube feeding)	Medical Device	Recall	Class II	Hospital
10/06/2016	Score Extension Stem for Total Knee Prosthesis - Cemented	Medical Device	Recall	Class II	Hospital
9/06/2016	Discovery MR750w (MRI System)	Medical Device	Recall for Product Correction	Class II	Hospital
9/06/2016	Target Nano Detachable Coil (used to obstruct or occlude blood flow in blood vessels)	Medical Device	Recall	Class I	Hospital
8/06/2016	AIRVO 2 / myAIRVO 2 Humidifier	Medical Device	Recall for Product Correction	Class III	Retail
8/06/2016	Blood Urea Nitrogen (BUN) Flex Reagent Cartridge (used with Dimension Vista System). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
8/06/2016	Compella Bariatric Bed System, Controllers and Air Surfaces	Medical Device	Recall for Product Correction	Class II	Hospital

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8/06/2016	Herculite Ultra, Herculite XRV, Point 4, and Premise Dental Composite (used in dental restoration)	Medical Device	Recall	Class III	Retail
8/06/2016	RaySearch RayStation 5	Medical Device	Recall for Product Correction	Class II	Hospital
8/06/2016	STATLOCK IAB Stabilisation Device	Medical Device	Recall for Product Correction	Class II	Hospital
7/06/2016	Medtronic Reveal LINQ Insertable Cardiac Monitor (ICM)	Medical Device	Recall for Product Correction	Class II	Hospital
7/06/2016	PowerPro Ambulance Cots	Medical Device	Recall for Product Correction	Class II	Hospital
6/06/2016	Medtronic deep brain stimulation (DBS) devices	Medical Device	Hazard Alert	Class I	Hospital
6/06/2016	Medtronic Deep Brain Stimulation (DBS) Extension Models 7483 and 37086	Medical Device	Hazard Alert	Class I	Hospital
3/06/2016	LumaDent Light Battery Charger	Medical Device	Recall	Class II	Retail
2/06/2016	Neonate Resuscitator with Coded Airway & Filter Resuscitator Kit	Medical Device	Recall	Class II	Hospital
1/06/2016	Sorbsan Calcium Alignate Dressings (Flat, Ribbon, Packing, Plus and Border) and Sorbsan Silver Calcium Alignate Dressing (Flat)	Medical Device	Recall	Class II	Hospital
30/05/2016	ADVIA Centaur XPT System	Medical Device	Recall for Product Correction	Class II	Hospital
30/05/2016	Ethicon Physiomesh Flexible Composite Mesh	Medical Device	Recall	Class II	Hospital
27/05/2016	Dräger Ventstar Paediatric Circuit, used in conjunction with the Dräger Oxylog 3000plus Transport Ventilator	Medical Device	Recall	Class I	Hospital
27/05/2016	EliA IgG Conjugate. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class III	Hospital
26/05/2016	ONLINE TDM Gentamicin assay and Preciest TDM I Calibrator. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
26/05/2016	Philips Brilliance iCT/iCT SP with software version 4.1.3, 4.1.5	Medical Device	Recall for Product Correction	Class II	Hospital
25/05/2016	2016 Fluvax, 10 x 0.5ml packs	Medicine	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
25/05/2016	Monaco software versions 5.10.00 and higher	Medical Device	Recall for Product Correction	Class I	Hospital
25/05/2016	Philips Brilliance 64 and Ingenuity CT/Core/Core128 with software version 4.1.3, 4.1.4 and 4.1.5	Medical Device	Recall for Product Correction	Class II	Hospital
25/05/2016	Self Tapping Bone Screws, 6.5 x 20 and 6.5 x 25	Medical Device	Hazard Alert	Class II	Hospital
23/05/2016	DuraDiagnost X-ray systems with software version 3.0.3	Medical Device	Recall for Product Correction	Class II	Hospital
23/05/2016	DuraDiagnost X-ray systems with software version 4.0.2, 4.0.3 and 4.0.4	Medical Device	Recall for Product Correction	Class II	Hospital
23/05/2016	Hettich Centrifuge Bucket Model 4464-R. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
23/05/2016	Zoledasta (Zoledronic Acid 5mg/100mL) injection solution	Medicine	Recall	Class II	Hospital
19/05/2016	Dimension Enzyme II Calibrator (used with Dimension clinical chemistry system). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
19/05/2016	Dimension Vista Enzyme 2 Calibrator (used on the Dimension Vista System). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
19/05/2016	Hexapod iGUIDE 2.1, iGUIDE 2.2	Medical Device	Recall for Product Correction	Class I	Hospital
19/05/2016	Specialty Size 33mm Reduced Diameter Reaming Cutter	Medical Device	Recall	Class II	Hospital
19/05/2016	Sterile-Packaged Knee Implants	Medical Device	Hazard Alert	Class II	Hospital
18/05/2016	Children's Panadol 5-12 Years Colourfree Suspension 48mg/mL	Medicine	Recall	Class II	Consumer
18/05/2016	ConMed ThermoGuard Plus ABC Paediatric Dual Dispersive Electrodes	Medical Device	Recall	Class I	Hospital
18/05/2016	RestoreSensor Implantable Neurostimulators	Medical Device	Hazard Alert	Class II	Hospital
18/05/2016	TRUEresult Blood Glucose Test Strip (10 counts) (used with the TRUEresult Blood Glucose Monitoring System). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Consumer
17/05/2016	Laryngeal Tube Set – size 4 (LTS-D S4 Adult)	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
16/05/2016	VITROS Immunodiagnostic Products AFP Reagent Packs and Calibrators. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
13/05/2016	Brilliance CT and Ingenuity CT systems with software version v4.1.3 and v4.1.4	Medical Device	Recall for Product Correction	Class III	Hospital
13/05/2016	DigitalDiagnost	Medical Device	Recall for Product Correction	Class III	Hospital
13/05/2016	MSK 1.5T Extreme and Optima MR430s (MRI Systems)	Medical Device	Recall for Product Correction	Class II	Hospital
13/05/2016	Surgical Clipper Charger	Medical Device	Recall	Class II	Hospital
12/05/2016	AVOXimeter System (a whole blood oximeter used during heart catheterisation procedures)	Medical Device	Recall for Product Correction	Class II	Hospital
12/05/2016	Brilliance CT 64-Channel with Essence Technology, Ingenuity Core, Ingenuity Core128 and Ingenuity CT, software versions v4.1.3, v4.1.4 and 4.1.5 (used for diagnostic computed tomography scanning)	Medical Device	Recall for Product Correction	Class II	Hospital
12/05/2016	Brilliance iCT and iCT SP, with software versions v4.1.3 and v4.1.5	Medical Device	Recall for Product Correction	Class II	Hospital
12/05/2016	LIFECODES HLA-C eRES SSO Typing Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
12/05/2016	MX 16-slice CT x-ray systems with software version v1.1.4.21426.	Medical Device	Recall for Product Correction	Class II	Hospital
12/05/2016	Resus-EZY Manual Resuscitator (single-use pulmonary resuscitator)	Medical Device	Recall	Class II	Hospital
12/05/2016	Revolution CT (diagnostic x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
12/05/2016	TnI-Ultra (Troponin) Assay, 100 and 500 tests (used in the determination of cardiac troponin). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
11/05/2016	Cordis PRECISE PRO RX Nitinol Stent System (Carotid)	Medical Device	Recall	Class I	Hospital
11/05/2016	HeartWare HVAD system	Medical Device	Hazard Alert	Class I	Hospital
11/05/2016	Multiple Assay for Enzymatic Creatinine, Cholesterol, Triglyceride, Uric Acid, Lactate, Lipase. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital

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10/05/2016	RAPID Hp StAR Kit (used in the detection of H. pylori). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
10/05/2016	Volcano S5, S5i, CORE, CORE Mobile Systems with software versions v3.2x, v3.3, v3.4.1 (used to diagnose anatomical defects of the heart or problems associated with myocardial infarction)	Medical Device	Recall for Product Correction	Class I	Hospital
9/05/2016	Centurion FMS (Fluidics Management System) Pack (used to control irrigation and aspiration in the eye during cataract surgery)	Medical Device	Recall	Class II	Hospital
9/05/2016	Rifadin IV 600mg (Rifampicin B.P. 600mg powder for I.V. infusion and diluent)	Medicine	Recall	Class II	Hospital
9/05/2016	Threader Monorail and Threader Over the Wire Micro-Dilatation Catheters (used during angioplasty procedures)	Medical Device	Recall for Product Correction	Class III	Hospital
6/05/2016	Ingenuity Core128 CT System	Medical Device	Recall for Product Correction	Class II	Hospital
6/05/2016	MobileDiagnost wDR 2, all software versions affected (diagnostic x-ray system)	Medical Device	Recall for Product Correction	Class I	Hospital
6/05/2016	SMR Glenosphere Impactor	Medical Device	Recall	Class II	Hospital
5/05/2016	D-Vapor and D-Vapor 3000 Vaporisers (used in connection with Baxter Desflurane Agent and Bottles)	Medical Device	Recall for Product Correction	Class II	Hospital
4/05/2016	Hydralyte Sports Lemon Lime 600mL Bottle	Medicine	Recall	Class II	Retail
3/05/2016	ADVIA Centaur XPT Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
3/05/2016	ADVIA Chemistry XPT System with software versions 1.0.3 and 1.1. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
3/05/2016	Birmingham Hip Product Range	Medical Device	Hazard Alert	Class II	Hospital
3/05/2016	Cortex Screw Ø 4.5mm, self-tapping, length 20mm, Pure Titanium	Medical Device	Recall	Class II	Hospital
3/05/2016	Xhibit Central Station (patient monitoring system)	Medical Device	Recall for Product Correction	Class I	Hospital
29/04/2016	ARCHITECT STAT High Sensitive Troponin-I Reagent Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
29/04/2016	Hamilton-G5 and Hamilton -S1 Ventilators with software versions v2.41, v2.42 and v2.50	Medical Device	Recall for Product Correction	Class II	Hospital
29/04/2016	ID-Papain Assay. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
29/04/2016	Maxi Air Blower Unit - Model 230V	Medical Device	Recall for Product Correction	Class II	Hospital
29/04/2016	Novocastra Liquid Mouse Monoclonal Antibody Calretinin. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
28/04/2016	ALUTEK and ALUXOID Immunotherapy Products	Medicine	Product Defect Alert	Class II	Hospital
28/04/2016	Concerto & Basic Shower Trolleys (used for assisted hygiene care)	Medical Device	Recall for Product Correction	Class II	Hospital
28/04/2016	DX-D 600 Digital Radiography System (general purpose x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
28/04/2016	Essure Permanent Birth Control	Medical Device	Recall for Product Correction	Class II	Hospital
28/04/2016	Groshong NXT PICC Connector (used to repair the damaged external segment of a catheter)	Medical Device	Recall for Product Correction	Class III	Hospital
28/04/2016	Image Suite Software Versions 3.0 and 4.0	Medical Device	Recall for Product Correction	Class II	Hospital
28/04/2016	Terumo CDI Blood Parameter Monitoring System 500	Medical Device	Recall for Product Correction	Class I	Hospital
27/04/2016	GE Revolution CT Computed Tomography X-ray systems	Medical Device	Recall for Product Correction	Class II	Hospital
27/04/2016	LenSx Laser System with Corneal Flap Capability (used to perform corneal flaps in LASIK surgery or other treatment involving the incision of the cornea)	Medical Device	Recall for Product Correction	Class II	Hospital
27/04/2016	Philips EPIQ Ultrasound System	Medical Device	Recall for Product Correction	Class II	Hospital
26/04/2016	G-scan Brio Magnetic Resonance System	Medical Device	Recall for Product Correction	Class II	Hospital
26/04/2016	ThinPrep 5000 Processor with Autoloader	Medical Device	Recall for Product Correction	Class II	Hospital
22/04/2016	Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pumps (IABP)	Medical Device	Recall for Product Correction	Class I	Hospital

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22/04/2016	Catheters with Beacon Tip Technology	Medical Device	Recall	Class I	Hospital
22/04/2016	CinchLock SS Knotless Anchor with Inserter (intended for the fixation of soft tissue to bone)	Medical Device	Recall	Class II	Hospital
22/04/2016	Dexamethasone Oral Solution 1mg/mL (used in the treatment of mild to moderate croup in paediatric patients)	Medicine	Recall	Class II	Hospital
22/04/2016	EnCor Probes (used for breast biopsies)	Medical Device	Recall for Product Correction	Class II	Hospital
22/04/2016	iLED 3/5, TruLight 3000/5000, Helion, TruVidia SD, TruVidia HD, VidiaPort Surgical Lighting, Camera and Monitoring Systems	Medical Device	Recall for Product Correction	Class II	Hospital
21/04/2016	Capnostream 20p Patient Monitors - battery pack (used for combined capnograph/pulse oximeter monitor)	Medical Device	Recall	Class II	Hospital
21/04/2016	Elecsys Estradiol Assay with Fulvestrant. An in-vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
21/04/2016	Given Imaging Bravo pH monitoring systems	Medical Device	Recall for Product Correction	Class II	Hospital
21/04/2016	Insulin-Like Growth Factor I (IGF-I) Assay (Used on Immulite and Immulite 1000 Systems). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
21/04/2016	PF6 Tube Assembly (a component of the Peripheral Vascular Infusion/Aspiration Catheter or "PAD" catheter)	Medical Device	Recall	Class II	Hospital
20/04/2016	Biosense Webster PENTARAY NAV and PENTARAY NAV eco Catheters (used for electrophysiological mapping of the heart)	Medical Device	Recall for Product Correction	Class II	Hospital
20/04/2016	DBL Vancomycin Hydrochloride for Intravenous Injection Infusion 500mg, 500,000 I.U./vial	Medicine	Recall	Class III	Hospital
19/04/2016	Ingenuity Core using software version 3.5.4	Medical Device	Recall for Product Correction	Class II	Hospital
19/04/2016	Lotus Valve System (a transcatheter aortic valve implantation (TAVI) system)	Medical Device	Recall for Product Correction	Class I	Hospital
19/04/2016	RAPIDQC Complete Solution Level 3. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital

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18/04/2016	Aperio eSlide Manager with ImageScope, software versions 12.2.1, 12.2.2 and 12.3. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
18/04/2016	Lightspeed CT, Discovery PET/CT (Computed tomography x-ray and nuclear medicine gamma camera diagnostic systems)	Medical Device	Recall for Product Correction	Class II	Hospital
14/04/2016	American Surgical Company (ASC) Neuro Sponges	Medical Device	Recall	Class II	Hospital
14/04/2016	D-Vapor and D-Vapor 3000 Vaporisers (used in connection with Baxter Desflurane Agent and Bottles)	Medical Device	Recall for Product Correction	Class II	Hospital
14/04/2016	IRISpec CA/CB/CC and IRISpec CA/CB Control Kits (quality control for the detection of Bilirubin). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
14/04/2016	Military Trauma & Haemorrhage Wound Dressing, size 10 x 17cm	Medical Device	Recall	Class II	Consumer
12/04/2016	Aquasil Easy Mix Putty (used for taking impressions of teeth)	Medical Device	Recall	Class III	Retail
12/04/2016	CareLink Monitor and CareLink Express Monitor	Medical Device	Recall for Product Correction	Class II	Hospital
12/04/2016	VITROS 3600 Immunodiagnosics System and VITROS 5600 Integrated System, software version 3.2.2 and below. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
11/04/2016	Cuff Controller with Clamp (monitors the cuff pressure of tracheal tubes for intubated patients)	Medical Device	Recall	Class II	Hospital
11/04/2016	e.cam and all Symbia systems with foresight detectors (Nuclear medicine gamma camera systems)	Medical Device	Recall for Product Correction	Class II	Hospital
11/04/2016	Fujifilm ED-530XT Duodenoscope	Medical Device	Recall for Product Correction	Class II	Hospital
11/04/2016	Mizuho General Purpose Operating Table	Medical Device	Recall for Product Correction	Class II	Hospital
8/04/2016	Aisys and Aisys CS2 Anaesthesia machines with the optional Vacuum Suction Function	Medical Device	Recall for Product Correction	Class II	Hospital
8/04/2016	LifeCycle for Prenatal Screening, Version 4.0 Revisions 2, 3 and 4. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital

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8/04/2016	Papoose Infant Spine Immobilisers	Medical Device	Recall for Product Correction	Class II	Hospital
8/04/2016	UniCel (DxH 800/DxH 600/ DxH Slidemaker Stainer) Coulter Cellular Analysis Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
8/04/2016	Vaxcel and Xcela PICC with PASV Valve Technology/Kits, BioFlo PICC Triple Lumen with Endexo and PASV Valve Technology/Kits	Medical Device	Recall	Class II	Hospital
7/04/2016	Hickman and Leonard Central Venous Catheter Kits	Medical Device	Recall for Product Correction	Class III	Hospital
7/04/2016	ID Anti-N and ID Anti-M/N. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
7/04/2016	ME DPHC 0001 delstream HC, 230V	Medical Device	Recall for Product Correction	Class II	Hospital
7/04/2016	Pentax ED-3490TK Video Duodenoscope	Medical Device	Recall for Product Correction	Class II	Hospital
6/04/2016	AutoSPECT Pro Reconstruction application on Extended Brilliance Workplace NM software version 2.0	Medical Device	Recall for Product Correction	Class II	Hospital
6/04/2016	Burinex Bumetanide 1mg tablet	Medicine	Recall	Class III	Retail
6/04/2016	Leksell Gammaknife Perfexion and Leksell Gammaknife Icon	Medical Device	Recall for Product Correction	Class I	Hospital
5/04/2016	10mm Direct Drive Clip Applier (Used for ligation of tubular structures or vessels in laparoscopic and general surgical procedures)	Medical Device	Recall	Class II	Hospital
5/04/2016	ARCHITECT Estradiol Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
5/04/2016	CELL-DYN Emerald Cleaner. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
5/04/2016	EZee-Nest Insert Cups used with ADVIA Centaur CP. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
5/04/2016	Gene Amplification Reagent – Lynoamp BC. An in vitro diagnostic medical device.	Medical Device	Recall	Class II	Hospital
5/04/2016	Oxoid Antimicrobial Susceptibility Testing Discs - Ticarcillin/Clavulanic Acid (TIM85 Timetin). An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital

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5/04/2016	Somatom Force with software versions, VA50A and VA50A_SP2 with paediatric kernel Hp38 (Computed Tomography (CT) system)	Medical Device	Recall for Product Correction	Class I	Hospital
4/04/2016	PneumoSure XL High Flow Insufflator (Used to create a cavity by insufflating CO2 during diagnostics and/or therapeutic laparoscopy)	Medical Device	Recall	Class II	Hospital
1/04/2016	AutoSPECT Pro Reconstruction application on Intellispace Portal software versions 5.0, 6.0 and 7.0	Medical Device	Recall for Product Correction	Class II	Hospital
1/04/2016	INTELEPACS Versions 4.5.1 to 4.12.1	Medical Device	Recall for Product Correction	Class II	Hospital
31/03/2016	Artis zee Systems with generator A100Plus or Artis zeego Systems with software version VC21B. (fluoroscopic angiographic x-ray systems)	Medical Device	Recall for Product Correction	Class II	Hospital
30/03/2016	Dimension Vista 500/ Dimension Vista 1500 Intelligent Lab Systems, software versions V. 3.6.1 SP1 or V. 3.6.2. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
30/03/2016	T34L and NIKI T34 Ambulatory syringe pumps	Medical Device	Recall for Product Correction	Class II	Hospital
24/03/2016	Acuson 2000 ultrasound system (with structural foam core).	Medical Device	Recall for Product Correction	Class II	Hospital
24/03/2016	Acuson SC200 ultrasound systems	Medical Device	Recall for Product Correction	Class II	Hospital
24/03/2016	ADVIA Chemistry Systems (using Trinder and Trinder-like assays). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
24/03/2016	Dimension and Dimension Vista Clinical Chemistry Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
24/03/2016	Fetch 2 Aspiration Catheter	Medical Device	Recall	Class I	Hospital
24/03/2016	MobileDiagnost wDR Rel1 and 2 (general purpose mobile digital x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
24/03/2016	TCAutomation System with Thermo Scientific Recapper (used with VITROS Automation Solutions). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital

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23/03/2016	Aisys CS2 and upgraded Aisys anaesthesia devices (with software version 10.X)	Medical Device	Recall for Product Correction	Class I	Hospital
23/03/2016	Brilliance CT and Ingenuity CT with software versions v4.13 and v4.1.4 (Computed tomography full-body x-ray system)	Medical Device	Recall for Product Correction	Class III	Hospital
22/03/2016	Betamin 100mg tablets (Thiamine Hydrochloride), Bottle of 100 Tablets	Medicine	Recall	Class II	Consumer
22/03/2016	da Vinci Si and Xi Surgical System - Touchpad Compact Flashcards	Medical Device	Recall for Product Correction	Class II	Hospital
22/03/2016	Integre S Surgical frequency doubled Nd YAG laser system and Retinal Rejuvenation Therapy System (2RT)	Medical Device	Recall for Product Correction	Class II	Hospital
22/03/2016	Omrix Pressure Regulators	Medical Device	Recall for Product Correction	Class II	Hospital
21/03/2016	Methotrexate Assay performed on Syva Emit Methotrexate Application (DVMTX.1) for the Dimension Vista System. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
21/03/2016	Symbia E and e.cam collimator	Medical Device	Recall for Product Correction	Class II	Hospital
21/03/2016	Versant kPCR Molecular System Sample Preparation. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
18/03/2016	Allura Xper with software release FD R8.1.16	Medical Device	Recall for Product Correction	Class II	Hospital
18/03/2016	Oxoid Nitrocefin (+ Reconstitution Fluid)	Medical Device	Recall	Class II	Hospital
16/03/2016	Neuroform Atlas Stent System	Medical Device	Recall for Product Correction	Class II	Hospital
15/03/2016	CARDIOSAVE Hybrid and Rescue Intra-aortic Balloon Pumps (IABP)	Medical Device	Recall for Product Correction	Class I	Hospital
15/03/2016	Hamilton Medical G5 / S1 Ventilator with software version V2.42	Medical Device	Recall for Product Correction	Class II	Hospital
15/03/2016	ORTHO VISION Analyser, software version 2.12.6 & below and ORTHO VISION Max Analyser, software version 2.12.10 (for ORTHO BioVue Cassettes). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
15/03/2016	Renasys GO External Power Supply Units supplied with Renasys GO NPWT Pumps (Negative Pressure Wound Therapy System)	Medical Device	Recall	Class II	Hospital
11/03/2016	ClaveGuard Diathermy Pencil	Medical Device	Recall	Class II	Hospital
11/03/2016	Dymista 125/50 Nasal Spray 17ml	Medicine	Recall	Class III	Retail
11/03/2016	TOPAZ MicroDebrider Wand (used for ablation and microdebridement in the tendons of the ankles, knees and shoulders)	Medical Device	Recall	Class II	Hospital
11/03/2016	Virage Occipital-Cervical-Thoracic (OCT) Spinal Fixation System - Closure Caps (used to stabilise support or correct alignment of spinal vertebrae)	Medical Device	Recall for Product Correction	Class II	Hospital
10/03/2016	Cios Alpha	Medical Device	Recall for Product Correction	Class II	Hospital
10/03/2016	e.cam system	Medical Device	Recall for Product Correction	Class II	Hospital
9/03/2016	Drill Sleeve 9.0/2.8, L 191 mm, f/AFN	Medical Device	Recall	Class II	Hospital
9/03/2016	HemoCue Glucose 201 RT Microcuvettes (used with HemoCue Glucose 201 RT and HemoCue Glucose 201 RT DM analysers). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
9/03/2016	Hydralyte Sports Berry, Oral Liquid 600mL	Medicine	Recall	Class II	Retail
9/03/2016	Syngo X-Workplace with software version VD10E (image processing workstation used with x-ray based diagnostic imaging system)	Medical Device	Recall for Product Correction	Class I	Hospital
8/03/2016	AvantGuard 1600 Li160A0	Medical Device	Recall for Product Correction	Class III	Hospital
8/03/2016	Cranial Screw PlusDrive ø 1.6 mm, Self-Drilling, L 3mm (part of the Low Profile Neuro System intended for use in selective trauma of the midface and craniofacial skeleton)	Medical Device	Recall	Class II	Hospital
8/03/2016	NIM-ECLIPSE Notebook Computer, NCCPU-E4	Medical Device	Recall for Product Correction	Class III	Hospital
8/03/2016	Universal Clamp System and UniWallis System (used during spinal cord surgery)	Medical Device	Recall for Product Correction	Class II	Hospital

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8/03/2016	VERION Reference Unit (Vision Planner) - used with the Alcon LenSx Laser System (Surgery planning system for ophthalmic surgery)	Medical Device	Recall for Product Correction	Class II	Hospital
4/03/2016	AXIOM Artis, Artis zee and Artis Q/Q.zen (fluoroscopic angiographic x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
4/03/2016	Dexcom G4 PLATINUM and Dexcom G5 Mobile receiver (Continuous Glucose Monitoring Device).	Medical Device	Recall for Product Correction	Class II	Consumer
4/03/2016	Freelite Human Kappa Integra Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
4/03/2016	Mums The One One Step hCG Urine Pregnancy Test	Medical Device	Recall	Class II	Consumer
4/03/2016	STERIS Quick Connects (used with the Steris System 1 Express and System 1 Plus sterilisers)	Medical Device	Recall for Product Correction	Class III	Hospital
4/03/2016	WIZARD2 Gamma Counters. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
3/03/2016	ARCTICGEL Pads (used with the Arctic Sun Temperature Management System)	Medical Device	Recall	Class II	Hospital
3/03/2016	Dimension Vista Chemistry 3 Calibrator. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
3/03/2016	Locking Screw Stardrive 1.5 mm and Cortex Screw Stardrive 1.5mm	Medical Device	Recall	Class II	Hospital
3/03/2016	SIGNA Pioneer MRI System	Medical Device	Recall for Product Correction	Class II	Hospital
1/03/2016	B.R.A.H.M.S Free BhCG Kryptor Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
1/03/2016	Horizon Medical Imaging (HMI) product versions 4.6.1 up to and including 11.9 and McKesson Radiology (MR) 12.0 and 12.1.1	Medical Device	Recall for Product Correction	Class II	Hospital
1/03/2016	i-STAT troponin I Assay Cartridges (cTnl). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
1/03/2016	ORTHO VISION Analyzer for ORTHO BioVue Cassettes, software version 2.12.6 and below. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
1/03/2016	Safe-T-Vue 6 and Safe-T-Vue10 Temperature Indicators (used to monitor the temperature of blood bags during transit)	Medical Device	Recall for Product Correction	Class II	Hospital

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1/03/2016	USB Communication Data Loss – Handheld Base Unit and Accu-Chek Inform II Base Unit	Medical Device	Recall for Product Correction	Class II	Hospital
29/02/2016	VITROS 5600 Integrated System. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
29/02/2016	VITROS Immunodiagnostic Products Total B-hCG II Reagent Packs & Calibrators (used with ECi/ECiQ, 3600 Immunodiagnostic Systems and 5600 Integrated Systems). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
26/02/2016	Blood Urea Nitrogen (BUN) Flex Reagent Cartridge (used with Dimension Vista System). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
26/02/2016	Covidien Emprint Percutaneous Antenna (short, standard & long) with Thermosphere Technology (used with microwave generator for coagulation of soft tissue)	Medical Device	Recall	Class I	Hospital
26/02/2016	GENTECH Generator (99Mo/99mTc Sterile Generator)	Medicine	Recall for Product Correction	Class II	Hospital
26/02/2016	Medtronic Reveal LINQ Insertable Cardiac Monitor (ICM)	Medical Device	Hazard Alert	Class II	Hospital
26/02/2016	QuikRead go wrCRP and QuikRead go wrCRP+Hb	Medical Device	Recall	Class II	Hospital
25/02/2016	IntelePACS InteleViewer software version 4.11.1 P144 (Radiology picture archiving and communication system)	Medical Device	Recall for Product Correction	Class II	Hospital
24/02/2016	ARROW Intra-Aortic Balloon Catheter and Percutaneous Insertion Kits	Medical Device	Recall	Class I	Hospital
24/02/2016	Coban 2 Compression Layer (active support bandage)	Medical Device	Recall	Class II	Hospital
24/02/2016	Coban 2 Lite Compression Layer (active support bandage)	Medical Device	Recall	Class III	Retail
24/02/2016	Renitec Plus (enalapril maleate/hydrochlorothiazide) 20/6mg tablets	Medicine	Recall	Class II	Retail
24/02/2016	Verso Shoulder Forked Retractor (Comprehensive Instrumentation (2 Prong Retractor))	Medical Device	Recall	Class II	Hospital
23/02/2016	175 cartons of GONAL-F follitropin alfa (rch) and 10 cartons of CETROTIDE cetorelix	Medicine	Recall	Class II	Retail
23/02/2016	Conceiveplease One Step HCG Urine Pregnancy test	Medical Device	Recall	Class II	Consumer

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
23/02/2016	ITD VESA 75/100 Adaptation with Rotation (Articulating Arm on Endoscope Trolley)	Medical Device	Recall for Product Correction	Class II	Hospital
23/02/2016	Maxagra 300 mg Capsules	Medicine	Recall	Class II	Consumer
22/02/2016	ADVIA Centaur Systems Calibrator E (Used with Advia Centaur, Centaur XP, Centaur XPT Systems). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
22/02/2016	iMDsoft MetaVision ICU (MV-ICU), Version 5.47.4622	Medical Device	Recall for Product Correction	Class III	Hospital
22/02/2016	Paracetamol Osteo-Tab, paracetamol 665 mg modified release tablet bottle (no other paracetamol brands are impacted)	Medicine	Recall	Class II	Retail
19/02/2016	Boston Scientific Urogynaecological Surgical Meshes	Medical Device	Recall for Product Correction	Class II	Hospital
19/02/2016	Sangofix set with hand pump (Blood/Solution Transfusion Set)	Medical Device	Recall	Class II	Hospital
19/02/2016	Spiggle & Theis ENT sinus single-use suction tubes (used for paranasal sinus suction)	Medical Device	Recall	Class II	Hospital
18/02/2016	cobas p 512 pre-analytical system. An in vitro diagnostic device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
18/02/2016	Nuelin SR 250 (theophylline 250mg) tablets, Bottle 100s	Medicine	Recall	Class II	Retail
17/02/2016	Cardiopulmonary Bypass Packs containing Terumo CDI H/S Cuvettes used with the CDI Blood Parameter Monitoring System 500	Medical Device	Recall for Product Correction	Class II	Hospital
17/02/2016	FGD (Fludeoxyglucose [18F]) Injection	Medicine	Recall	Class II	Hospital
17/02/2016	Helioseal Clear, 1.25g syringes	Medical Device	Recall	Class II	Retail
17/02/2016	Powerheart G3 Defibrillation Electrodes (used in Powerheart G3 9300A, 9300E, 9300P, 9390A, and 9390E Automatic External Defibrillator (AEDs))	Medical Device	Recall	Class II	Retail
16/02/2016	MitraClip System (Product Number # MSK02ST) containing the Clip Delivery System (Part number # CDS02ST) and the Steerable Guide Catheter (Part number # SGC01ST)	Medical Device	Recall for Product Correction	Class I	Hospital
16/02/2016	RayStation 3.0, 3.5, 4.0, 4.5 and 4.7 (Radiation therapy treatment planning system)	Medical Device	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
16/02/2016	Syntometrine Injection 1 mL Ampoule	Medicine	Recall	Class III	Wholesale
15/02/2016	3.0T GEMflex Coil used with GE Healthcare 3.0T Scanners (used to transmit and receive RF pulses for diagnostic MRI procedures)	Medical Device	Recall for Product Correction	Class II	Hospital
15/02/2016	Berichrom Antithrombin III Kits. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
15/02/2016	Sureclip and Sureclip Plus Haemostasis Clips (Gastrointestinal endotherapy clip applier)	Medical Device	Recall	Class II	Hospital
11/02/2016	Depuy Synthes Universal Battery Charger II (UBC II)	Medical Device	Recall	Class II	Hospital
11/02/2016	Klikfit CT Syringe with QFT and 75cm Extension tube	Medical Device	Recall	Class II	Hospital
11/02/2016	Leica M525 OH4 and M720 OH5 Surgical Microscope Stands with 400W Illumination	Medical Device	Recall for Product Correction	Class II	Hospital
11/02/2016	Merifluor EBV VCA IgM IFA (an Immunofluorescence Test for the Detection of Antibodies). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
11/02/2016	Rotor Yokes (used in Allegra X-5 Centrifuge). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
10/02/2016	Drager V Series Ventilator with the Optional PS500 Installed	Medical Device	Recall for Product Correction	Class I	Hospital
10/02/2016	Ondansetron Tablets - Ondansetron-DRLA and Ondansetron-SZ 4mg and 8mg	Medicine	Recall	Class III	Retail
10/02/2016	Terumo CDI H/S Cuvette	Medical Device	Recall for Product Correction	Class II	Hospital
10/02/2016	Trinity Acetabular Shell	Medical Device	Recall	Class II	Hospital
10/02/2016	VIDAS TOXO IgM Assay (used for the detection of toxoplasmosis antibodies). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
9/02/2016	Colleague P1.7 CXE Single Channel Pump and Colleague P1.7 CXE Triple Channel Pump (Infusion Pump)	Medical Device	Recall for Product Correction	Class II	Hospital
9/02/2016	Veletri Consumables Kit - Infusion administration set containing B. Braun Water for Injections	Medical Device	Recall	Class II	Consumer

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
8/02/2016	COULTER ReticPrep Reagent Kit (used for reticulocyte counting). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
8/02/2016	DVR ePAKs	Medical Device	Recall	Class II	Hospital
8/02/2016	Liquichek Specialty Immunoassay Controls. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
8/02/2016	PRN 50-M+ Digital Writer	Medical Device	Recall for Product Correction	Class II	Hospital
4/02/2016	Carestation 620 A1, 650 A1, and 650c A1 Anaesthesia devices and service kits	Medical Device	Recall for Product Correction	Class I	Hospital
4/02/2016	Glidescope Titanium Single-Use Video Laryngoscope Blades	Medical Device	Recall	Class I	Hospital
4/02/2016	Surgical Clipper Charger	Medical Device	Recall	Class II	Hospital
3/02/2016	3M ESPE Adper Single Bond 2	Medical Device	Recall	Class III	Retail
3/02/2016	Clobex clobetasol propionate 500 microgram/mL Shampoo Application Bottle 125mL	Medicine	Recall for Product Correction	Class II	Retail
3/02/2016	D-10 Rack Loader. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
3/02/2016	iChemVelocity Automated Urine Chemistry System using iChemVelocity Urine Chemistry Strips. An in vitro diagnostic device (IVD)	Medical Device	Recall	Class II	Hospital
3/02/2016	Kangaroo Polyurethane Feeding Tube, Radiopaque Line, Safe Enteral Connections 6.5 Fr/Ch (2.2 mm) x 36" (91 cm)	Medical Device	Recall	Class II	Hospital
3/02/2016	Puritan Bennett 980 Series Ventilator System PB980	Medical Device	Recall for Product Correction	Class I	Hospital
3/02/2016	Terumo CVS CDI H/S Cuvette provided within the Medtronic Perfusion Tubing Pack	Medical Device	Recall for Product Correction	Class II	Hospital
2/02/2016	Anti-Jk (Jk1).	Medical Device	Recall	Class I	Hospital
2/02/2016	HomeChoice Pro Automated PD System devices	Medical Device	Recall for Product Correction	Class III	Consumer
2/02/2016	Water for Injections 100 mL bottle (for parenteral use)	Medicine	Recall	Class II	Hospital
1/02/2016	Panocell 16 and Panocell 20. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class III	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
28/01/2016	Acetaminophen (Paracetamol) Reagent (used with L3K Assay in conjunction with the Architect cSystem Analyser). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
28/01/2016	Endobon Xenograft Granules	Medical Device	Recall	Class II	Retail
28/01/2016	PyroTitan Humeral Resurfacing Arthroplasty Shapers	Medical Device	Recall	Class II	Hospital
28/01/2016	Super Arrow-Flex Percutaneous Sheath Introducer Set	Medical Device	Recall	Class II	Hospital
28/01/2016	Trilogy dual prescription ventilators with software versions 13.2.04, 13.2.05, 14.0.00, and 14.1.01	Medical Device	Recall for Product Correction	Class I	Consumer
27/01/2016	TJF-Q180V Duodenoscope	Medical Device	Recall for Product Correction	Class II	Hospital
25/01/2016	DIAMOX (acetazolamide) 250mg tablet bottle	Medicine	Recall	Class II	Consumer
25/01/2016	LCP Distal Tibial Plates 3.5 anterolateral, left, 9 holes, length 132mm Stainless Steel Sterile	Medical Device	Recall	Class II	Hospital
22/01/2016	Beaver 4.0mm Banana Blade	Medical Device	Recall	Class II	Hospital
21/01/2016	Liko Universal SlingBar 350, SlingBar 450 and SlingBar 600 (used with Golvo, Uno, LikoLight, Likoall, Multirall and Viking XS/S/M/L mobile patient lifts)	Medical Device	Recall for Product Correction	Class II	Consumer
20/01/2016	Hexad 12-Lead ECG Monitoring derivation with Philips IntelliVue Patient Monitors, software versions K.21.54 or L.00.96	Medical Device	Recall for Product Correction	Class I	Hospital
18/01/2016	Astral Ventilators - ResMed Astral 100 & Astral 150 with SR1.1 software (SX544-0301)	Medical Device	Recall for Product Correction	Class II	Consumer
18/01/2016	Bond Ready-to-Use Primary Antibody and Probe kits used with Bond Polymer Refine Detection Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
18/01/2016	BrightView X/XCT/XCT Upgrade	Medical Device	Recall for Product Correction	Class II	Hospital
18/01/2016	Curlin 6000 and Painsmart IOD Ambulatory Infusion Pumps	Medical Device	Recall for Product Correction	Class II	Hospital
18/01/2016	PS900 Power Module supplied with 12 Lead ECG Interp. 210mm Basic Monitors	Medical Device	Recall for Product Correction	Class III	Hospital

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15/01/2016	ADVIA Centaur Systems, Dimension Vista Systems & IMMULITE Systems Estradiol Assays	Medical Device	Recall for Product Correction	Class I	Hospital
15/01/2016	Brain Metastases v1.0.0 and Adaptive Hybrid Surgery Analysis (AHSA) v1.0.0	Medical Device	Recall for Product Correction	Class I	Hospital
15/01/2016	Eclipse Treatment Planning System v 11, 13.0, 13.5 and 13.6 using Pencil Beam Convolution (PBC) Algorithm 11.0.31	Medical Device	Recall for Product Correction	Class I	Hospital
15/01/2016	Flocare Transition Giving Sets (Enteral feeding tube)	Medical Device	Recall for Product Correction	Class II	Consumer
15/01/2016	ImmunoCAP Specific IgG/IgG4 i1 Control H. An in vitro diagnostic device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
15/01/2016	Ingenuity CT/Core/Core128/Flex, Brilliance CT Big Bore /iCT/iCT SP Systems	Medical Device	Recall for Product Correction	Class II	Hospital
14/01/2016	Central Venous Catheter and Pressure Monitoring Sets	Medical Device	Recall	Class I	Hospital
14/01/2016	Saline 0.9% in 240ml elastomeric device	Medicine	Recall	Class I	Hospital
13/01/2016	Rayner Intraocular Lenses - Sulcoflex Aspheric 653L, Sulcoflex Toric 653T, C-flex Aspheric 970C, Superflex Aspheric 920H, Sulcoflex Aspheric 653L, T-flex Aspheric 623T	Medical Device	Hazard Alert	Class I	Hospital
12/01/2016	Aespire 7900, Aespire View, Aestiva 7900, Aestiva MRI, Aisys, Aisys CS2, Avance, and Avance CS2 Anesthesia devices installed from April 20, 2015 through October 2015. Service kits containing the ventilator Drive Gas Check Valve shipped from April 20, 2015 through October 2015 are also affected	Medical Device	Recall for Product Correction	Class II	Hospital
12/01/2016	Steris Amsco Warming Cabinet	Medical Device	Recall for Product Correction	Class III	Hospital
8/01/2016	BCS / BCS XP Automated Blood Coagulation Analyser with Dade Innovin .An in vitro diagnostic device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
8/01/2016	Integra Camino Intracranial Pressure (ICP) Monitor and the Integra Licox PtO2 and Temperature Monitor	Medical Device	Recall for Product Correction	Class II	Hospital
8/01/2016	One Step HCG Urine Pregnancy Test. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Retail

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
7/01/2016	Extraction Screw for PFNA Blade	Medical Device	Recall	Class I	Hospital
7/01/2016	HeartWare HVAD Controller AC Adapter and HeartWare HVAD Battery	Medical Device	Hazard Alert	Class I	Hospital
7/01/2016	INNOVANCE PFA P2Y. An in vitro diagnostic device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
7/01/2016	VITROS Chemistry System. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
6/01/2016	ADVIA Centaur PSA 100 test kit and 500 test kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
6/01/2016	AQURE data management system	Medical Device	Recall for Product Correction	Class II	Hospital
6/01/2016	Cook Beacon Tip Angiography Catheters	Medical Device	Recall	Class I	Hospital
5/01/2016	EliA SmDP Well	Medical Device	Recall	Class II	Hospital
4/01/2016	Guide Wires and K-Wires for T2 and Gamma Nailing Systems	Medical Device	Recall	Class II	Hospital
4/01/2016	Mavig Monitor suspension arms manufactured before January 2009 (used with x-ray fluoroscopic imaging systems)	Medical Device	Recall for Product Correction	Class II	Hospital
4/01/2016	Optima XR200amx, Optima XR220amx and Brivo XR285amx X-ray imaging systems	Medical Device	Recall for Product Correction	Class II	Hospital
24/12/2015	API ZYM B. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
24/12/2015	da Vinci Xi instrument & accessories	Medical Device	Recall for Product Correction	Class II	Hospital
24/12/2015	PFNA Nails (used during internal fixation surgery)	Medical Device	Recall	Class II	Hospital
24/12/2015	Syner-Kinase Urokinase powder for solution for injection or infusion, 10,000 IU vial (used for lysis of blood clots in cannulas)	Medicine	Recall	Class II	Hospital
24/12/2015	TruLight 3000, TruLight 5000, iLED 3, iLED 5 and TruVidia Lighting and Video Systems	Medical Device	Recall for Product Correction	Class II	Hospital
24/12/2015	VariAx 2 3.5 mm screws	Medical Device	Recall for Product Correction	Class II	Hospital
23/12/2015	Coulter S-CAL Calibrator Kits used on the Unicel DxH 800, DxH 600, LH 750 and LH 780 Systems.	Medical Device	Recall for Product Correction	Class III	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
23/12/2015	Oxylog Transport Ventilator	Medical Device	Recall for Product Correction	Class I	Hospital
22/12/2015	2-Way Foley Catheters and 2-Way Council Tip Foley Catheters (used for urinary drainage)	Medical Device	Recall for Product Correction	Class II	Hospital
22/12/2015	96 Deep Well Plate 2mL (used on the VERSANT kPCR Sample Preparation and Tissue Preparation System)	Medical Device	Recall	Class II	Hospital
22/12/2015	All Magnetom MRI systems with superconductive magnets	Medical Device	Recall for Product Correction	Class II	Hospital
22/12/2015	Ambu AuraGain Single Use Laryngeal Mask – Sterile	Medical Device	Recall	Class II	Hospital
22/12/2015	Dengue NS1 Ag Strip	Medical Device	Recall	Class II	Hospital
22/12/2015	Maxolon Metoclopramide 10mg Tablets, Blister pack 100s	Medicine	Recall	Class II	Retail
22/12/2015	VerifyNow Aspirin Test Kit	Medical Device	Recall	Class II	Hospital
21/12/2015	All Giraffe Carestation Beds shipped between 18 September 2015 and 1 November 2015	Medical Device	Recall for Product Correction	Class I	Hospital
21/12/2015	BD Vacutainer Heparin Tube. n in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
21/12/2015	Samarys Peek Anterior Cervical Cage	Medical Device	Hazard Alert	Class I	Hospital
21/12/2015	TCM CombiM module (used with Radiometer Transcutaneous Monitors)	Medical Device	Recall	Class II	Hospital
18/12/2015	Synream Medullary Reamer Head Size 13.5mm	Medical Device	Recall	Class II	Hospital
17/12/2015	Reflotron Uric Acid (used with Reflotron Plus & Reflotron Sprint Single test chemistry systems) An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
16/12/2015	IntelliVue Information Centre (PIIC) iX (centralised patient monitor)	Medical Device	Recall for Product Correction	Class I	Hospital
16/12/2015	Kirschner Wire 1.6 mm, with drill tip, length 200 mm	Medical Device	Recall for Product Correction	Class III	Hospital
16/12/2015	miraDry System (used for the treatment of primary axillary hyperhidrosis)	Medical Device	Recall for Product Correction	Class II	Hospital
15/12/2015	Arcadophta SARL– Arcotane 5ml	Medical Device	Recall	Class I	Hospital
15/12/2015	Hypochlorite 1% Solution & Hypochlor 1% Solution	Medical Device	Recall	Class III	Retail

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15/12/2015	STALORAL and PHOSTAL	Medical Device	Recall	Class I	Consumer
11/12/2015	BladderScan BVI 9600 with AortaScan mode portable ultrasound instrument	Medical Device	Recall for Product Correction	Class I	Hospital
11/12/2015	Genotropin 5 mg and 12 mg GoQuick Pre-filled Pens	Medicine	Product Defect Alert	Class III	Retail
10/12/2015	Gynecare Thermachoice III Thermal Balloon Ablation Silicone Catheter	Medical Device	Recall	Class II	Hospital
10/12/2015	MediRedi Fistula Packs	Medical Device	Recall	Class II	Hospital
10/12/2015	MOSAIQ version 2.5 and above - Medical Oncology only	Medical Device	Recall for Product Correction	Class II	Hospital
10/12/2015	PFN/PFNA Insertion Handle (used for the insertion of Proximal Femur Nail during internal fixation surgery)	Medical Device	Recall	Class II	Hospital
9/12/2015	ADVIA Centaur XPT System, with software versions V1.0.1, V1.0.2 and V1.0.3	Medical Device	Recall for Product Correction	Class II	Hospital
9/12/2015	Multiple dental abutment products and their accessories.	Medical Device	Recall	Class II	Retail
9/12/2015	Sysmex XN and XN-L Series - All Sysmex XN analysers versions 16 to 19	Medical Device	Recall for Product Correction	Class III	Hospital
9/12/2015	Unicel DxH 800, SMS and 600 systems, with software versions 3.0.2.0 and 1.1.1.0. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
8/12/2015	Polymer Refine Red Detection (used for testing and identification of neoplasm). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
8/12/2015	Titanium Fluted Stem Extender	Medical Device	Recall	Class III	Hospital
7/12/2015	Absorb Bioresorbable Vascular Scaffold (BVS) System (Bioresorbable balloon expandable scaffold with bioresorbable polymeric drug coating mounted on a balloon dilatation catheter)	Medical Device	Recall for Product Correction	Class II	Hospital
7/12/2015	ACUITY Pro 9 Fr Guide Catheter	Medical Device	Recall	Class II	Hospital
7/12/2015	Bayer Source Administration Sets (SAS) used with the Medrad Intego PET Infusion System [Catalogue Number INT CSS]	Medical Device	Recall	Class II	Hospital

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7/12/2015	ENA RELISA Single Well Screen (576 well) Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
7/12/2015	Endo GIA Ultra Universal Stapler Handles (Short, Standard & XL versions)	Medical Device	Recall	Class II	Hospital
7/12/2015	Shape Arm Kit Left and Shape Arm Kit Right (Mounting/positioning system for flat panel monitors)	Medical Device	Recall for Product Correction	Class I	Hospital
7/12/2015	Switch Point Infinity 3 (Operating Room Management System)	Medical Device	Recall for Product Correction	Class III	Hospital
3/12/2015	Opti-Mist Nebuliser / Nebuliser Mask Products	Medical Device	Recall	Class II	Hospital
3/12/2015	Oxoid Antimicrobial Susceptibility Testing Disc QD15 Quinupristin / Dalfopristin, CT1644B	Medical Device	Recall	Class II	Hospital
2/12/2015	300mL Canister (with Gel) for use with the ActiV.A.C. Therapy System	Medical Device	Recall	Class II	Hospital
2/12/2015	Birmingham Hip Modular Head (BHHM) - Monoblock version	Medical Device	Hazard Alert	Class II	Hospital
2/12/2015	Etest PIPTAZO PTC 256 (used for testing of Enterobacteria strains). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class I	Hospital
2/12/2015	Fresenius Medical Care (FME) Dialysis Fistula Pack 5 and Safety AVF Needle - Fixed Wing	Medical Device	Recall	Class II	Hospital
2/12/2015	MediRedi A.V. Fistula Pack	Medical Device	Recall	Class II	Hospital
2/12/2015	Sapphire Multi-Therapy and Sapphire Epidural Pumps with software versions 11.00 and below	Medical Device	Recall for Product Correction	Class II	Hospital
1/12/2015	syngo X-Workplace with software VD10E and tabcard "4D"	Medical Device	Recall for Product Correction	Class II	Hospital
30/11/2015	A.L.P.S. 4.0mm Cancellous Locking Screws (non-sterile)	Medical Device	Hazard Alert	Class II	Hospital
30/11/2015	ADVIA Chemistry Halogen Lamp	Medical Device	Recall for Product Correction	Class III	Hospital
27/11/2015	Brainlab Brain Metastases v1.0.0 and Adaptive Hybrid Surgery Analysis v1.0.0	Medical Device	Recall for Product Correction	Class I	Hospital
27/11/2015	Careline Colostrum 820mg chewable tablets 200's and 400's with expiry dates of 10/2016, 04/2017 and 09/2017	Medicine	Recall	Class III	Retail

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27/11/2015	Ingenuity CT, Ingenuity Core, Ingenuity Core128, Brilliance 64, Brilliance iCT SP, Brilliance iCT systems with software versions 4.1.2, 4.1.3 and 4.1.4	Medical Device	Recall for Product Correction	Class III	Hospital
27/11/2015	Nebulisers / Nebuliser Mask Products	Medical Device	Recall	Class II	Hospital
26/11/2015	IntellaTip MiFi XP Asymmetric (N4) Curve Temperature Ablation Catheters	Medical Device	Recall	Class I	Hospital
25/11/2015	Drager V Series Ventilator with the Optional PS500 battery Installed	Medical Device	Recall for Product Correction	Class I	Hospital
25/11/2015	Karma Wheelchairs	Medical Device	Recall for Product Correction	Class II	Hospital
24/11/2015	Abtectcell III 0.8% and Abtectcell III 0.8% Bulk Pack. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class I	Hospital
24/11/2015	AHG Control Cells 3%. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
23/11/2015	Artis systems with large display module	Medical Device	Recall for Product Correction	Class II	Hospital
23/11/2015	ENDOEYE Video Telescope	Medical Device	Recall for Product Correction	Class I	Hospital
23/11/2015	Oxoid Antimicrobial Susceptibility Testing Disc for Penicillin G (P1). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
20/11/2015	A.V. Fistula sets for Haemodialysis - Safety AVF Needle fixed wing	Medical Device	Recall	Class II	Hospital
20/11/2015	VITROS 4600 Chemistry System and VITROS 5,1 FS Chemistry System. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
20/11/2015	Xper Flex Cardio Patient Monitoring System	Medical Device	Recall for Product Correction	Class II	Hospital
19/11/2015	Non Buffered Formalin. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
18/11/2015	ADVIA Centaur and ADVIA Centaur XP	Medical Device	Recall for Product Correction	Class II	Hospital
17/11/2015	Allura Xper, Allura Clarity & Integris	Medical Device	Recall for Product Correction	Class I	Hospital
17/11/2015	AU480, AU680, AU5800 Chemistry Analysers. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
17/11/2015	Bard Arctic Sun 5000 Temperature Management System	Medical Device	Recall for Product Correction	Class II	Hospital
17/11/2015	Dimension Integrated Chemistry Systems.	Medical Device	Recall for Product Correction	Class II	Hospital
17/11/2015	Two and three stage I.V. Poles (used as an optional accessory to a stretcher)	Medical Device	Recall for Product Correction	Class II	Hospital
16/11/2015	artus C. trachomatis Plus kits	Medical Device	Recall for Product Correction	Class II	Hospital
16/11/2015	ECG Electrode SKINTACT W-60	Medical Device	Recall	Class III	Hospital
16/11/2015	HemoCue HbA1c 501 Test Cartridge. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
16/11/2015	Provide Protection Caps and Provide Impression Copings	Medical Device	Recall	Class II	Retail
16/11/2015	Various surgical instruments actuated by the da Vinci Si Single Site Grip Release mechanism	Medical Device	Recall for Product Correction	Class I	Hospital
13/11/2015	Allura Xper and Allura Clarity - software releases 1.2.7, or 2.0.6, or 7.2.x where x<8 or 7.6.x or 7.8.x or 8.1.x where x< 16 or 8.2.x where x<16	Medical Device	Recall for Product Correction	Class II	Hospital
13/11/2015	BARRIER Easywarm (Active Self Warming Blanket) and BARRIER Easywarm+ (Flexible Active Self Warming Blanket)	Medical Device	Recall for Product Correction	Class III	Hospital
13/11/2015	Compounded Fentanyl and/or Fentanyl Bupivacaine combinations stored in Becton-Dickinson Syringes 3ml or 10ml Plastipak Syringes	Medicine	Recall	Class II	Hospital
13/11/2015	InSync III Cardiac Resynchronisation Therapy Pacemakers (CRT-P)	Medical Device	Hazard Alert	Class I	Hospital
13/11/2015	VITROS 3600 and 5600 Systems using Software Version 3.2 and Below. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
12/11/2015	ECG Electrode	Medical Device	Recall	Class II	Hospital
12/11/2015	Lymph-flo Injection Composite Pack (Technetium99m-ATC (Tc99m-ATC))	Medicine	Recall	Class III	Hospital
12/11/2015	Screw Inserter for TFN-Advanced (TFNA) Proximal Femoral Nailing System	Medical Device	Recall	Class II	Hospital
11/11/2015	Arceole C3F8 and SF6	Medical Device	Recall	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
11/11/2015	Tina-quant Albumin. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
10/11/2015	Attachment for Acetabular and Medullary Reaming (used with the Compact Air Drive II, an air-driven power tool for use in traumatology, endoprosthesis and spinal column surgery)	Medical Device	Recall	Class I	Hospital
10/11/2015	DGDE DirectGuide™ Drill Extender and kits containing the DGDE Drill Extender	Medical Device	Recall	Class II	Retail
10/11/2015	Oxoid Antimicrobial Susceptibility Testing Disc Cefoxitin. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
9/11/2015	Bard 100% Latex-Free Urinary Drainage Bag with Anti-Reflux Chamber and Bard EZ-Lok	Medical Device	Recall	Class II	Hospital
9/11/2015	ichem VELOCITY Urine Chemistry Strips. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
9/11/2015	LeMaitre Single Lumen Embolectomy Catheter 3F, 80 cm	Medical Device	Recall	Class II	Hospital
9/11/2015	MAQUET HCU 30 Base Unit	Medical Device	Recall for Product Correction	Class I	Hospital
9/11/2015	Rainbow Reusable Sensors for rainbow SET Devices with SpCO, SpO ₂ , and SpMet. (used with pulse oximeter for the measurement of parameters such as arterial oxygen).	Medical Device	Recall	Class II	Hospital
6/11/2015	Alaris System Syringe Module	Medical Device	Recall for Product Correction	Class I	Hospital
6/11/2015	Chlorhexidine and Cetrimide irrigation solution 30mL Steritube ampoules (chlorhexidine gluconate 0.05%w/v and cetrimide 0.5%w/v)	Medicine	Recall	Class II	Consumer
6/11/2015	Optisure Dual Coil Defibrillation Leads	Medical Device	Hazard Alert	Class I	Hospital
6/11/2015	Philips HeartStart MRx Defibrillator/Monitor	Medical Device	Recall for Product Correction	Class II	Hospital
6/11/2015	Philips MX 16-slice Computer tomography x-ray system (software upgrade from v2.0.0.21479 to v2.0.0.21480)	Medical Device	Recall for Product Correction	Class II	Hospital
5/11/2015	Oxoid Anti-microbial Susceptibility Testing Disc CT0024B Gentamicin (CN 10) 5x50 discs	Medical Device	Recall	Class II	Hospital
5/11/2015	QConnect HBVNAT Positive	Medical Device	Recall	Class III	Hospital

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4/11/2015	Prius Elite Bed	Medical Device	Recall for Product Correction	Class II	Hospital
4/11/2015	Ultra-Fine Insulin Syringe for use with U-100 insulin	Medical Device	Recall	Class II	Hospital
3/11/2015	Human Total 25-OH Vitamin D IVD ELISA Kit. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class III	Hospital
3/11/2015	IOLMaster 500, software version 7.5.2, 7.7.2 and 7.7.3	Medical Device	Recall for Product Correction	Class II	Hospital
3/11/2015	Vented Paclitaxel Set (infusion set used during the administration of medication of anaesthetic drugs)	Medical Device	Recall	Class II	Hospital
2/11/2015	N Latex β 2-Microglobulin	Medical Device	Recall	Class II	Hospital
29/10/2015	ADVIA Centaur XPT. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
29/10/2015	SOMATOM Definition AS when used with Patient table PHS1600 and software license for "Adaptive 4D Spiral"	Medical Device	Recall for Product Correction	Class II	Hospital
29/10/2015	Vital Signs LightWand Stylet	Medical Device	Recall	Class II	Hospital
29/10/2015	Zarontin (ethosuximide) 250mg capsule bottle	Medicine	Recall	Class II	Retail
28/10/2015	Access Free T3 Reagent Kit (For use with the Access Family of Immunoassay Systems). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
28/10/2015	ADVIA Chemistry XPT Systems with software version 1.0.3. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
28/10/2015	eVent Medical Inspiration LS & i Series Ventilator Systems	Medical Device	Recall for Product Correction	Class I	Hospital
28/10/2015	Revolution CT Scanners, software version 15MW03.12	Medical Device	Recall for Product Correction	Class II	Hospital
26/10/2015	All Welch Allyn KleenSpec Corded Illumination Systems	Medical Device	Recall for Product Correction	Class II	Hospital
26/10/2015	Amphirion Deep Percutaneous Transluminal Angioplasty (PTA) Balloon Dilation Catheter	Medical Device	Recall	Class I	Hospital
26/10/2015	LifePack 1000 Automated External Defibrillator (AED's), software version 2.42 or earlier	Medical Device	Recall for Product Correction	Class I	Hospital

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23/10/2015	Oxoid M.I.C Evaluator for Penicillin 256 microgram/ml	Medical Device	Recall	Class II	Hospital
22/10/2015	Access CEA Reagent Kit (For use with the Access Family of Immunoassay Systems). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
22/10/2015	Quidel Sofia Legionella FIA. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
21/10/2015	BenchMark ULTRA with software versions VSS 11.9 or higher, and DISCOVERY ULTRA clinical chemistry analysers (used for detecting and preparing tissue morphology and components). An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
21/10/2015	Sodium Chromate (Cr-51) 8MBq/mL Injections	Medicine	Recall	Class III	Hospital
20/10/2015	Brianlab iPlan RT Image (versions below v.4.1.2) / iPlan RT and BrainSCAN (discontinued in 2002)	Medical Device	Recall for Product Correction	Class I	Hospital
20/10/2015	Epilim EC200 sodium valproate 200mg tablet blister pack (used for the treatment of primary generalised epilepsy)	Medicine	Recall	Class II	Retail
20/10/2015	LIFECODES LifeScreen Deluxe (LMX). An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class III	Hospital
20/10/2015	MONACO, version 5.10.00 and above	Medical Device	Recall for Product Correction	Class I	Hospital
20/10/2015	MoPyc Radial Head Prosthesis Stem (used in elbow reconstruction)	Medical Device	Recall for Product Correction	Class II	Hospital
20/10/2015	Roche Clinical Chemistry tests using NAD(H) or NADP(H) reaction. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
20/10/2015	Triathlon MIS Modular Distal Capture	Medical Device	Recall	Class II	Hospital
19/10/2015	AU480 Clinical Chemistry Analyser - software version 1.81	Medical Device	Recall for Product Correction	Class II	Hospital
19/10/2015	Multiple Children's Suspensions, Pack size 200 ml	Medicine	Recall	Class I	Consumer
19/10/2015	Synchron Systems Enzymatic Creatinine (CR-E) and Uric Acid (URIC) Reagents. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
15/10/2015	Vaios Total Shoulder Replacement System	Medical Device	Hazard Alert	Class II	Hospital

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15/10/2015	VariSource iX Control Software	Medical Device	Recall for Product Correction	Class II	Hospital
14/10/2015	Cook Beacon Tip Angiography Catheters	Medical Device	Recall	Class I	Hospital
14/10/2015	Enzygnost Anti-VZV/IgG	Medical Device	Recall	Class II	Hospital
13/10/2015	Centricity PACS-IW with Universal Viewer Versions 5.0 SP2 and higher and Centricity Universal Viewer versions 6.0 and higher (used for storage and retrieval of images used in radiology)	Medical Device	Recall for Product Correction	Class I	Hospital
13/10/2015	Disposable Myringotomy blade with handle (used during surgery on the ear drum to relieve pressure)	Medical Device	Recall	Class II	Hospital
13/10/2015	LifeCycle for Prenatal Screening software	Medical Device	Recall for Product Correction	Class II	Hospital
13/10/2015	Plum 360 Infusion Pump, Software Version 15.01.XX.009	Medical Device	Recall for Product Correction	Class I	Hospital
13/10/2015	Zimmer Natural Nail CM Long-Cephalomedullary Nails	Medical Device	Recall for Product Correction	Class II	Hospital
12/10/2015	EndoBarrier Gastrointestinal Liner System	Medical Device	Hazard Alert	Class II	Hospital
12/10/2015	EnVision Flex/HRP visualisation reagent, part of EnVision Flex/Flex+ Kits	Medical Device	Recall	Class II	Hospital
9/10/2015	Allura Xper FD Release 8.2.16	Medical Device	Recall for Product Correction	Class I	Hospital
9/10/2015	Neupogen (filgrastim) 480microgram 10s	Medicine	Recall	Class II	Hospital
9/10/2015	Pangea, USS II Polyaxial, Matrix Deformity, Matrix Degenerative and Pangea Degenerative Systems, Pedicle Awl 4.0mm with Canevasit and Silicone Handle (internal fixation system)	Medical Device	Recall for Product Correction	Class II	Hospital
9/10/2015	Philips Brilliance 16-Slice (Air), Brilliance 64 CT, Ingenuity Core, Ingenuity Core 128, Brilliance CT Big Bore, Ingenuity Flex. Software versions V3.6.1, V3.6.2, V3.6.4, and V3.6.5	Medical Device	Recall for Product Correction	Class II	Hospital
8/10/2015	Ethicon HARMONIC ACE+ 7 Laparoscopic Shears	Medical Device	Recall	Class II	Hospital
8/10/2015	Sydney IVF PVP (Used during microinjection techniques for reducing sperm motility to enable easier capture using a pipette)	Medical Device	Recall	Class III	Hospital

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7/10/2015	ARIA for Radiation Oncology and ARIA Oncology Information System for Radiation Oncology, Versions 10.X, 11.X, 13.0 or 13.5 with Clinical Assessment licence only	Medical Device	Recall for Product Correction	Class I	Hospital
7/10/2015	MAJ-1606 instrument adaptor (designed for use with the Olympus MAJ-1607 instrument channel water tube)	Medical Device	Recall	Class II	Hospital
7/10/2015	OLS-500 & OLS-700 surgical lights	Medical Device	Recall for Product Correction	Class II	Hospital
2/10/2015	Duracon Augments - Tibial Wedge Implants	Medical Device	Hazard Alert	Class II	Hospital
1/10/2015	Apohealth & Terry White Children's Paracetamol and Ibuprofen children's suspensions	Medicine	Recall	Class II	Consumer
1/10/2015	Exeter Small and Large Tapered Pin Reamer (used as part of the Exeter Procedure Pack)	Medical Device	Recall	Class II	Hospital
1/10/2015	Giraffe Shuttle Products (uninterruptable power supply for Giraffe Products)	Medical Device	Recall for Product Correction	Class II	Hospital
1/10/2015	PCA Tapers, LFIT V40 Tapers, V40 Tapers (Vitallium Femoral Heads)	Medical Device	Recall	Class II	Hospital
1/10/2015	VITROS Chemistry Products Calibrator Kit 9 (used on VITROS 250, 350, 4600, 5600 and 5,1 FS Systems). An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class I	Hospital
30/09/2015	MiniMed 640G insulin pump	Medical Device	Recall for Product Correction	Class II	Consumer
30/09/2015	Prism Medical P300 and C300 Lifts	Medical Device	Recall	Class II	Consumer
30/09/2015	Shuttle Discovery Seat (designed for children aged between six months and four years who have a physical disability)	Medical Device	Recall for Product Correction	Class II	Consumer
29/09/2015	AXIOM Artis dFA, dFC, dFCM, dBA, dBC, dBCM, dMP systems with SW version VB35D	Medical Device	Recall for Product Correction	Class II	Hospital
29/09/2015	AXIOM Artis FA, FC, dFA, dFC, dFCM, BA, BC, dBA, dBC, dBCM, MP, dMP systems with SW version VB23N/P	Medical Device	Recall for Product Correction	Class II	Hospital
29/09/2015	Brainlab Patient Data Manager	Medical Device	Recall for Product Correction	Class I	Hospital
29/09/2015	HeartWare Ventricular Assist System Battery	Medical Device	Recall	Class I	Hospital

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29/09/2015	MULTIGENT Ammonia Ultra Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
25/09/2015	Alkaline Phosphatase (ALPAMP, ALPDEA and ALPA_c) used on the ADVIA 1200, 1650, 1800, 2400, and XPT Chemistry Systems	Medical Device	Recall	Class II	Hospital
25/09/2015	EPREX PROTECS 4000U 6X0.4ML SYR.	Medicine	Recall	Class III	Retail
25/09/2015	Intramedullary (SP 2 IM) Rod 400mm Instrument	Medical Device	Recall	Class II	Hospital
25/09/2015	PORT-A-CATH Plastic Hub Needles, 0.9mm (20G) x 19mm (3/4 in) 90 deg	Medical Device	Recall	Class II	Hospital
25/09/2015	PreciControl ClinChem Multi 1Lot No. 174787 & 174794	Medical Device	Recall for Product Correction	Class III	Hospital
22/09/2015	REFRESH NIGHT TIME and Ircal Eye Ointments	Medical Device	Recall	Class II	Consumer
21/09/2015	Neoss Guide – Drill-Hubs I to V included in Neoss	Medical Device	Recall	Class II	Hospital
18/09/2015	ALBAclone Anti-Leb, (LEB2) 1 x 5mL	Medical Device	Recall	Class II	Hospital
18/09/2015	Medtronic Navigated Solera Driver Tips for Spinal Surgery	Medical Device	Recall for Product Correction	Class II	Hospital
18/09/2015	Retractor for Sciatic Nerve; and Retractor for Sciatic Nerve, long	Medical Device	Recall	Class II	Hospital
18/09/2015	Unitek Victory Mini Tube Lower Left Buccal Tube	Medical Device	Recall	Class III	Hospital
17/09/2015	True Cut Oscillating Blade, 0.9mm x 80mm x 12mm, single use device (used to cut skeletal bone and tissue)	Medical Device	Recall	Class III	Hospital
16/09/2015	GE 3.0T MR Systems (Full body MRI system):	Medical Device	Recall for Product Correction	Class I	Hospital
16/09/2015	Monaco 5.10.00	Medical Device	Recall for Product Correction	Class I	Hospital
16/09/2015	Suction Adapter Type A (Gauge)	Medical Device	Recall for Product Correction	Class II	Hospital
15/09/2015	4FR Single Lumen Pressure Injectable Peripherally Inserted Central Catheter (PICC)	Medical Device	Recall for Product Correction	Class I	Hospital
15/09/2015	Application Instrument for Sternal ZIPFIX	Medical Device	Recall for Product Correction	Class I	Hospital

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15/09/2015	Brio Charging System Model 6721 (used with Deep Brain Stimulator, Brio IPG Model 65-6788)	Medical Device	Recall	Class I	Hospital
15/09/2015	Bulk Loader Module for cobas p 471 centrifuge unit	Medical Device	Recall for Product Correction	Class II	Hospital
14/09/2015	EIZO Medical Monitors	Medical Device	Recall for Product Correction	Class II	Hospital
14/09/2015	Novocastra Lyophilised Mouse Monoclonal Antibody CD10 Reagents. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class I	Hospital
14/09/2015	seleXys TH+ and seleXys TPS acetabular shells	Medical Device	Hazard Alert	Class II	Hospital
11/09/2015	GF-UCT180 Ultrasonic Gastrovideoscope	Medical Device	Recall for Product Correction	Class II	Hospital
10/09/2015	Liko Viking mobile lifts	Medical Device	Recall for Product Correction	Class II	Hospital
10/09/2015	SEROPHENE clomiphene citrate 50mg tablet	Medicine	Recall	Class III	Retail
8/09/2015	Base array component of the MAKO RIO Robotic Arm	Medical Device	Recall for Product Correction	Class II	Hospital
8/09/2015	Flexi-Slip endotracheal tube stylets	Medical Device	Recall	Class I	Hospital
8/09/2015	Gram Crystal Violet stain MV1031	Medical Device	Recall	Class III	Hospital
8/09/2015	Maxi Air Blower Unit - Model 230V	Medical Device	Recall for Product Correction	Class II	Hospital
7/09/2015	CA1:1L EVO 15 (Contrangle used in dentistry)	Medical Device	Recall	Class II	Retail
4/09/2015	iChem Velocity Urine Chemistry Strips. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
4/09/2015	KIMVENT Closed Suction Systems (Tube, tracheal, general-purpose, single-use)	Medical Device	Recall for Product Correction	Class II	Hospital
4/09/2015	Medtronic CryoConsole	Medical Device	Recall for Product Correction	Class II	Hospital
4/09/2015	RAPIDPoint 500 Measurement Cartridges used on the RAPIDPoint 500 System. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital

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4/09/2015	Spectra Optia Apheresis System (intended to be used to separate blood extracted from a donor or patient into various components, while the donor/patient is connected to the unit)	Medical Device	Recall for Product Correction	Class I	Hospital
2/09/2015	Blackmores Triple Action Bone Formula	Medicine	Recall	Class III	Retail
2/09/2015	Coloplast urogynaecological surgical mesh	Medical Device	Recall for Product Correction	Class I	Hospital
2/09/2015	GYNEMESH PS and TVT Devices	Medical Device	Recall for Product Correction	Class I	Hospital
2/09/2015	MetaVision ICU (MV-ICU)	Medical Device	Recall for Product Correction	Class II	Hospital
1/09/2015	ALITUOT Delivery System Complete Set (orthopaedic surgical kit, used to place injectable synthetic cortical bone void filler in weakened or diminished bone stock)	Medical Device	Recall	Class II	Hospital
1/09/2015	BD Affirm VPIII Microbial Identification Tests (used for the testing of multiple infectious organisms). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
31/08/2015	ACUSON SC2000 ultrasound systems with software versions VB10B and lower	Medical Device	Recall for Product Correction	Class II	Hospital
31/08/2015	Medi-Trace Cadence Adult Multi-Function Defibrillation Electrodes, Pre-connect (used in conjunction with Automatic External Defibrillators)	Medical Device	Recall	Class I	Hospital
31/08/2015	syngo Lab Data Manager with software version VA12B. (Software used to supplement operational functions). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
28/08/2015	ADVIA Centaur, ADVIA Centaur XP, ADVIA Centaur XPT – HbsAgII Assay	Medical Device	Recall for Product Correction	Class III	Hospital
28/08/2015	Allura Xper FD	Medical Device	Recall for Product Correction	Class II	Hospital
28/08/2015	Apo-Paracetamol 500mg tablets, Bottle, 1000,	Medicine	Recall	Class II	Retail
28/08/2015	Bactroban Cream (mupirocin calcium 2% w/w) 15g; and Bactroban Nasal Ointment (mupirocin calcium 2% w/w) 3g	Medicine	Recall	Class II	Wholesale
28/08/2015	Cios Alpha mobile C-arm x-ray system	Medical Device	Recall for Product Correction	Class II	Hospital

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28/08/2015	Dimetapp Daytime/Night time Liquid Caps	Medicine	Recall	Class II	Retail
28/08/2015	Philips HeartStart MRx Monitor/Defibrillator with Q-CPR	Medical Device	Recall for Product Correction	Class III	Hospital
27/08/2015	ABL90Flex battery module used with Radiometer ABL90FLEX blood gas analyser (Optional battery). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
27/08/2015	CONTOUR NEXT control solutions. In vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class I	Hospital
27/08/2015	Disposable Reflective Marker Spheres	Medical Device	Recall for Product Correction	Class II	Hospital
27/08/2015	Mitoxantrone Hydrochloride Injection Concentrate 20mg/10ml	Medicine	Recall	Class III	Hospital
27/08/2015	Shen Neng Ching Fei Yi Hou Pien	Medicine	Recall	Class II	Retail
27/08/2015	WATCHMAN Left Atrial Appendage Closure Device with Delivery System	Medical Device	Recall for Product Correction	Class I	Hospital
26/08/2015	chromID S.aureus agar (SAID/MRSA). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
25/08/2015	Actifuse ABX and Actifuse MIS System	Medical Device	Recall	Class I	Hospital
25/08/2015	Edwards Pressure Monitoring Kit & Set, Model Number: PXMK2043	Medical Device	Recall	Class II	Hospital
21/08/2015	Alaris System Syringe Module	Medical Device	Recall for Product Correction	Class I	Hospital
21/08/2015	DIRECTVIEW Software versions 5.6 & greater and 5.7 with DR LLI Auto Stitch option on DRX Evolution with Premium and Full Featured Wall Stands	Medical Device	Recall for Product Correction	Class II	Hospital
21/08/2015	LX3 Microscope Floor Stand used with the LuxOR Ophthalmic Microscope and LuxOR Ophthalmic Microscope with Q-VUE 3D Assistant Visualisation (used during ophthalmic surgical procedure for cataract, retina and cornea)	Medical Device	Recall for Product Correction	Class I	Hospital
20/08/2015	Brilliance 64, Ingenuity CT, Ingenuity Core, and Ingenuity Core128 with the following versions:	Medical Device	Recall for Product Correction	Class II	Hospital

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20/08/2015	RF enabled St. Jude Medical Ellipse, Fortify Assura, Unify Assura, and Quadra Assura Implantable Cardioverter Defibrillators (ICDs) and Assurity and Allure Pacemakers when used with Merlin@home RF Remote Monitoring Transmitter Model EX1150	Medical Device	Hazard Alert	Class II	Hospital
19/08/2015	Alcon 23 Gauge and 25 Gauge Valved entry systems	Medical Device	Recall for Product Correction	Class II	Hospital
19/08/2015	Fentanyl Intranasal Spray 600ug/2mL	Medicine	Recall	Class II	Hospital
19/08/2015	PROFEMUR NECK VAR/VAL 8DG, Long Cobalt Chrome, Part number PHAC1254	Medical Device	Hazard Alert	Class II	Hospital
17/08/2015	Etoposide (as phosphate) 200mg in 10mL in 20mL and 165mg in 8.3mL in 10mL syringe for Intravenous injection	Medicine	Recall	Class I	Hospital
17/08/2015	FreeStyle Optium Neo Blood Glucose and Ketone Monitoring System. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Retail
17/08/2015	Xia 3 Titanium Torque Wrench	Medical Device	Recall	Class II	Hospital
13/08/2015	DigitalDiagnost, Release 4.1/4.1.1	Medical Device	Recall for Product Correction	Class II	Hospital
13/08/2015	Extension Set	Medical Device	Recall	Class II	Hospital
13/08/2015	Philips Trauma Diagnost X-ray Systems	Medical Device	Recall for Product Correction	Class II	Hospital
13/08/2015	VEPTR Vertical Expandable Prosthetic Titanium Rib	Medical Device	Recall	Class II	Hospital
13/08/2015	Volcano IVUS Ultrasound Imaging System	Medical Device	Recall for Product Correction	Class II	Hospital
12/08/2015	ACUSON SC2000 ultrasound systems with software versions VA16A to VA30A and the Stress Echo Option	Medical Device	Recall for Product Correction	Class II	Hospital
12/08/2015	ADVIA Chemistry System – Urea Nitrogen and Urea Nitrogen Concentrated Assays. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
12/08/2015	Arrow International 4Fg Seldinger Conversion Set with Long Sheath	Medical Device	Recall	Class II	Hospital
12/08/2015	EXACTRAC Version 6.0.0 through to 6.0.5	Medical Device	Recall for Product Correction	Class I	Hospital

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12/08/2015	Sinus-SuperFlex-635 Self-expanding Nitinol Stent System	Medical Device	Recall	Class I	Hospital
11/08/2015	BD Vacutainer Eclipse Signal Blood Collection Needle with Integrated Holder 21G & 22G.	Medical Device	Recall for Product Correction	Class II	Hospital
11/08/2015	VIRAZOLE (Ribavirin) Solution for Injection 0.1g/mL, 12 x 5 mL vials	Medicine	Recall	Class I	Hospital
7/08/2015	Access Thyroglobulin Reagent Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
7/08/2015	AIR LIQUIDE Medical Carbon Dioxide labelled as Medical Air	Medicine	Recall	Class II	Hospital
7/08/2015	DePuy Synthes Socket, Hexagonal Ø 4.0mm/11.0mm.	Medical Device	Recall	Class II	Hospital
6/08/2015	Siesta i TS machine	Medical Device	Recall for Product Correction	Class II	Hospital
5/08/2015	Bortezomib 2.4mg Syringe	Medicine	Recall	Class II	Hospital
5/08/2015	Leica ASP200S & Leica ASP300S. In vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
5/08/2015	Medcomp Hemo-Cath LT and Hemo-Cath ST Hemodialysis catheters	Medical Device	Recall for Product Correction	Class I	Hospital
4/08/2015	IntelePACS software versions from 4.5.1 to 4.11.1.	Medical Device	Recall for Product Correction	Class II	Hospital
4/08/2015	Waratah Private General Packs and Waratah Private Knee/Shoulder Arthro Pack	Medical Device	Recall for Product Correction	Class II	Hospital
3/08/2015	GE Healthcare LightSpeed CT scanners & Discovery PET CT scanners with replacement MDAS 16 5V Power Supply (part number 2334455)	Medical Device	Recall for Product Correction	Class II	Hospital
3/08/2015	UniCel DxC ISE Reference reagent tubing	Medical Device	Recall for Product Correction	Class II	Hospital
31/07/2015	Contact Detach Infusion Sets (used in conjunction with a pump to deliver a continuous dose of insulin)	Medical Device	Recall for Product Correction	Class II	Consumer
31/07/2015	RAPIDPoint 500 Blood Gas Analyzer	Medical Device	Recall for Product Correction	Class I	Hospital
29/07/2015	Pharmacy Care Children's Paracetamol Suspension for 6 To 12 Years and Pharmacy Care Children's Paracetamol Elixir for 1 to 5 Years	Medicine	Recall	Class I	Consumer

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
29/07/2015	Pharmacy Choice Children's Paracetamol 6 To 12 Years Concentrated 200ml and Pharmacy Choice Ibuprofen Children's Suspension	Medicine	Recall	Class I	Consumer
28/07/2015	Artis systems used in conjunction with Artis table	Medical Device	Recall for Product Correction	Class II	Hospital
28/07/2015	Dimension Creatinine and Dimension Vista Creatinine Assays. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
28/07/2015	Product-CD30 (Ber-H2)	Medical Device	Recall	Class III	Hospital
28/07/2015	Sureshot Humeral 3.2mm AO Drill	Medical Device	Recall	Class II	Hospital
24/07/2015	Back Table Cover supplied in a limited range of Operating Room Packs	Medical Device	Recall for Product Correction	Class II	Hospital
23/07/2015	Da Vinci Xi Surgical System - Breakage of input disks of Endowrist instruments	Medical Device	Recall for Product Correction	Class II	Hospital
23/07/2015	N Latex β 2-Microglobulin. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
22/07/2015	ReTurnBelt wipeable	Medical Device	Recall	Class II	Hospital
21/07/2015	iChemVELOCITY Automated Urine Chemistry System using iChemVELOCITY Urine Chemistry Strips	Medical Device	Recall for Product Correction	Class II	Hospital
21/07/2015	Medtronic Activa PC, Activa SC, Activa RC, Kinetra and Soletra Implantable Deep Brain Stimulators (DBS)	Medical Device	Hazard Alert	Class I	Hospital
21/07/2015	MR ACGD Cabinet FRU X Gradient Cable used with GE MRI System	Medical Device	Recall for Product Correction	Class I	Hospital
21/07/2015	NeoMode software used on Puritan Bennett 980 Series (PB980) Universal Ventilator System	Medical Device	Recall for Product Correction	Class I	Hospital
20/07/2015	Cook Beacon Tip angiography catheters	Medical Device	Recall	Class I	Hospital
20/07/2015	Medtronic MiniMed 640G Insulin Pumps	Medical Device	Recall for Product Correction	Class I	Consumer
17/07/2015	Reamer/Irrigator/Aspirator (RIA)	Medical Device	Recall for Product Correction	Class II	Hospital
17/07/2015	Siemens e.cam Systems	Medical Device	Recall for Product Correction	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
16/07/2015	Sapphire Infusion Pump	Medical Device	Recall for Product Correction	Class II	Hospital
15/07/2015	Bard Rival PTA Catheters	Medical Device	Recall for Product Correction	Class II	Hospital
15/07/2015	Radiometer 905-873 Fixation Kit N20	Medical Device	Recall	Class II	Hospital
15/07/2015	Vygon SA – Y connector code 884.08	Medical Device	Recall	Class I	Hospital
15/07/2015	X3 TRIATHLON INSERT CR#2 9MM	Medical Device	Recall	Class II	Hospital
14/07/2015	ARCHITECT B12 Reagent kit	Medical Device	Recall for Product Correction	Class II	Hospital
14/07/2015	Artis Q and Q.zen Floorstand and ArtisQ and Q.zen Biplane Floorstand systems with SW version VD10E	Medical Device	Recall for Product Correction	Class II	Hospital
14/07/2015	DELFI Xpress PIGF Kit	Medical Device	Recall for Product Correction	Class II	Hospital
14/07/2015	Navigational System II - Cart	Medical Device	Recall for Product Correction	Class II	Hospital
14/07/2015	Tumor Localization (TumorLOC) software application used on Philips PET/CT combination diagnostic imaging systems	Medical Device	Recall for Product Correction	Class I	Hospital
9/07/2015	MicroGas 7650 Operator Manual used with Radiometer MicroGas 7650 Transcutaneous Monitor	Medical Device	Recall for Product Correction	Class II	Hospital
8/07/2015	Artis systems with SW version VC14J	Medical Device	Recall for Product Correction	Class II	Hospital
8/07/2015	iPlan RT Dose, versions 4.0 and 4.1 (including all subversions)	Medical Device	Recall for Product Correction	Class I	Hospital
8/07/2015	Milestone Wand STA Hand Piece model STA-5050-305	Medical Device	Recall	Class III	Retail
8/07/2015	Optional PS500 External Power Supply Unit used in connection with Dräger V Series Ventilators: Infinity V500; Babylog VN500; Evita V300	Medical Device	Recall for Product Correction	Class I	Hospital
8/07/2015	Terry White Chemists Ibuprofen Children's Suspension Ibuprofen 20 mg/mL oral liquid bottle 200 mL	Medicine	Recall	Class I	Consumer
7/07/2015	ACUSON S Family Ultrasound Systems utilising the 18L6 HD and/or 6C1 HD biopsy guidelines	Medical Device	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
7/07/2015	Aequalis IM Nail Targeting Jig	Medical Device	Recall	Class II	Hospital
7/07/2015	MOSAIQ versions 2.41 and higher	Medical Device	Recall for Product Correction	Class I	Hospital
7/07/2015	VITROS 5,1 FS System	Medical Device	Recall for Product Correction	Class II	Hospital
3/07/2015	ACUSON S1000, ACUSON S2000, or ACUSON S3000 Ultrasound Systems with software version VC30A, VC30B, VC30C, or VC31A	Medical Device	Recall for Product Correction	Class II	Hospital
3/07/2015	Acuson S2000 and Acuson S3000 Ultrasound Systems with the Virtual Touch IQ option	Medical Device	Recall for Product Correction	Class I	Hospital
3/07/2015	Medline procedure packs containing Unomedical Suction Tubing (Sterile and Non-sterile)	Medical Device	Recall	Class II	Hospital
3/07/2015	Neria Infusion Administration Set	Medical Device	Recall	Class II	Consumer
2/07/2015	ADVIA Chemistry Systems - Acetaminophen N-acetylcysteine (NAC). An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
2/07/2015	Ceiling Supply Unit klinoPORT	Medical Device	Recall for Product Correction	Class II	Hospital
2/07/2015	Chemmart & Pharmacy Choice Ibuprofen Children's Suspension 20mg/mL and Chemmart Children's Paracetamol 6 to 12 years Concentrated 200mL 48mg/mL oral liquid bottles, Pack Size 200 mL	Medicine	Recall	Class I	Consumer
2/07/2015	Invivo Expression MRI Patient Monitoring System - Product 865214	Medical Device	Recall for Product Correction	Class I	Hospital
2/07/2015	Multigate Custom Procedure Packs containing Convatec's Unomedical brand Suction Tube	Medical Device	Recall	Class II	Hospital
2/07/2015	Multiple Allura systems	Medical Device	Recall for Product Correction	Class I	Hospital
2/07/2015	Philips HeartStart XL+ Defibrillator/Monitor	Medical Device	Recall for Product Correction	Class I	Hospital
1/07/2015	Procise EZ View with Integrated Cable	Medical Device	Recall	Class II	Hospital
30/06/2015	Neptune 2 Rovers	Medical Device	Recall for Product Correction	Class III	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
30/06/2015	SENSE Body Coil 1.5T used with ACS NT, Intera 1.5T and Achieva 1.5T MR Systems	Medical Device	Recall for Product Correction	Class II	Hospital
29/06/2015	Enbrel etanercept (reh) 25 mg powder for injection vial plus diluent syringe	Medicine	Recall	Class III	Hospital
29/06/2015	Parechovirus r-gene. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
29/06/2015	Pull Reduction Device for Percutaneous Drill Guide 4.3mm (Supplied as part of the VA Distal Femur set)	Medical Device	Recall	Class II	Hospital
29/06/2015	SERFAS 90° Energy Probe (90R Probe)	Medical Device	Recall	Class II	Hospital
26/06/2015	Abutment Retrieval Instrument Zirconia CC RP/WP	Medical Device	Recall	Class III	Retail
26/06/2015	All Precision 500D Radiographic and Fluoroscopic (R&F) Systems and Advantx Legacy/Legacy-D Radiographic and Fluoroscopic (R&F) Systems	Medical Device	Recall for Product Correction	Class II	Hospital
26/06/2015	i-STAT PT/INR Cartridges	Medical Device	Recall for Product Correction	Class II	Hospital
26/06/2015	Masimo uSpO2 and HPLP Oximetry Cables	Medical Device	Recall	Class I	Hospital
26/06/2015	Single and dual LCD monitor suspensions used on Precision RXi fluoroscopic imaging systems	Medical Device	Recall for Product Correction	Class II	Hospital
26/06/2015	Stryker Trauma rHead Recon, Bipolar & Radial Stem Implants (Components of elbow joint implants)	Medical Device	Recall	Class II	Hospital
25/06/2015	Reusable Stripper and Cleaver Accessories used with Sureflex and Aura Laser Fibers	Medical Device	Recall	Class II	Hospital
24/06/2015	cCrea A+B Membranes used with ABL800 series blood gas analyser range	Medical Device	Recall for Product Correction	Class II	Hospital
24/06/2015	GM-KO-67000-120 Paediatric 120" Circuit	Medical Device	Recall	Class II	Hospital
23/06/2015	3M ESPE Lava Ultimate CAD/CAM Restorative	Medical Device	Recall for Product Correction	Class II	Retail
23/06/2015	Brainlab Cranial Navigation System (all versions before Cranial 3.0)	Medical Device	Recall for Product Correction	Class I	Hospital
22/06/2015	Artis zee and Artis zeego systems used in conjunction with a triple focus x-ray tube assembly	Medical Device	Recall for Product Correction	Class II	Hospital

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22/06/2015	Barco Surgical Displays	Medical Device	Recall for Product Correction	Class II	Hospital
19/06/2015	ARGON Bone Marrow I-type aspirate/biopsy needles & ARGON Trap-Lok Bone Marrow biopsy needles	Medical Device	Recall	Class II	Hospital
19/06/2015	Cook LapSac Surgical Tissue Pouch	Medical Device	Recall for Product Correction	Class II	Hospital
19/06/2015	Drager Fabius MRI Anaesthesia Machine	Medical Device	Recall for Product Correction	Class I	Hospital
19/06/2015	Lunderquist Extra-Stiff Wire Guide	Medical Device	Recall	Class II	Hospital
19/06/2015	Medtronic MiniMed Sure-T infusion sets	Medical Device	Recall for Product Correction	Class II	Consumer
19/06/2015	MobileDiagnost wDR 1 and 2	Medical Device	Recall for Product Correction	Class II	Hospital
19/06/2015	TOPCON – 3D Optical Coherence Tomography 3D OCT-1 MAESTRO machines	Medical Device	Recall for Product Correction	Class II	Hospital
17/06/2015	Edwards Lifesciences Heart Reference Sensor	Medical Device	Recall for Product Correction	Class I	Hospital
17/06/2015	Immulin (all systems) - Sample Cup Holders and Microsample Inserts. In vitro diagnostic medical devices (IVD)	Medical Device	Recall	Class II	Hospital
17/06/2015	Suction Tube	Medical Device	Recall	Class II	Hospital
16/06/2015	CEFOTAXIME CT 256 WW F100. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
16/06/2015	Paclitaxel Suspension (Abraxane) 207.5mg in 0.9% Sodium Chloride	Medicine	Recall	Class II	Retail
16/06/2015	Sorin 1T & 3T Heater Cooler	Medical Device	Recall for Product Correction	Class I	Hospital
12/06/2015	Access 2 Immunoassay Systems	Medical Device	Recall for Product Correction	Class II	Hospital
12/06/2015	BIRMINGHAM HIP Resurfacing (BHR) System	Medical Device	Hazard Alert	Class II	Hospital
12/06/2015	NDI Disposable Reflective Marker Spheres	Medical Device	Recall	Class II	Hospital
12/06/2015	Philips Respironics Devices used for Auto Servo-Ventilation Therapy:	Medical Device	Recall for Product Correction	Class I	Hospital

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12/06/2015	SOMATOM Emotion 6 / 16 Slice Configuration systems manufactured before February 2008	Medical Device	Recall for Product Correction	Class I	Hospital
12/06/2015	Tina-quant Soluble Transferrin Receptor (STFR): Elevated imprecision with QC Level 1	Medical Device	Recall	Class II	Hospital
12/06/2015	UniCel DxI Immunoassay Systems	Medical Device	Recall for Product Correction	Class II	Hospital
10/06/2015	Ultrasound Q-Station version 3.0 or higher	Medical Device	Recall for Product Correction	Class II	Hospital
9/06/2015	Stryker Neurovascular Excelsior SL-10/Excelsior 1018 Microcatheters	Medical Device	Recall	Class II	Hospital
5/06/2015	ACCURUS Vitrectomy probes	Medical Device	Recall	Class I	Hospital
5/06/2015	Artis zee Floorstand, Artis zee Biplane Floorstand and Artis zee Multi Purpose systems with SW version VC21B	Medical Device	Recall for Product Correction	Class II	Hospital
5/06/2015	Disposable StrykeFlow Tip	Medical Device	Recall	Class II	Hospital
5/06/2015	SofPort Advanced Optics Aspheric IOL, Model LI61AO	Medical Device	Hazard Alert	Class II	Hospital
5/06/2015	Tibial Alignment Guide – iAssist Knee System	Medical Device	Recall for Product Correction	Class II	Hospital
5/06/2015	VITROS Performance Verifier I for unconjugated bilirubin (Bu)	Medical Device	Recall for Product Correction	Class II	Hospital
4/06/2015	Per-Q-Cath PICCs	Medical Device	Recall for Product Correction	Class II	Hospital
3/06/2015	TJF-Q180V Duodenoscope	Medical Device	Recall for Product Correction	Class I	Hospital
3/06/2015	Verathon GlideScope GVL and AVL Reusable Video Laryngoscope Blades	Medical Device	Recall for Product Correction	Class II	Hospital
2/06/2015	Digital Radiography X-Ray System DX-D 100 Type 5410 or DX-D 100 Wireless Type 5411	Medical Device	Recall for Product Correction	Class II	Hospital
2/06/2015	MAGNUS Hybrid OR table column 1180.01B2	Medical Device	Recall for Product Correction	Class II	Hospital
2/06/2015	Medtronic Navigated Cannulated Taps	Medical Device	Recall for Product Correction	Class II	Hospital

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2/06/2015	Roche clinical chemistry tests - ALT, AST, CK, CK-MB, GLDH and NH3 using the NAD(H) or NADP(H) reaction	Medical Device	Recall for Product Correction	Class II	Hospital
29/05/2015	DigitalDiagnost Release 4.0.x	Medical Device	Recall for Product Correction	Class II	Hospital
29/05/2015	Eon Wall Charger Model 3701 and Eon Portable Charger Model 3711 (Implantable pulse generator chargers)	Medical Device	Recall	Class I	Hospital
28/05/2015	CADD- Solis Ambulatory Infusion Pumps	Medical Device	Recall for Product Correction	Class II	Hospital
28/05/2015	Shen Neng Qianbai Biyan Pian - (A Rhinitis Treatment in Traditional Chinese Medicine)	Medicine	Recall	Class II	Retail
28/05/2015	syngo Workflow SLR with versions VA31, VA32, VB10, or VB20A (TBC)	Medical Device	Recall for Product Correction	Class II	Hospital
28/05/2015	Ultraview SL Command Module	Medical Device	Recall for Product Correction	Class II	Hospital
27/05/2015	18F-Fludeoxyglucose Injection	Medicine	Recall	Class II	Hospital
27/05/2015	LifeCycle for Prenatal Screening v4.0, v4.0 Rev 2 and v4.0 Rev 3. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
27/05/2015	ONCENTRA Brachy version 3.x and 4.x	Medical Device	Recall for Product Correction	Class I	Hospital
27/05/2015	Surface Applicator Set with Leipzig-style Cone	Medical Device	Recall for Product Correction	Class II	Hospital
25/05/2015	ADVIA Centaur Tni-Ultra	Medical Device	Recall for Product Correction	Class II	Hospital
25/05/2015	Pulsar-35 and Pulsar-18 and peripheral self-expanding Nitinol stent systems (with stent length of 200 mm only)	Medical Device	Recall	Class I	Hospital
25/05/2015	Teflon Tube T2 Humerus, Sterile	Medical Device	Hazard Alert	Class II	Hospital
22/05/2015	EPREX (Epoetin alfa) syringes	Medicine	Recall	Class III	Retail
22/05/2015	EVOTECH Endoscope Cleaner and Reprocessor (ECR)	Medical Device	Recall for Product Correction	Class III	Hospital
21/05/2015	CareFusion - AVEA Ventilator	Medical Device	Recall for Product Correction	Class I	Hospital

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20/05/2015	Berichrom Protein C on Sysmex CA-1500, CA-7000, CS-2000i and CS-5100 instruments. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
20/05/2015	Dimension Vista 500 and 1500 Intelligent Lab System. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
20/05/2015	Philips Model AFFINITI 70 Ultrasound System Versions 1.0.2 or lower with Pediatric Cardiology option	Medical Device	Recall for Product Correction	Class II	Hospital
20/05/2015	VITROS Immunodiagnostic Products NT-proBNP Assay. An in-vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
18/05/2015	Animas 2020 and Animas IR 1200 Insulin Pumps	Medical Device	Recall	Class I	Consumer
18/05/2015	Apex 10mm reamer	Medical Device	Recall	Class I	Hospital
18/05/2015	APO-Dipyridamole Aspirin 200mg/25mg capsules in bottles of 60s	Medicine	Recall	Class III	Wholesale
18/05/2015	CHISEL BLADES	Medical Device	Recall	Class III	Hospital
18/05/2015	DuraDiagnost 3.0/4.0 X-ray system	Medical Device	Recall for Product Correction	Class II	Hospital
18/05/2015	Expression MRI Patient Monitoring System	Medical Device	Recall for Product Correction	Class II	Hospital
18/05/2015	PenAdapt	Medical Device	Recall	Class II	Hospital
18/05/2015	TCAutomation / enGen Laboratory Automation Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
18/05/2015	WIZARD2 Gamma Counters	Medical Device	Recall for Product Correction	Class II	Hospital
15/05/2015	IntelePACS	Medical Device	Recall for Product Correction	Class II	Hospital
15/05/2015	Manual Collimator Exchange system in use with an ADAC VERTEX Plus, CARDIO, SOLUS or VERTEX V60 imaging system	Medical Device	Recall for Product Correction	Class II	Hospital
15/05/2015	Philips Model AFFINITI 70 Ultrasound System without Pediatric Cardiology option	Medical Device	Recall for Product Correction	Class II	Hospital
15/05/2015	Philips Model EPIQ 7 Ultrasound System with Pediatric Cardiology option	Medical Device	Recall for Product Correction	Class II	Hospital

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15/05/2015	RAPIDLab 1260/1265 Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
14/05/2015	High Strength Niu Huang Jiedu Tablets 60's	Medicine	Recall	Class II	Consumer
14/05/2015	Philips Model AFFINITI 50 Ultrasound System	Medical Device	Recall for Product Correction	Class II	Hospital
14/05/2015	Philips Model EPIQ 7 Ultrasound System without Paediatric Cardiology option	Medical Device	Recall for Product Correction	Class II	Hospital
14/05/2015	ReMed devices used for Adaptive Servo-Ventilation (ASV) Therapy	Medical Device	Recall for Product Correction	Class I	Consumer
13/05/2015	Cios Alpha mobile C-arm x-ray system	Medical Device	Recall for Product Correction	Class II	Hospital
13/05/2015	Immulate 2000 and Immulate 2000 XPI – Italian Cypress Allergen	Medical Device	Recall	Class II	Hospital
13/05/2015	Microtek Medical System Drapes used with da Vinci, da Vinci Si, da Vinci Si/S Systems	Medical Device	Recall	Class II	Hospital
13/05/2015	Prius Hospital Bed	Medical Device	Recall for Product Correction	Class III	Hospital
13/05/2015	Shiley Neonatal, Paediatric and Long Paediatric Tracheostomy Tube, Cuffless and with TaperGuard Cuff	Medical Device	Recall	Class I	Hospital
13/05/2015	Trinder tests on Roche Analysers – Hitachi 902, COBAS c111, COBAS c311/501/502/701/702 & COBAS INTEGRA 400 plus/800. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
13/05/2015	ULTRA FAST-FIX Knot Pusher/Suture Cutter, Straight	Medical Device	Recall	Class II	Hospital
12/05/2015	Astral Ventilators	Medical Device	Recall for Product Correction	Class I	Consumer
12/05/2015	Brainlab Navigation Software Spine & Trauma 3D versions 2.0 /2.1 and Navigation Software Cranial / ENT version 2.1	Medical Device	Recall for Product Correction	Class I	Hospital
12/05/2015	Diego Elite Tubesets	Medical Device	Recall	Class II	Hospital
12/05/2015	Philips Model EPIQ 5 Ultrasound System Versions 1.3.2 or lower without Paediatric Cardiology option	Medical Device	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
12/05/2015	Philips Model EPIQ 5 Ultrasound System with Versions 1.3.2 or lower with Paediatric Cardiology option	Medical Device	Recall for Product Correction	Class II	Hospital
11/05/2015	MRS Traverse Switch	Medical Device	Recall for Product Correction	Class II	Hospital
8/05/2015	Medline Procedure Packs containing Covidien Devon Light Gloves	Medical Device	Recall for Product Correction	Class II	Hospital
7/05/2015	Corpatch Easy Paediatric (defibrillator electrodes)	Medical Device	Recall	Class I	Hospital
7/05/2015	HeartWare HVAD System	Medical Device	Recall for Product Correction	Class I	Hospital
7/05/2015	Invacare Platinum Oxygen Concentrator	Medical Device	Recall for Product Correction	Class I	Consumer
7/05/2015	Sekisui Diagnostics Acetaminophen Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
6/05/2015	Sapheon (Covidien) VenaSeal Closure System	Medical Device	Recall	Class II	Hospital
5/05/2015	MV1031 Gram Crystal Violet 4L. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
5/05/2015	Remel PathoDx Strep Grouping Kit 60 Test containing Remel PathoDx Strep B Group Latex. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
5/05/2015	TFN-ADVANCED Proximal Femoral Nailing System (TFNA)	Medical Device	Recall for Product Correction	Class II	Hospital
4/05/2015	LP rotate, sizes 25-27 cat.1-6.	Medical Device	Recall	Class II	Consumer
1/05/2015	VITEK2 AST-YS06 & VITEK2 AST-YS07 Test Kits	Medical Device	Recall for Product Correction	Class I	Hospital
1/05/2015	V-Sign Sensor	Medical Device	Recall	Class II	Hospital
30/04/2015	OPTI Blood Gas analysers - An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
30/04/2015	Transwarmer Infant Transport Mattress	Medical Device	Recall	Class II	Hospital
29/04/2015	Tavo ophthalmic Table	Medical Device	Recall for Product Correction	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
28/04/2015	Factor IX coagulation studies on the BCS / BCS XP Automated Blood Coagulation Analyser (Actin, Actin FSL and Pathromtin SL)	Medical Device	Recall for Product Correction	Class II	Hospital
28/04/2015	IMMULITE 2000 IMMULITE 2000 XPi Immunoassay System. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
27/04/2015	18F-Fludeoxyglucose Injection	Medicine	Recall	Class II	Hospital
27/04/2015	D-Fend/D-Fend+ water traps used with Compact Airway Modules E/M-C(Ai)O(V)(X) and Cardiocap/5 monitors	Medical Device	Recall for Product Correction	Class I	Hospital
27/04/2015	Talon Grasping Device	Medical Device	Recall	Class II	Hospital
24/04/2015	DBL Methotrexate 2.5mg tablets in bottles of 30	Medicine	Recall	Class II	Consumer
24/04/2015	Devon Light Glove	Medical Device	Recall	Class II	Retail
24/04/2015	Invacare TDX series and Storm Series power wheelchairs with 20"-24" width configurations with Formula CG Recline seating system (i.e. Tilt/Recline, Tilt/Recline/Elevate, or Recline only) and a conventional style back	Medical Device	Recall for Product Correction	Class I	Consumer
24/04/2015	Philips Dameca Siesta i TS with an EGM software version lower than 4.0.8 / 7.0.8	Medical Device	Recall for Product Correction	Class I	Hospital
24/04/2015	Thermablate Endometrial Ablation System (EAS)	Medical Device	Recall for Product Correction	Class II	Hospital
23/04/2015	Connecting Screw for Insertion of Dynamic Hip Screw (DHS) Blade	Medical Device	Recall	Class II	Hospital
23/04/2015	Dimension Vista Systems LOCI Thyroid Stimulating Hormone. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
23/04/2015	Oscillating Saw Attachment for Colibri/Colibri II Small Electric Drive	Medical Device	Recall for Product Correction	Class I	Hospital
23/04/2015	Siemens Ysio Max, Luminos dRF Max, Luminos Agile Max and Uroskop Omnia Max with software version VE10E	Medical Device	Recall for Product Correction	Class II	Hospital
22/04/2015	Codan Extension Set With SAFTI-JECT SV Swabable Valve Needleless Connector And a Back Check Valve - 28 cm. (Tubing to extend the length of an IV administration set)	Medical Device	Recall for Product Correction	Class III	Hospital

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22/04/2015	SonoSitePowerPark Dock and Stand Module(s) used with SonoSite Ultrasound Systems	Medical Device	Recall for Product Correction	Class II	Hospital
21/04/2015	Accu-Chek Spirit Combo insulin pump and Accu-Chek Spirit insulin pump. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Consumer
20/04/2015	Birmingham Hip Modular Head (BHHM)	Medical Device	Hazard Alert	Class II	Hospital
20/04/2015	Ki67-MM1 Bond Ready To Use, An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class I	Hospital
20/04/2015	Philips Ultrasound QLAB versions 10.0 with a2DQ and/or aCMQ plug-ins installed with Philips Xcelera software	Medical Device	Recall for Product Correction	Class II	Hospital
17/04/2015	Amylase Assay used with ADVIA Chemistry Systems	Medical Device	Recall for Product Correction	Class II	Hospital
17/04/2015	Counterfeit Durex branded condoms purchased from Groupon website	Medical Device	Recall	Class I	Consumer
17/04/2015	Different Brands of Pantoprazole Tablets in Blisters of 30's.	Medicine	Recall	Class III	Retail
17/04/2015	Intuitive Surgical Inc. da Vinci Xi Surgical System Patient Cart Arms	Medical Device	Recall for Product Correction	Class II	Hospital
16/04/2015	LEMTRADA (alemtuzumab) 10mg/mL injection concentrated vial	Medicine	Recall for Product Correction	Class II	Hospital
16/04/2015	Magellan Robotic System (Catheter controller steering unit)	Medical Device	Recall for Product Correction	Class I	Hospital
15/04/2015	Harris Oxygen Flowmeter	Medical Device	Recall for Product Correction	Class II	Hospital
14/04/2015	Dako Beta-2-Microglobulin PET Kits. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
14/04/2015	Karl Storz Tissue Morcellation System	Medical Device	Recall for Product Correction	Class II	Hospital
14/04/2015	VITROS Chemistry Systems. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
13/04/2015	Bard Max-Core Disposable Core Biopsy Instrument	Medical Device	Recall	Class I	Hospital
13/04/2015	enGen Laboratory Automation Systems, An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
13/04/2015	ID-LISS/Coombs Cards. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
13/04/2015	STERIS Caviwave Pro Ultrasonic Cleaning System	Medical Device	Recall for Product Correction	Class II	Hospital
10/04/2015	Baxter Irrigation solutions	Medical Device	Recall	Class II	Hospital
10/04/2015	Dianeal peritoneal dialysis solutions	Medicine	Recall	Class I	Consumer
10/04/2015	Easyvision Umere Daily Contact Lenses (-6.50)	Medical Device	Recall	Class II	Consumer
10/04/2015	KARMA Corneal Inlay	Medical Device	Recall for Product Correction	Class II	Hospital
8/04/2015	Curam Duo Forte 875mg/125mg Tablets 10 strip	Medicine	Recall	Class III	Retail
7/04/2015	18F-Fludeoxyglucose Injection	Medicine	Recall	Class II	Hospital
2/04/2015	Aegis Standing Sling - Lift, patient transfer, sling/harness/strap	Medical Device	Recall for Product Correction	Class II	Retail
2/04/2015	Nobel Replace Conical Connection PMC RP 5.0x13mm	Medical Device	Recall	Class III	Hospital
1/04/2015	CIDEX OPA Solution Test Strips	Medical Device	Recall for Product Correction	Class III	Hospital
1/04/2015	Uninterruptible Power Supply (UPS) supplied with Philips Computed Tomography / Advanced Molecular Imaging Systems	Medical Device	Recall for Product Correction	Class II	Hospital
31/03/2015	Alaris System PC Unit model 8015	Medical Device	Recall for Product Correction	Class II	Hospital
31/03/2015	Cross-Link Clamp for Rods, 6.0 mm	Medical Device	Recall	Class II	Hospital
31/03/2015	Edwards Fem-Flex II Femoral Arterial Cannula, sizes 8, 10 & 12 French	Medical Device	Recall	Class II	Hospital
30/03/2015	CBCII AMBULATING BULB (PK10), 1/8 TROCAR W/DRAIN (PK10), 1/4 TROCAR W/DRAIN (PK10)	Medical Device	Recall	Class II	Hospital
30/03/2015	KA351 - My Mobility Walking Frame with Front Wheels, Large, Aluminium, APO Grey, and	Medical Device	Recall for Product Correction	Class II	Retail
27/03/2015	Angular Stable Locking System (ASLS), 5.0 mm, Resorbable (Used with Synthes cannulated titanium intramedullary nails)	Medical Device	Recall	Class II	Hospital
27/03/2015	Bard ConQuest PTA Balloon Dilatation Catheter	Medical Device	Recall	Class I	Hospital
27/03/2015	Captia Malaria EIA	Medical Device	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
27/03/2015	da Vinci Si EndoWrist One Vessel Sealer and da Vinci Xi EndoWrist Vessel Sealer	Medical Device	Recall for Product Correction	Class II	Hospital
27/03/2015	Radiometer immunoassay AQT90FLEX Analyser	Medical Device	Recall for Product Correction	Class I	Hospital
26/03/2015	ADVIA Chemistry Systems Lipase Assay	Medical Device	Recall for Product Correction	Class II	Hospital
26/03/2015	Trellis 6 and Trellis 8 Peripheral Infusion System	Medical Device	Recall	Class II	Hospital
25/03/2015	GE MRI Systems	Medical Device	Recall for Product Correction	Class II	Hospital
24/03/2015	LCS COMPLETE RPS Knee System	Medical Device	Hazard Alert	Class II	Hospital
23/03/2015	AngioDynamics Morpheus Smart PICC CT (Central venous catheters)	Medical Device	Recall	Class II	Hospital
23/03/2015	Hydrophilic Acrylic Single Use Intraocular Lens system packs	Medical Device	Recall	Class III	Retail
20/03/2015	FX CorDiax High-Flux dialysers and FX CorDiax Haemodiafilters	Medical Device	Recall for Product Correction	Class I	Hospital
19/03/2015	Artis Q/Q.zen systems	Medical Device	Recall for Product Correction	Class II	Hospital
19/03/2015	Catalys Precision Laser System	Medical Device	Recall for Product Correction	Class II	Hospital
19/03/2015	Divercleanse 750ml	Medical Device	Recall	Class II	Retail
19/03/2015	Hemodialysis Monitor	Medical Device	Recall	Class II	Hospital
19/03/2015	Model 5392 Dual-Chamber External Pulse Generator	Medical Device	Recall for Product Correction	Class I	Hospital
19/03/2015	RaySearch RayStation 3.5, RayStation 4.0, RayStation 4.5, and RayStation 4.7 (Radiation therapy treatment planning system)	Medical Device	Recall for Product Correction	Class II	Hospital
19/03/2015	T2100 Treadmill	Medical Device	Recall for Product Correction	Class II	Retail
18/03/2015	Persona Trabecular Metal Tibial Plate, all sizes	Medical Device	Hazard Alert	Class II	Hospital
17/03/2015	Cobas c 501 / c 502 and COBAS INTEGRA. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital

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17/03/2015	METAL SHELL, CEM.LESS 'DeltaLox' SCREW FIX., TiNb-COAT (Acetabular shell component used for hip replacement)	Medical Device	Hazard Alert	Class II	Hospital
16/03/2015	Aiming Arm 125deg and Aiming Arm 130deg for TFN-ADVANCED (TFNA) System	Medical Device	Recall	Class II	Hospital
16/03/2015	Patient Specific Radiopharmaceuticals	Medicine	Recall	Class II	Hospital
13/03/2015	Access 2 Immunoassay Systems	Medical Device	Recall for Product Correction	Class I	Hospital
13/03/2015	Brilliance CT 64-channel with Essence technology, Brilliance iCT, Brilliance iCT SP, Ingenuity Core, Ingenuity Core128, Ingenuity Elite and Ingenuity CT	Medical Device	Recall for Product Correction	Class II	Hospital
13/03/2015	EXACTRAC 6.x (Image Guided RadiationTherapy Patient Positioning System)	Medical Device	Recall for Product Correction	Class I	Hospital
13/03/2015	Remote controls for JUPITER, ARTIS and TruSystem 7500 operating tables	Medical Device	Recall for Product Correction	Class II	Hospital
13/03/2015	VITROS 5,1 FS Chemistry Systems using Software Version 2.8 & Below. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
12/03/2015	Getinge 46-Series Washer Disinfector with PACS 300/350	Medical Device	Recall for Product Correction	Class I	Hospital
12/03/2015	IMMULITE 2000/IMMULITE 2000 XPi water and liquid waste bottles	Medical Device	Recall for Product Correction	Class II	Hospital
12/03/2015	Kenex ceiling-suspended radiation shields and surgical lamps	Medical Device	Recall for Product Correction	Class I	Hospital
11/03/2015	Insertor f/TEN	Medical Device	Recall for Product Correction	Class II	Hospital
11/03/2015	Q Vax Skin Test	Medicine	Recall	Class II	Retail
6/03/2015	Dostinex (cabergoline), Cabaser (cabergoline) & Methoblastin (methotrexate) - All Batches	Medicine	Recall for Product Correction	Class II	Consumer
6/03/2015	ONLINE DAT Cannabinoids II / 100 tests / 200 tests	Medical Device	Recall	Class III	Hospital
6/03/2015	Signature Orthopadics' Logical Ceramic Liner (for use with hip replacement systems)	Medical Device	Recall	Class II	Hospital
6/03/2015	Sonidet – Medical Equipment & Instrument Detergent	Medical Device	Recall	Class II	Hospital
5/03/2015	DePuy Synthes Trauma DHS/DCS Impactor Tip	Medical Device	Recall	Class II	Hospital

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5/03/2015	HALCION (triazolam) & PONSTAN (mefenamic acid) & XANAX (alprazolam) - All Batches	Medicine	Recall	Class II	Consumer
5/03/2015	Self-Righting Luer Slip Tip Cap, Yellow in the DISCPAC packaging	Medical Device	Recall for Product Correction	Class III	Hospital
3/03/2015	AQUAPAK BRITISH and INTL 340 SW, 340 ML W/040B Humidifier Adaptors	Medical Device	Recall	Class II	Hospital
3/03/2015	Edwards Lifesciences Heart Reference Sensor	Medical Device	Recall	Class II	Hospital
2/03/2015	Cure Sleeve (a dental barrier sleeve for curing light to prevent cross contamination)	Medical Device	Recall	Class II	Retail
2/03/2015	PVC TUBING X-RAY (includes an x-ray detectable line and is used for securing the perfusion lines during cardiopulmonary bypass)	Medical Device	Recall	Class I	Hospital
27/02/2015	ARCHITECT Anti-HBc II Reagent Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
26/02/2015	BD Q-Syte Luer Access Split Septum Device	Medical Device	Recall	Class I	Hospital
26/02/2015	SANDEL Weighted Safety Scalpels	Medical Device	Recall	Class II	Hospital
25/02/2015	Bead Block (Embolitic Bead)	Medical Device	Recall for Product Correction	Class II	Hospital
25/02/2015	RT12 Tube Rotor-Kit (RT12) & StatSpin MP Centrifuge (SSMP)	Medical Device	Recall for Product Correction	Class II	Hospital
24/02/2015	GENESIS II KNEE SYSTEM – Non Porous Tibial Base Plate	Medical Device	Hazard Alert	Class II	Hospital
24/02/2015	LFIT V40 Femoral Head	Medical Device	Hazard Alert	Class II	Hospital
24/02/2015	Philips Anaesthesia Machines Siesta i Breasy, Siesta i Whispa, Dameca MRI 508, Siesta i TS & IntelliSave AX700	Medical Device	Recall for Product Correction	Class I	Hospital
24/02/2015	Triathlon Distal Capture Assembly	Medical Device	Recall for Product Correction	Class II	Hospital
23/02/2015	GemLock Long Hex Driver	Medical Device	Recall	Class II	Hospital
23/02/2015	Philips Anaesthesia Machines IntelliSave AX700, Dameca MRI 508, Siesta i Whispa, Siesta i TS & Siesta Breasy	Medical Device	Recall for Product Correction	Class II	Hospital
23/02/2015	XALKORI (crizotinib 200 mg and 250 mg) Capsules	Medicine	Recall for Product Correction	Class III	Retail

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20/02/2015	Philips HeartStart MRx Monitor/Defibrillators	Medical Device	Recall for Product Correction	Class I	Hospital
20/02/2015	ROPIVACAINE PFIZER Solution for Injection 400 mg/200 mL and 200 mg/100 mL bags	Medicine	Recall	Class II	Hospital
19/02/2015	Intuitive Harmonic ACE Instruments (used with the da Vinci Standard, S, and Si Surgical Systems)	Medical Device	Recall for Product Correction	Class II	Hospital
18/02/2015	IMMULITE 2000 and IMMULITE 2000 XPi - GI-MA (CA 19-9) Positive Bias. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
18/02/2015	LiNA Xcise Laparoscopic Morcellator	Medical Device	Recall for Product Correction	Class II	Hospital
18/02/2015	T2100 and T2000 Treadmill power cords	Medical Device	Recall for Product Correction	Class I	Hospital
18/02/2015	VITEK 2 system version 7.01. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
17/02/2015	5mm and 8mm Harmonic ACE Instruments IFU (for use with 5mm Harmonic ACE instruments (PNs 400274 and 400275))	Medical Device	Recall for Product Correction	Class III	Hospital
17/02/2015	AQUARIUS Regional Citrate Anticoagulation (RCA) Hemofiltration Device	Medical Device	Recall for Product Correction	Class I	Hospital
17/02/2015	Medicina Orange Enteral Feeding Pump (MD-OP900)	Medical Device	Recall	Class II	Hospital
17/02/2015	Radiometer ABL90Flex analysers running V3.1MR1 or below	Medical Device	Recall for Product Correction	Class I	Hospital
13/02/2015	Allura Xper R7.2.x (Fluoroscopic diagnostic x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
12/02/2015	CARDIOHELP Perfusion System, Software versions prior to 3.4.6.0	Medical Device	Recall for Product Correction	Class III	Hospital
12/02/2015	Elecsys CMV IgM assay (04784618190) - Diluent Universal. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
11/02/2015	PlasmaSORD	Medical Device	Recall for Product Correction	Class II	Hospital
11/02/2015	Proteus XR/a X-ray imaging systems manufactured with wall stand model number 2260354.	Medical Device	Recall for Product Correction	Class I	Hospital

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10/02/2015	ADVIA Chemistry 1800 and 2400 Instructions For Use (IFU) Updates. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
10/02/2015	Amulet (FDR MS-1000), Amulet f (FDR MS-2500) & Amulet Innovality (FDR MS-3500) with Biopsy Unit	Medical Device	Recall for Product Correction	Class II	Hospital
10/02/2015	Drill set long, drill stop compatible for D 4.8mm Implant	Medical Device	Recall	Class II	Hospital
10/02/2015	Oxoid Antimicrobial Susceptibility Testing Discs TIM85(Timentin), CT0449B	Medical Device	Recall	Class II	Hospital
10/02/2015	Prosthesis, internal, spine, disc	Medical Device	Recall	Class II	Hospital
10/02/2015	VaccZyme Anti-Haemophilus Influenzae B	Medical Device	Recall for Product Correction	Class III	Hospital
10/02/2015	Zenith Alpha Thoracic Endovascular Graft	Medical Device	Hazard Alert	Class I	Hospital
9/02/2015	Morce Power Plus 2307	Medical Device	Recall for Product Correction	Class II	Hospital
6/02/2015	Acutronic Fabian HFO (High Frequency Oscillation) Ventilators , software versions below GUI 3.0.2.7	Medical Device	Recall for Product Correction	Class I	Hospital
6/02/2015	Allura Systems: Field extensions Vascular R7.6	Medical Device	Recall for Product Correction	Class I	Hospital
6/02/2015	Cobas EGFR MutationTest Kit	Medical Device	Recall	Class II	Hospital
6/02/2015	Engstrom Carestation and Engstrom Pro Ventilators (that were provided with an accessory cart as part of the original order)	Medical Device	Recall for Product Correction	Class I	Hospital
6/02/2015	GE Healthcare MRI systems with superconducting magnets	Medical Device	Recall for Product Correction	Class I	Hospital
6/02/2015	Invacare PerfectO2 Oxygen Concentrator	Medical Device	Recall for Product Correction	Class I	Consumer
6/02/2015	M2a 38 Acetabular Cup, M2a 38 Femoral Head, M2a Magnum Tri-Spike Acetabular Cup & M2a Magnum Femoral Heads	Medical Device	Hazard Alert	Class II	Hospital
6/02/2015	qube Compact Monitor & XPRESSON Bedside Monitor	Medical Device	Recall for Product Correction	Class II	Hospital
5/02/2015	CARDIOSAVE Hybrid Intra-Aortic Balloon Pump (IABP)	Medical Device	Recall for Product Correction	Class I	Hospital

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4/02/2015	AK 200 S and AK 200 ULTRA S nocturnal home hemodialysis machines	Medical Device	Recall for Product Correction	Class I	Consumer
4/02/2015	AKINETON, biperiden hydrochloride	Medicine	Recall	Class II	Consumer
4/02/2015	Colaspase 10iu in 1mL 0.9% Sodium Chloride	Medicine	Recall	Class I	Hospital
4/02/2015	VITEK 2 System version 7.01. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
3/02/2015	ADVIA Centaur Systems Progesterone Kits	Medical Device	Recall for Product Correction	Class III	Hospital
3/02/2015	Birmingham Hip Resurfacing (BHR) System	Medical Device	Hazard Alert	Class II	Hospital
3/02/2015	CDAS upgraded Intera MR systems equipped with the Basic Triggering Unit	Medical Device	Recall for Product Correction	Class I	Hospital
3/02/2015	IntelliSpace Critical Care & Anaesthesia Information Systems	Medical Device	Recall for Product Correction	Class I	Hospital
3/02/2015	SIM System with SIM dock power supply model Franmar FRA012-S05-I	Medical Device	Recall for Product Correction	Class I	Retail
2/02/2015	Puritan Bennett 980 Series Ventilator System	Medical Device	Recall for Product Correction	Class II	Hospital
30/01/2015	Airlight ROM brace (An Orthosis that encompasses the knee joint)	Medical Device	Recall for Product Correction	Class II	Hospital
30/01/2015	CADD Medication Cassette Reservoir, 50ml	Medical Device	Recall	Class II	Hospital
30/01/2015	DuraDiagnost X-ray System	Medical Device	Recall for Product Correction	Class I	Hospital
30/01/2015	NEO-MERCAZOLE, carbimazole, 5mg tablets	Medicine	Recall	Class II	Retail
30/01/2015	Philips IntelliVue Information Center (PIIC) iX system (A Centralized Patient Monitoring System)	Medical Device	Recall for Product Correction	Class I	Hospital
30/01/2015	Siemens Capillary Caps for RAPIDLyte Multicap and Multicap-S Blood Collection Capillaries	Medical Device	Recall for Product Correction	Class II	Hospital
29/01/2015	CS 8100 & CS 8100 3D	Medical Device	Recall for Product Correction	Class I	Retail
29/01/2015	DigitalDiagnost Release 4.0.0. and 4.0.1	Medical Device	Recall for Product Correction	Class III	Hospital

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29/01/2015	Medtronic Minimed 640G Infusion Pump used in clinical trials	Medical Device	Recall for Product Correction	Class II	Consumer
29/01/2015	MultiDiagnost Eleva Flat Detector (FD) System	Medical Device	Recall for Product Correction	Class II	Hospital
29/01/2015	MultiDiagnost Eleva II/TV Systems	Medical Device	Recall for Product Correction	Class II	Hospital
29/01/2015	Various Sterile-Packaged Femoral Heads (Various sizes, neck lengths and taper sizes)	Medical Device	Recall	Class II	Hospital
28/01/2015	ADVIA Chemistry Systems Drug Calibrator I for Phenytoin 2 and Phenobarbital 2 Assays. An in vitro Diagnostic Medical Device.	Medical Device	Recall for Product Correction	Class II	Retail
28/01/2015	Brilliance iCT and Brilliance iCT SP with software versions 4.1.0.xxxxx, or 4.1.1.xxxxx, or 4.1.2.xxxxx	Medical Device	Recall for Product Correction	Class II	Hospital
23/01/2015	Brainlab Offset Cup Impactor Universal	Medical Device	Recall for Product Correction	Class I	Hospital
23/01/2015	InterStim & InterStim II	Medical Device	Hazard Alert	Class II	Hospital
22/01/2015	Artis Dialysis System equipped with SW 8.15.06 and 8.33.02	Medical Device	Recall for Product Correction	Class I	Hospital
22/01/2015	FORUM Software	Medical Device	Recall for Product Correction	Class I	Retail
22/01/2015	MiniCap with Povidone-Iodine Solution	Medical Device	Recall	Class I	Consumer
22/01/2015	Xcela PICC with PASV Valve Technology/Kits, BioFlo PICC with Endexo and PASV Valve Technology/Kits	Medical Device	Recall	Class II	Hospital
20/01/2015	Aequalis Ascent Flex Reversed Cut Guide (Instrument for use in the implantation of joint prostheses)	Medical Device	Recall	Class II	Wholesale
20/01/2015	Integra Mayfield Ultra 360 Base Unit	Medical Device	Recall for Product Correction	Class I	Hospital
20/01/2015	Medicina DS03 Silo Dressing 3.0mm – DS04 Silo Dressing 4.0mm – DS05 Silo Dressing 5.0mm – DS06 Silo Dressing 6.0mm	Medical Device	Recall	Class II	Hospital
20/01/2015	Medicina Keyhole Dressing KDX	Medical Device	Recall	Class II	Hospital
20/01/2015	PharmAust 30ml Chlorhexidine in Ethanol 70% (Red Tint)	Medical Device	Recall	Class III	Hospital

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20/01/2015	System 6 Aseptic Battery Kit	Medical Device	Recall for Product Correction	Class I	Hospital
19/01/2015	ACUSON SC2000 ultrasound systems	Medical Device	Recall for Product Correction	Class II	Hospital
19/01/2015	Medicina Low Profile Gastrostomy Button	Medical Device	Recall	Class II	Hospital
19/01/2015	Medicina Nasogastric Plaster NS01 (Nasal Strip)	Medical Device	Recall	Class III	Hospital
19/01/2015	Medicina SILOBAG	Medical Device	Recall	Class II	Hospital
19/01/2015	PowerLED, Hied, Xten, Standop Volista, Hanaulux 3000 range - SA Ceiling Suspension	Medical Device	Recall for Product Correction	Class II	Hospital
19/01/2015	Single Limb Circuit for Pneupac Ventilators, with PEEP Valve	Medical Device	Recall	Class I	Hospital
16/01/2015	MEDPOR Barrier Sheets – Orbital Floor Implant 38mm X 50mm X 1.6mm	Medical Device	Recall	Class II	Hospital
16/01/2015	SONY LMD-1951MD MONITORS	Medical Device	Recall for Product Correction	Class I	Hospital
15/01/2015	Persona (TASP) Tibial Articular Surface Provisional Shim	Medical Device	Recall for Product Correction	Class II	Hospital
15/01/2015	syngo.plaza	Medical Device	Recall for Product Correction	Class I	Hospital
14/01/2015	Brilliance CT 16 Air, 64, Big Bore, iCT, iCT SP, Ingenuity CT, Ingenuity Core, Ingenuity Core128 and Ingenuity Flex	Medical Device	Recall for Product Correction	Class I	Hospital
14/01/2015	Hand-held Barcode Scanner used with VITROS clinical chemistry systems. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class I	Hospital
9/01/2015	Maquet demonstration unit fiber-optic Intra-Aortic Balloon Catheter	Medical Device	Recall for Product Correction	Class II	Hospital
7/01/2015	da Vinci Standard Surgical System, da Vinci S Surgical System, da Vinci Si Surgical System, da Vinci Si-e Surgical System including all instruments and accessories used with the da Vinci surgical systems	Medical Device	Recall for Product Correction	Class I	Hospital
7/01/2015	HeartWare Controller	Medical Device	Recall	Class I	Hospital
7/01/2015	Virazole (ribavirin powder for solution)	Medicine	Recall	Class I	Hospital

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24/12/2014	Anti-dsDNA Kit. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class III	Hospital
24/12/2014	Cheek Retractor, f/MatrixMANDIBLE U-shaped, flexible	Medical Device	Recall	Class II	Hospital
24/12/2014	Minor Plastics Pack IVF Australia	Medical Device	Recall	Class II	Hospital
24/12/2014	Monaco (radiation therapy planning system)	Medical Device	Recall for Product Correction	Class II	Hospital
24/12/2014	Radiometer ABL90Flex analysers running V3.1MR1 or below	Medical Device	Recall for Product Correction	Class I	Hospital
23/12/2014	Bending/Cutting Pliers with Nose, for LOCK Plates 2.0	Medical Device	Recall	Class II	Hospital
23/12/2014	Dimetapp Daytime/Nighttime Liquid Caps capsule blister pack	Medicine	Recall	Class II	Retail
23/12/2014	Enzymatic Creatinine, Cholesterol, Uric Acid, Lactate, and Lipase Assays	Medical Device	Recall for Product Correction	Class I	Hospital
23/12/2014	Focal Release 4.80.00	Medical Device	Recall for Product Correction	Class II	Hospital
23/12/2014	MEVATRON, PRIMUS, ONCOR and ARTISTE Digital Linear Accelerators	Medical Device	Recall for Product Correction	Class II	Hospital
23/12/2014	NCL-L-CD15. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class I	Hospital
22/12/2014	Affinis Inverse inlay ceramys & Affinis Fracture ceramic heads (Total Shoulder System that is designed for treating shoulder conditions)	Medical Device	Recall for Product Correction	Class II	Hospital
19/12/2014	Basic Custom Procedure Pack	Medical Device	Recall for Product Correction	Class III	Hospital
19/12/2014	PF4 IgG assay (Thrombophilia and coagulation inhibitor assay). An in vitro Diagnostic Medical Device (IVD).	Medical Device	Recall	Class II	Hospital
19/12/2014	RF enabled St. Jude Medical Ellipse, Fortify Assura, Unify Assura, and Quadra Assura Implantable Cardioverter Defibrillators (ICDs) and Assurity and Allure Pacemakers when used with Merlin@home RF Remote Monitoring Transmitter Model EX1150	Medical Device	Hazard Alert	Class II	Hospital
19/12/2014	Sensei X Robotic Catheter System	Medical Device	Recall for Product Correction	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
19/12/2014	Trellis 8 Peripheral Infusion System	Medical Device	Recall for Product Correction	Class I	Hospital
19/12/2014	Triathlon Tibial Alignment Ankle Clamp EM	Medical Device	Recall for Product Correction	Class II	Hospital
18/12/2014	EndoBarrier Gastrointestinal Liner with Delivery System	Medical Device	Hazard Alert	Class II	Hospital
18/12/2014	Fluoron Gas Tamponade EasyGas SF6	Medical Device	Recall	Class II	Hospital
18/12/2014	Jurnista 16 MG 14 Tablets	Medicine	Recall	Class II	Retail
18/12/2014	LENTIS HydroSmart Foldable Intraocular Lenses in Glass Vials	Medical Device	Hazard Alert	Class II	Hospital
18/12/2014	Puritan Bennett 980 Series Ventilator System	Medical Device	Recall for Product Correction	Class I	Hospital
17/12/2014	Saw Palmetto 4600	Medicine	Recall	Class III	Retail
16/12/2014	Alere Actim Partus. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
16/12/2014	Captia Malaria EIA (An in vitro Diagnostic Medical Device (IVD))	Medical Device	Recall for Product Correction	Class II	Hospital
16/12/2014	Depuy Synthes Trauma RIA (Reamer/Irrigator/Aspirator) system	Medical Device	Recall	Class II	Hospital
15/12/2014	Cartia LOW DOSE ASPIRIN 100mg tablet blister 7's pack	Medicine	Recall	Class III	Retail
15/12/2014	Ysio Max, Luminos dRF Max and Luminos Agile Max (with software version VE10 including SmarthOrtho license)	Medical Device	Recall for Product Correction	Class II	Hospital
12/12/2014	AQT90Flex TnI (troponin) Test Kit. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
12/12/2014	Artis Q and Artis Q.zen Ceiling Systems (Fluoroscopic angiographic x-ray system))	Medical Device	Recall for Product Correction	Class II	Hospital
12/12/2014	Artis Zeego Systems (Fluoroscopic angiographic x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
12/12/2014	HemosIL PT-Fibrinogen HS PLUS, An in-vitro diagnostic medical device (IVD)	Medical Device	Recall	Class I	Hospital
12/12/2014	Proteus XR/a X-ray Imaging Systems	Medical Device	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
11/12/2014	iPlan RT / iPlan RT Dose Radiation Treatment Planning Software used in combination with a localiser and one of the positioning solutions Target Positioner, ExacTrac v.4.5 or v.5.x, ExacTrac Vero (versions 2.1, 3.0, 3.1, 3.1.1, 3.2.0, 3.2.1)	Medical Device	Recall for Product Correction	Class I	Hospital
11/12/2014	Phadia 1000 Instrument (Allergy testing system). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
10/12/2014	Alere INRatio & INRatio2 PT/INR Monitor System. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Consumer
10/12/2014	Eon Mini Implantable Pulse Generator (IPG) Model 65-3788 and Eon Mini Charging System Model 3721	Medical Device	Recall	Class I	Hospital
10/12/2014	Eon/Eon C/ Eon Mini/ Prodigy Neurostimulation Systems and Octrode/ Quattrode Percutaneous Leads and Accessories	Medical Device	Hazard Alert	Class II	Hospital
10/12/2014	Philips M1783A and M5526A 12 Pin Sync Cables	Medical Device	Recall for Product Correction	Class I	Hospital
10/12/2014	QIAsymphony DSP Virus/Pathogen Midi Kit. An in vitro Diagnostic Medical Device (IVD)	Medical Device	Recall	Class II	Hospital
9/12/2014	Philips HeartStart MRx Monitor/Defibrillator	Medical Device	Recall for Product Correction	Class I	Hospital
9/12/2014	Synthes Small Electric Drive Hand Piece (Drill Surgical System)	Medical Device	Recall	Class II	Hospital
8/12/2014	Humeral broaches Aequalis (6/6.5 diameter)	Medical Device	Recall	Class II	Hospital
8/12/2014	Philips HeartStart MRx Monitor/Defibrillators	Medical Device	Recall for Product Correction	Class I	Hospital
5/12/2014	Philips HeartStart MRx Monitor/Defibrillator	Medical Device	Recall for Product Correction	Class I	Hospital
5/12/2014	Trilogy Bone Screws – 6.5mm X 35mm & 6.5mm X 25mm	Medical Device	Hazard Alert	Class II	Hospital
4/12/2014	Defibrillation Electrode for Children (Leonhard Lang) used with GE defibrillators	Medical Device	Recall	Class I	Hospital
4/12/2014	DRX Revolution Mobile X-Ray System	Medical Device	Recall for Product Correction	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
4/12/2014	i-Optics' Cassini, Corneal Topographer, with a recent software upgrade to version 2.0.0	Medical Device	Recall for Product Correction	Class II	Hospital
4/12/2014	Philips HeartStart MRx Monitor/Defibrillator	Medical Device	Recall for Product Correction	Class II	Hospital
4/12/2014	Sirius Polish Cemented Stem 34B & Sirius Polish Cemented Stem 38C	Medical Device	Hazard Alert	Class II	Hospital
4/12/2014	Stryker Laparoscopic Manual Instruments and Accessories	Medical Device	Recall for Product Correction	Class II	Hospital
2/12/2014	3i T3, Full Osseotite Tapered & Parallel Walled Dental Implants	Medical Device	Recall	Class II	Retail
28/11/2014	AtriCure CryoICE cryo-ablation probe (CRYO2)	Medical Device	Recall	Class I	Hospital
28/11/2014	DBL (TM) Mitoxantrone Hydrochloride Injection Concentrate 20mg/10mL injection vial	Medicine	Recall	Class II	Hospital
28/11/2014	SpermMar IgA (Fertipro) (Test for sperm antibodies against IgA)	Medical Device	Recall	Class III	Hospital
28/11/2014	VITROS 3600 Immunodiagnostic Systems, VITROS 4600 Chemistry Systems & VITROS 5600 Integrated Systems, Software Versions 3.1 & Below	Medical Device	Recall for Product Correction	Class II	Hospital
27/11/2014	BrightView SPECT, BrightView X and BrightView XCT Software	Medical Device	Recall for Product Correction	Class I	Hospital
27/11/2014	BrightView SPECT, BrightView X and BrightView XCT Systems	Medical Device	Recall for Product Correction	Class I	Hospital
27/11/2014	DX-D 600 X-ray System, Versions below 3.6	Medical Device	Recall for Product Correction	Class I	Hospital
27/11/2014	EPIQ 7 V1.0.x/1.1.x with QLAB a2DQ and/or aCMQ plug-ins	Medical Device	Recall for Product Correction	Class I	Hospital
27/11/2014	EPIQ5 Vi .0.x/1 .1 .x with QLAB a2DQ and/or aCMQ plug-ins	Medical Device	Recall for Product Correction	Class I	Hospital
27/11/2014	FAKWP (Fineline 6100258) and FAKSITE (Fineline 5820595) First Aid Kits	Medical Device	Recall	Class II	Retail
27/11/2014	LumaDent Light Battery Packs	Medical Device	Recall	Class II	Hospital
27/11/2014	Philips Ultrasound QLAB versions 10 and 10.1 .x with a2DQ and/or aCMQ plug-ins	Medical Device	Recall for Product Correction	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
27/11/2014	Philips Ultrasound Q-Station 3.0 with a2DQ and/or aCMQ Q-Apps	Medical Device	Recall for Product Correction	Class I	Hospital
26/11/2014	Iron Plus Capsules	Medicine	Recall	Class III	Wholesale
26/11/2014	KimVent Microcuff Subglottic Suctioning Endotracheal Tube, 7.0 mm, 7.5 mm, 8.0 mm, 8.5 mm & 9.0 mm	Medical Device	Recall	Class I	Hospital
26/11/2014	PF Saline Nasal Spray 30ml	Medicine	Recall	Class II	Retail
24/11/2014	syngo Imaging XS and syngo.plaza (Radiology picture archiving and communication system)	Medical Device	Recall for Product Correction	Class II	Hospital
21/11/2014	Biograph mCT and Biograph mCT Flow systems running VG50A software and equipped with the Adaptive 3D Intervention option	Medical Device	Recall for Product Correction	Class I	Hospital
21/11/2014	Esprit V1000 and Esprit/V200 Conversion Ventilator	Medical Device	Recall for Product Correction	Class I	Hospital
21/11/2014	IMMULITE 2000 and IMMULITE 2000 XPi	Medical Device	Recall	Class II	Hospital
21/11/2014	LIAISON Borrelia IgG. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
21/11/2014	McGRATH MAC Video Laryngoscope Blade Size #2	Medical Device	Recall	Class I	Hospital
21/11/2014	Pico 70 Arterial Blood sampler	Medical Device	Recall	Class I	Hospital
21/11/2014	Silane (dentine adhesive)	Medical Device	Recall	Class II	Retail
21/11/2014	Sunrise Medical Sunlift Hoist	Medical Device	Recall for Product Correction	Class II	Consumer
20/11/2014	BrightView XCT SPECT/CT systems	Medical Device	Recall for Product Correction	Class II	Hospital
20/11/2014	HomeChoice PRO Automated PD System Automated PD System Devices	Medical Device	Recall for Product Correction	Class II	Hospital
19/11/2014	3f Enable Aortic Bioprosthesis - Model 6000	Medical Device	Hazard Alert	Class I	Hospital
18/11/2014	Boston Scientific AUTOGEN DR Implantable Cardioverter-Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds)	Medical Device	Hazard Alert	Class I	Hospital
18/11/2014	DePuy Synthes ATTUNE Intuition Distal Femoral Jig	Medical Device	Recall	Class II	Hospital
14/11/2014	AlignRT patient positioning/tracking video camera system	Medical Device	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
14/11/2014	CareLink Clinical Therapy Management Software	Medical Device	Recall for Product Correction	Class II	Hospital
14/11/2014	Rocket IPC Drainage Bottle (A collection device used to collect fluid or air from the pleural cavity)	Medical Device	Recall for Product Correction	Class II	Hospital
13/11/2014	Alcon INFINITI Ultrasound PAKs - INFINITI Microsmooth Tapered Kelman 30°	Medical Device	Recall for Product Correction	Class II	Hospital
13/11/2014	Alere Determine HIV-1/2 Ag/Ab Combo (an in vitro diagnostic medical device)	Medical Device	Recall for Product Correction	Class II	Hospital
13/11/2014	Dimension Vista Systems - Theophylline (THEO) Flex Reagent Cartridge. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class III	Hospital
13/11/2014	Liquid Specific Protein (LSP) Calibrator. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
13/11/2014	Revaclear and Revaclear Max Dialysers (Hollow-fibre haemodialysis dialyser)	Medical Device	Recall	Class II	Hospital
13/11/2014	Stellaris PC with Laser System (Cataract extraction/vitreotomy system)	Medical Device	Recall for Product Correction	Class II	Hospital
12/11/2014	ArthroCare Corporation HipVac 50 Coblation Wand	Medical Device	Recall	Class II	Hospital
12/11/2014	Horse Blood Agar. An in vitro Diagnostic Medical Device (IVD)	Medical Device	Recall	Class III	Hospital
11/11/2014	cCrea A+B Membrane Unit for use on the ABL800 series blood gas analyser range	Medical Device	Recall for Product Correction	Class II	Hospital
11/11/2014	Elekta X-ray Volume Imaging System (XVI), software versions 5.0.0 and 5.0.1 (Electronic Imaging Device (EID) used with radiation therapy treatment)	Medical Device	Recall for Product Correction	Class I	Hospital
10/11/2014	HemoCue Glucose 201 Microcuvettes single packed	Medical Device	Recall for Product Correction	Class I	Hospital
10/11/2014	IH-1000 (immuno-haematology instrument). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
7/11/2014	Dimension Vista 500 Intelligent Lab System & Dimension Vista 1500 Intelligent Lab System	Medical Device	Recall for Product Correction	Class II	Hospital
7/11/2014	Gelflex Sterile Eye Wash Normal Saline 10mL Ampoule	Medical Device	Recall	Class II	Retail
7/11/2014	STERIS 5085 and 5085SRT Surgical Table	Medical Device	Recall for Product Correction	Class II	Hospital

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6/11/2014	Fisher & Paykel Healthcare Infant Warmer Pivot Securing Nut	Medical Device	Recall for Product Correction	Class I	Hospital
4/11/2014	Endo Wrist One Vessel Sealer (INS-410322) for the da Vinci Si (IS3000) Surgical System	Medical Device	Recall for Product Correction	Class I	Hospital
4/11/2014	MammoDiagnost DR	Medical Device	Recall for Product Correction	Class II	Hospital
31/10/2014	Anaerobic Agar Plate. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
31/10/2014	Hamilton Active Family SPF 50+ 225mL	Medicine	Recall	Class III	Wholesale
31/10/2014	Relief ACP Oral Care Gel supplied separately and in Zm CH 25% Kits	Medical Device	Recall	Class II	Consumer
30/10/2014	Mindray V-Series Patient Monitors with 12-lead ECG interpretation capabilities	Medical Device	Recall for Product Correction	Class II	Hospital
30/10/2014	Mindray's V-Series Patient Monitors, software versions 2.4.0.18, 2.4.0.50, 2.4.0.60 and 2.4.1.18	Medical Device	Recall for Product Correction	Class I	Hospital
30/10/2014	Panorama Central Station, software versions 10.0 to 11.3 and patient Monitoring Network	Medical Device	Recall for Product Correction	Class II	Hospital
29/10/2014	AFB III Staining Kit (An in vitro diagnostic medical device (IVD))	Medical Device	Recall for Product Correction	Class II	Hospital
29/10/2014	Philips IntelliVue Patient Monitors and Philips Avalon Fetal Monitors	Medical Device	Recall for Product Correction	Class I	Hospital
29/10/2014	TORISEL temsirolimus 25 mg concentrate for injection vial and diluent vial composite pack	Medicine	Recall	Class II	Hospital
29/10/2014	Zimmer NexGen Trabecular Metal Tibial (Replacement) Impactor Pad Instruments	Medical Device	Recall for Product Correction	Class II	Hospital
28/10/2014	Thermo Scientific MAS CardiImmune XL	Medical Device	Recall	Class II	Hospital
28/10/2014	ThermoCool SmartTouch Catheter Family (used to facilitate electrophysiological mapping of the heart and to undertake RF ablations)	Medical Device	Recall for Product Correction	Class I	Hospital
24/10/2014	E-Z Gas II Effervescent Granules Antacid/Antiflatulent 4g packet	Medicine	Recall	Class III	Hospital
24/10/2014	Zovirax (aciclovir) Ophthalmic Ointment 30mg/g	Medicine	Recall	Class II	Retail
23/10/2014	AVS PL SPACER (Used as an aid in spinal fixation)	Medical Device	Recall	Class III	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
23/10/2014	Burinex (Bumetanide) Injection 2mg/4mL (Pack of 5 ampoules)	Medicine	Recall	Class II	Hospital
23/10/2014	Symbia S and T Series camera systems (SPECT/CT nuclear medicine diagnostic imaging system)	Medical Device	Recall for Product Correction	Class II	Hospital
23/10/2014	Thioglycollate Broth 5mL. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
21/10/2014	APC Plus Victory Series Twin Upper Left Cuspid -3T/10A with Distal Hook (Unitek Orthodontic Metal Brackets - Orthodontic bracket, metal)	Medical Device	Recall	Class III	Retail
21/10/2014	IMMULITE, IMMULITE 1000, IMMULITE 2000 and IMMULITE 2000 XPi - Calcitonin Control Module	Medical Device	Recall for Product Correction	Class II	Hospital
20/10/2014	50mm Left Standard Ti Mandible	Medical Device	Hazard Alert	Class II	Hospital
17/10/2014	Artis zeego systems with a C - arm (Fluoroscopic X-ray systems)	Medical Device	Recall for Product Correction	Class II	Hospital
17/10/2014	Sapphire Administration IV Set AP424 (Patient Controlled Analgesia IV set for use with the Sapphire infusion pump)	Medical Device	Recall for Product Correction	Class II	Hospital
17/10/2014	Surveyor S12 and Surveyor S19 Patient Monitors	Medical Device	Recall for Product Correction	Class II	Hospital
17/10/2014	UNIVERSAL Modular Electric/Battery Double Trigger Handpiece (Surgical power tool)	Medical Device	Recall for Product Correction	Class II	Hospital
15/10/2014	ADVIA Centaur and ADVIA Centaur XP (An in vitro diagnostic medical device (IVD))	Medical Device	Recall for Product Correction	Class II	Hospital
15/10/2014	Dimetapp Saline Nasal Drops for Infants	Medical Device	Recall	Class II	Retail
14/10/2014	Edwards Lifesciences Vent Catheter	Medical Device	Recall for Product Correction	Class I	Hospital
14/10/2014	Leksell Gamma Knife Perfexion (teletherapy device indicated for stereotactic irradiation of head structures)	Medical Device	Recall for Product Correction	Class I	Hospital
10/10/2014	0.9% Sodium Chloride for Irrigation 2000ml and Water for Irrigation 2000ml	Medical Device	Recall	Class I	Hospital
10/10/2014	Allura Xper Systems	Medical Device	Recall for Product Correction	Class I	Hospital
10/10/2014	Hudson Nebuliser Adaptor - AQUAPAK	Medical Device	Recall	Class II	Hospital

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10/10/2014	Ingenuity CT, Ingenuity Core, Ingenuity Core128 with Continuous Computed Tomography (CCT) Option and have been upgraded from Software Version 3.x to Version 4.0.0 / 4.0.1	Medical Device	Recall for Product Correction	Class I	Hospital
10/10/2014	MultiDiagnost Eleva with Flat Detector Systems	Medical Device	Recall for Product Correction	Class I	Hospital
10/10/2014	PHILIPS MX 16-slice CT System, software: v1.1.3.1167; v1.1.4.21425; v1.1.4.21424; v1.1.4.21422	Medical Device	Recall for Product Correction	Class II	Hospital
10/10/2014	Small Form Factor Console PC (Used Access 2 Immunoassay System and the UniCel DxC 600i SYNCHRON Access Clinical System). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
10/10/2014	Sodium Chloride For Injection – MS 0.9% W/V, 50 X 5ML Ampoules	Medicine	Recall	Class I	Wholesale
9/10/2014	Puritan Bennett 980 Series Ventilator System	Medical Device	Recall for Product Correction	Class I	Hospital
9/10/2014	Selector Tubing Kit for use with CUSA Selector Ultrasonic Aspirators	Medical Device	Recall for Product Correction	Class I	Hospital
8/10/2014	ADVIA Centaur, ADVIA Centaur XP and ADVIA Centaur CP - BNP Ready Pack Lot 038174	Medical Device	Recall for Product Correction	Class II	Hospital
8/10/2014	Dimension Vista Systems Mass CKMB Isoenzyme Calibrator (MMB CAL). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
8/10/2014	Multiple ProcedurePak Trays with Ecolab-Microtek Medical Basin Liners	Medical Device	Recall	Class II	Hospital
8/10/2014	Puritan Bennett 980 Series Ventilator System	Medical Device	Recall for Product Correction	Class I	Hospital
7/10/2014	Abbott RealTime Assay Application CD-ROM	Medical Device	Recall	Class II	Hospital
7/10/2014	Calibrator E used for calibration of the ADVIA Centaur Systems Cortisol, Progesterone and Testosterone assays	Medical Device	Recall for Product Correction	Class III	Hospital
7/10/2014	Discovery MR750, Optima MR450w equipped with the GEM option, and Discovery MR750w equipped with the GEM option products that are running DV 25 software release (MRI System)	Medical Device	Recall for Product Correction	Class I	Hospital

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7/10/2014	IMRIS Operating Room table (ORT300)	Medical Device	Recall for Product Correction	Class I	Hospital
3/10/2014	AMPLITUDE Orthopaedic Surgical Instruments	Medical Device	Recall for Product Correction	Class II	Hospital
3/10/2014	Lifemed Urinary Drainage Bag with Pump	Medical Device	Recall	Class II	Hospital
3/10/2014	OEC 9800, OEC UroView 2800, OEC MiniView 6800, OEC FlexiView 8800 (mobile fluoroscopic x-ray diagnostic system)	Medical Device	Recall for Product Correction	Class I	Hospital
2/10/2014	CLINITEK Status, CLINITEK Status+, and CLINITEK Status Connect Systems	Medical Device	Recall for Product Correction	Class II	Hospital
2/10/2014	COLGATE TOTAL ORIGINAL toothpaste tube 220g	Medicine	Recall	Class III	Consumer
1/10/2014	Accu-Chek Spirit Combo Insulin Pumps	Medical Device	Recall for Product Correction	Class I	Consumer
1/10/2014	Autostainer Link 48, AS480	Medical Device	Recall for Product Correction	Class II	Hospital
1/10/2014	Proclear Toric Soft Hydrophilic Contact Lenses	Medical Device	Recall	Class II	Retail
1/10/2014	Trident Acetabular System Hemispherical Surgical Protocol & Product Reference Guide	Medical Device	Recall for Product Correction	Class II	Hospital
30/09/2014	Panbio Q Fever IgM ELISA (An in vitro diagnostic medical device (IVD))	Medical Device	Recall	Class II	Hospital
26/09/2014	MENINGITEC meningococcal serogroup C conjugate vaccine suspension for injection pre-filled syringe	Medicine	Recall	Class II	Retail
26/09/2014	Multiple Models of GE Nuclear Medicine Systems:	Medical Device	Recall for Product Correction	Class II	Hospital
26/09/2014	Persona Distal Valgus Alignment Guide (supplied as part of the reusable surgical kit)	Medical Device	Recall for Product Correction	Class II	Hospital
26/09/2014	Zimmer Persona Tibial Articular Surface Provisional (TASP) Instruments	Medical Device	Recall for Product Correction	Class II	Hospital
25/09/2014	Aeroneb Pro and Solo Nebuliser Systems - FRIWO power adapter	Medical Device	Recall for Product Correction	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
25/09/2014	Artis zee and Artis zeego systems (software versions VC14 and VC21) with the A100 generator and specific manufacturing lots of 3 focal spot x-ray tube (fluoroscopic angiographic x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
25/09/2014	Covidien Medi-Trace Cadence Defibrillation Electrodes	Medical Device	Recall for Product Correction	Class I	Hospital
25/09/2014	Dimension Vista Hemoglobin A1c Flex Reagent Cartridge. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
25/09/2014	Stereo Biopsy Device used with Mammomat Inspiration Mammography System	Medical Device	Recall for Product Correction	Class II	Hospital
24/09/2014	BOC Medical Grade Compressed Air supplied in Size D Cylinders	Medicine	Recall	Class II	Hospital
24/09/2014	Expression Information Portal - IP5 (secondary display control unit for Expression MRI patient monitoring system)	Medical Device	Recall for Product Correction	Class II	Hospital
24/09/2014	Grifols Australia Perfect Panel cells	Medical Device	Recall for Product Correction	Class I	Hospital
24/09/2014	IMMULITE/IMMULITE 1000 - Cortisol Assay - An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class I	Hospital
22/09/2014	AcrySof CACHET PHAKIC Lens	Medical Device	Hazard Alert	Class I	Hospital
22/09/2014	Codman Neuro EDS 3 CSF External Drainage Systems	Medical Device	Recall	Class I	Hospital
22/09/2014	COGNIS Implantable Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) and TELIGEN DR & VR Implantable Cardioverter -Defibrillators (ICDs)	Medical Device	Hazard Alert	Class I	Hospital
22/09/2014	Premise Universal Restorative Body Syringe and Unidose, Shade A2	Medical Device	Recall	Class III	Retail
19/09/2014	SwitchPoint Infinity 3 - SPI3	Medical Device	Recall for Product Correction	Class III	Hospital
18/09/2014	Aeroneb Pro/Solo Nebuliser Systems FRIWO power adapter	Medical Device	Recall for Product Correction	Class I	Hospital
18/09/2014	m24sp Instrument System (sample extraction system). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
18/09/2014	Salfo Talaris Tibial Impactor	Medical Device	Recall for Product Correction	Class II	Retail
17/09/2014	ADVIA Centaur/Centaur XP/Centaur CP Systems HBc Total (HBcT) Assay	Medical Device	Recall	Class II	Hospital
17/09/2014	VITROS 4600 Chemistry Systems & VITROS 5600 Integrated Systems Using Software Version 3.0	Medical Device	Recall for Product Correction	Class II	Hospital
16/09/2014	ADVIA Centaur Cleaning Solution. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class III	Hospital
16/09/2014	NaCl, Enzyme Test and Cold Agglutinins	Medical Device	Recall	Class II	Hospital
16/09/2014	VIDAS Anti HBs Total II. An in vitro Diagnostic Medical Device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
15/09/2014	942-073, D8088_Crea A, D8089_Crea B Membranes used on the ABL827 blood gas analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
15/09/2014	Defibrillator/pacer SLIM corpuls3	Medical Device	Recall for Product Correction	Class I	Retail
15/09/2014	Human IgG4 Kit Immage Kit	Medical Device	Recall for Product Correction	Class II	Hospital
15/09/2014	Optional PS500 External Power Supply Unit Used in connection with Dräger V Series Ventilators	Medical Device	Recall for Product Correction	Class I	Hospital
15/09/2014	Puritan Bennett 840 Ventilator	Medical Device	Recall for Product Correction	Class I	Hospital
15/09/2014	Ysio Max, Luminos dRF Max, Luminos Agile Max, Uroskop Omnia Max with software version VE10A to VE10C	Medical Device	Recall for Product Correction	Class II	Hospital
12/09/2014	Dade Innovin Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
12/09/2014	Phenocell A 3%. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
11/09/2014	IntelliSpace Portal, software versions 5.0.0, 5.0.1, 5.0.2, 6.0.0, 6.0.1, 6.0.2	Medical Device	Recall for Product Correction	Class I	Hospital
10/09/2014	DePuy Charnley Pin Retractor & Handle Set (orthopaedic hip joint replacement instrument)	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
9/09/2014	Babytherm 8004/8010 and Babytherm 8000WB for newborns (Infant warmers and open infant care units)	Medical Device	Recall for Product Correction	Class I	Hospital
9/09/2014	Pinnacle3, software versions 9.0, 9.2, 9.4, 9.6 (Radiation Treatment Planning System)	Medical Device	Recall for Product Correction	Class I	Hospital
5/09/2014	MobileDiagnost wDR (Mobile digital x-ray imaging system)	Medical Device	Recall for Product Correction	Class II	Hospital
5/09/2014	Phenocell A 3%. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
5/09/2014	Spectra Optia Apheresis System with Software Version 11	Medical Device	Recall for Product Correction	Class I	Hospital
5/09/2014	Ysio Systems with fixed detector in the wall stand, software version VC10 (Diagnostic digital x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
4/09/2014	Horizon Cardiology Hemo – versions 13.0 and 13.1 (cardiology/cath lab information management system)	Medical Device	Recall for Product Correction	Class I	Hospital
3/09/2014	Scherbak Weights – 400 gr and 800 gr (used with Scherbak vaginal speculum)	Medical Device	Recall	Class II	Hospital
3/09/2014	Vision Sciences Battery Charger (VANSON V-95) and rechargeable Lithium-Ion Batteries supplied with BLS-1000 portable LED light source kits or as standalone items. (Light Source for endoscopic procedures)	Medical Device	Recall	Class II	Hospital
2/09/2014	IntelliSpace PACS 4.4 (Radiology picture archiving and communication system)	Medical Device	Recall for Product Correction	Class I	Hospital
2/09/2014	Intuitive Surgical Battery Box of the da Vinci STM and da Vinci SiTM Surgical Systems	Medical Device	Recall for Product Correction	Class II	Hospital
1/09/2014	ZOLL ProPadz Sterile Multi-Function Electrodes	Medical Device	Recall	Class II	Hospital
29/08/2014	4D Integrated Treatment Console (4DITC) Version: 10 and 11 (Used for accurate treatment delivery by monitoring linear accelerator parameters)	Medical Device	Recall for Product Correction	Class I	Hospital
29/08/2014	Bard DuaLok Breast Lesion Localization Wire	Medical Device	Recall	Class II	Hospital
29/08/2014	Cortex Screw Ø 3.5 mm, self-tapping, length 28 mm, Stainless Steel	Medical Device	Recall	Class II	Hospital
29/08/2014	Maintenance Solution Amino Acid 4% + Heparin, TE & Zinc	Medicine	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
29/08/2014	Patient Data Module (PDM) Used with CARESCAPE Monitor B850, B650, or B450 (Multiparameter Patient Monitor)	Medical Device	Recall for Product Correction	Class I	Hospital
29/08/2014	V5Ms transesophageal transducer (used for ultrasound imaging)	Medical Device	Recall for Product Correction	Class I	Hospital
27/08/2014	CLAW and CLAW II Plates (An internal fixation device for the stabilisation of fractured bones and/or bone fragments)	Medical Device	Hazard Alert	Class I	Hospital
27/08/2014	DePuy S-ROM Noiles Rotating Hinge Femur with Pin	Medical Device	Recall	Class II	Hospital
27/08/2014	Spectra Optia Apheresis System - Return Line Air Detector (RLAD)	Medical Device	Recall for Product Correction	Class II	Hospital
26/08/2014	Omrix Pressure Regulator (Surgical air pipeline regulator)	Medical Device	Recall	Class I	Hospital
22/08/2014	ADVIA Centaur and ADVIA Centaur XP Immunoassay Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
22/08/2014	CentraLink Data Management System V14 (Analyser software for in vitro diagnostic medical device (IVD))	Medical Device	Recall for Product Correction	Class II	Hospital
22/08/2014	Precise Treatment Table (A patient treatment support and positioning table for radiation therapy and simulation use.)	Medical Device	Recall for Product Correction	Class I	Hospital
22/08/2014	Test Tube Heater - Power Supply Unit	Medical Device	Recall	Class III	Hospital
22/08/2014	Vapotherm Disposable Patient Circuit System (Delivers high flow humidified gases via a nasal cannula or other patient interface)	Medical Device	Recall	Class II	Hospital
21/08/2014	Haemoglobin A1c (HbA1c) Flex Reagent Cartridge (An in vitro diagnostic medical device (IVD) used with Dimension Vista Systems)	Medical Device	Recall for Product Correction	Class II	Hospital
21/08/2014	Luminos dRF and Luminos dRF Max systems	Medical Device	Recall for Product Correction	Class II	Hospital
21/08/2014	TOPPER Xtra Absorbent Dressing Pads, Sterile	Medical Device	Recall	Class II	Hospital
20/08/2014	ADVIA Centaur & ADVIA Centaur XP Immunoassay System (An in vitro diagnostic medical device (IVD))	Medical Device	Recall for Product Correction	Class I	Hospital
20/08/2014	Neoflow Flow Sensor and Neoflow Insert	Medical Device	Recall	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
20/08/2014	Tegris OR Table Control (Operating room device management system)	Medical Device	Recall for Product Correction	Class II	Hospital
18/08/2014	Herculite Ultra	Medical Device	Recall	Class III	Retail
18/08/2014	HS66 Turbo LTSF Steriliser	Medical Device	Recall for Product Correction	Class II	Hospital
18/08/2014	OXYGEN Sterile Protection	Medical Device	Recall	Class II	Hospital
18/08/2014	Philips HeartStart FR3, software version 2.0 (Automated external defibrillator (AED))	Medical Device	Recall for Product Correction	Class I	Retail
18/08/2014	St. Jude Medical Ellipse VR/DR Implantable Cardioverter Defibrillators (ICDs)	Medical Device	Hazard Alert	Class I	Hospital
18/08/2014	Vanguard 360 Femoral Boss Reamer	Medical Device	Recall	Class II	Hospital
14/08/2014	HeartWare Ventricular Assist System batteries	Medical Device	Recall	Class I	Hospital
14/08/2014	Monaco and Focal (radiation treatment planning systems)	Medical Device	Recall for Product Correction	Class I	Hospital
14/08/2014	VELCADE (bortezomib) 3.5 mg powder for injection vial	Medicine	Recall	Class II	Hospital
11/08/2014	LIAISON Biotrin Parvovirus B19 IgM	Medical Device	Recall for Product Correction	Class II	Hospital
11/08/2014	Red Back Spider Antivenom 500U Injection Vial	Medicine	Recall	Class I	Hospital
8/08/2014	ADVIA Centaur CP – BNP	Medical Device	Recall for Product Correction	Class II	Hospital
8/08/2014	BD Epicenter v6.20A (used in conjunction with Bruker MALDI BioTyper) An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
8/08/2014	Chemistry 1 Calibrator used on Dimension Vista Systems (Magnesium assay calibrator). An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
8/08/2014	Processor HDTV Visera Elite, Processor HDTV Exera III, 3d Visualization Unit, Light Source Xenon Visera Elite, Light Source Xenon Exera III, High Flow Co2 Insufflator, Scopeguide Unit & Video System Center (components or parts of endoscopes)	Medical Device	Recall for Product Correction	Class II	Hospital
8/08/2014	STERIS 4085, 4085 SS and 4085 Feather Weight Leg Section (FLWS) Surgical tables	Medical Device	Recall for Product Correction	Class II	Hospital

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8/08/2014	Symbia T Series and Symbia Intevo Camera System (SPECT/CT diagnostic imaging system)	Medical Device	Recall for Product Correction	Class I	Hospital
8/08/2014	Transpac Monitoring Kits	Medical Device	Recall	Class I	Hospital
7/08/2014	Bayer Elevit with Iodine Tablets	Medicine	Recall	Class III	Retail
6/08/2014	Shigella dysenteriae Polyvalent (1 – 10) Agglutinating Serum (reagent intended for the identification of Shigella dysenteriae). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
5/08/2014	Ultrafilter U9000 (Used on Gambro Haemodialysis Delivery Systems.)	Medical Device	Recall for Product Correction	Class I	Hospital
1/08/2014	Amoxicillin + clavulanic acid 20 & 10 ig discs. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
1/08/2014	E.CAM or Symbia E System: Rear Casters of the Collimator Cart	Medical Device	Recall for Product Correction	Class II	Hospital
31/07/2014	BD BBL Vancomycin Screen Agar	Medical Device	Recall	Class II	Hospital
31/07/2014	Kodak DirectView DR 7500 (Diagnostic x-ray system)	Medical Device	Recall for Product Correction	Class I	Hospital
31/07/2014	Of Spiggle & Theis PTFE Ventilation Tubes	Medical Device	Recall for Product Correction	Class II	Hospital
31/07/2014	Philips Ultrasound QLAB versions 10.0 and 10.1	Medical Device	Recall for Product Correction	Class II	Hospital
31/07/2014	T-PAL (Transforaminal Posterior Atraumatic Lumbar Cage System)	Medical Device	Recall for Product Correction	Class I	Hospital
30/07/2014	PRISMA, PRISMAFLEX, X-MARS and ADSORBA sets	Medical Device	Recall for Product Correction	Class II	Hospital
29/07/2014	Surgical Instruments with flexible shafts	Medical Device	Recall for Product Correction	Class II	Hospital
29/07/2014	Sysmex CS-2000i/CS-2100i/CS-5100 Automated blood coagulation analysers. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
25/07/2014	Clinical Chemistry ICT Serum Calibrator. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
25/07/2014	Discovery XR656 Wall Stand System (X-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital

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25/07/2014	Expression IP5 Information Portal (Multiparameter patient monitor for use during MRI procedure)	Medical Device	Recall for Product Correction	Class II	Hospital
25/07/2014	Prinivil (Lisinopril) 10mg and 20mg Tablets	Medicine	Recall	Class II	Retail
24/07/2014	CHEMMART PHARMACY IBUPROFEN 200mg Soft Gel capsule blister pack (Pack sizes: 20s, 40s, 100s)	Medicine	Recall	Class III	Retail
24/07/2014	Codman Certas Programmable Valves (Hydrocephalic valve)	Medical Device	Hazard Alert	Class I	Hospital
24/07/2014	COSEAL Surgical Sealant 2ml and 4ml	Medical Device	Recall	Class II	Hospital
24/07/2014	Panbio Q Fever IgM ELISA. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
24/07/2014	VITROS Immunodiagnostic Products CA 19-9 Calibrators and Reagent Packs	Medical Device	Recall	Class I	Hospital
22/07/2014	Allura Xper R8.2.0 (Fluoroscopic diagnostic x-ray system)	Medical Device	Recall for Product Correction	Class I	Hospital
22/07/2014	Cooper Surgical TransWarmer Infant Transport Mattress (Produces heat through chemical reaction)	Medical Device	Recall	Class II	Hospital
21/07/2014	Alegria Anti-Intrinsic Factor Assay	Medical Device	Recall	Class II	Hospital
18/07/2014	AVS ARIA Implant Inserter	Medical Device	Recall	Class I	Hospital
18/07/2014	Injectomat Agilia Range (Std, MC & TIVA), Volumat Agilia Range (Std & MC)	Medical Device	Recall for Product Correction	Class II	Hospital
18/07/2014	Philips Gel-E Donut and Squishon 2 (Gel filled Pillow)	Medical Device	Recall	Class II	Hospital
18/07/2014	TXR-ME (Tri-Ex Extraction Balloon with Multiple Sizing)	Medical Device	Recall	Class II	Hospital
16/07/2014	EmbryoScope Time-Lapse Incubator	Medical Device	Recall for Product Correction	Class II	Hospital
16/07/2014	Sonopet Console (Ultrasonic Surgical Aspirator System)	Medical Device	Recall for Product Correction	Class II	Hospital
15/07/2014	Minstrel Patient Transfer Lift with Scale	Medical Device	Recall for Product Correction	Class I	Retail
15/07/2014	National Workplace First Aid Kit & Sports & Outdoors First Aid Kit	Medical Device	Recall	Class II	Retail
15/07/2014	Philips Ingenia 1.5T and 3.0T MR Systems	Medical Device	Recall for Product Correction	Class I	Retail

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14/07/2014	Brainlab Patient Data Manager	Medical Device	Recall for Product Correction	Class I	Hospital
14/07/2014	CARESCAPE respiratory modules E-sCO ₂ , E-sCOV, E-sCAiO, E-sCAiOV, E-sCAiOE, E-sCAiOVE & the Airway Gas Option N-CAiO	Medical Device	Recall for Product Correction	Class I	Hospital
14/07/2014	LIFEPAK 1000 Defibrillator	Medical Device	Recall for Product Correction	Class I	Hospital
11/07/2014	Artis Q and Artis Q zen systems (Fluoroscopic X-ray systems)	Medical Device	Recall for Product Correction	Class II	Hospital
11/07/2014	Artis zee and Artis zeego systems	Medical Device	Recall for Product Correction	Class II	Hospital
11/07/2014	Pasteur Pipettes for use in IVF	Medical Device	Recall	Class II	Retail
10/07/2014	5mL Reaction Vessels used with the m2000sp Instrument. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class I	Hospital
10/07/2014	ProcedurePak (surgical procedure packs)	Medical Device	Recall	Class II	Hospital
10/07/2014	Specular Microscope SP-1P (non-invasive photographic microscope)	Medical Device	Recall for Product Correction	Class II	Hospital
9/07/2014	MobileDiagnost wDR (digital x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
9/07/2014	VITROS 3600 Immunodiagnostic Systems, VITROS 4600 Chemistry Systems & VITROS 5600 Integrated Systems (Software Versions 3.0 & below)	Medical Device	Recall for Product Correction	Class II	Hospital
8/07/2014	LED Single Bay Battery Charger, supplied with LED Headlight System	Medical Device	Recall	Class II	Hospital
8/07/2014	RECLAIM Distal Stem with Taper Sleeve Protector (Press-fit hip femur prosthesis)	Medical Device	Recall for Product Correction	Class II	Hospital
8/07/2014	TRIGEN INTERTAN Intramedullary Nail 13MM X 20CM 125D	Medical Device	Recall	Class II	Hospital
7/07/2014	Bartels Herpes Simplex Virus Fluorescent Monoclonal Antibody Test. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class III	Hospital
7/07/2014	HOYA Corporation (PENTAX Medical) – Gas/Water Feeding Valve	Medical Device	Recall for Product Correction	Class II	Hospital

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7/07/2014	Large Clip Applier for use with the da Vinci STM and da Vinci SiTM	Medical Device	Recall for Product Correction	Class II	Hospital
7/07/2014	NexGen Complete Knee Solution MIS Total Knee Procedure Stemmed Tibial Component, Precoat	Medical Device	Hazard Alert	Class II	Hospital
4/07/2014	3M ESPE Filtek Supreme XTE Flowable Restorative (Dental material)	Medical Device	Recall	Class III	Hospital
4/07/2014	Affinity Four Birthing Bed	Medical Device	Recall for Product Correction	Class II	Hospital
4/07/2014	Cordis EMPIRA NC RX PTCA Dilatation Catheter ("75RxyyyN") and Cordis EMPIRA RX PTCA Dilatation Catheter ("85RxyyyS")	Medical Device	Recall for Product Correction	Class I	Hospital
4/07/2014	Horizon Cardiology Hemo1 – versions 12.2 HF4 and earlier	Medical Device	Recall for Product Correction	Class II	Hospital
4/07/2014	InTouch Critical Care Bed	Medical Device	Recall for Product Correction	Class II	Hospital
4/07/2014	qube Compact Monitor (Transportable multiparameter patient monitor)	Medical Device	Recall for Product Correction	Class II	Hospital
4/07/2014	Slide-in Plug Adaptor for Charger used with Haag Streit UK Perkins MkIII Tonometer	Medical Device	Recall for Product Correction	Class II	Hospital
4/07/2014	Thioglycollate Medium (bacteria culture media). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
3/07/2014	m24sp Instrument System (sample extraction system). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
3/07/2014	Panthera-Puncher 9, An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
2/07/2014	BD Vacutainer CPT Cell Preparation Tube. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
2/07/2014	C-Series High Energy Linear Accelerator	Medical Device	Recall for Product Correction	Class I	Hospital
2/07/2014	RAPIDQC Complete Quality Control Material (QC reagent for use with blood gas instruments). An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
1/07/2014	Lancet, Low Flow and Micro Flow	Medical Device	Recall	Class II	Retail

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30/06/2014	Damon TMA - Low Friction Archwire (orthodontic wire)	Medical Device	Recall for Product Correction	Class III	Retail
30/06/2014	Horizon Medical Imaging Products Versions 4.6.1 up to and including 11.9 and McKesson Radiology 12.0 (Radiology picture archiving and communication system)	Medical Device	Recall for Product Correction	Class II	Hospital
30/06/2014	MSA Hip System	Medical Device	Hazard Alert	Class II	Hospital
27/06/2014	BrightView XCT and BrightView X- upgraded with the XCT Flat Panel Detector (Gamma camera)	Medical Device	Recall for Product Correction	Class II	Hospital
27/06/2014	Crepe Bandage 5cm x 1.5m	Medical Device	Recall	Class II	Hospital
26/06/2014	Micro-Injection Pipettes for IVF procedures	Medical Device	Recall	Class III	Hospital
25/06/2014	ACL Top Family of instruments (haemostasis testing systems). An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class I	Hospital
25/06/2014	DX-D 100 Digital Radiography X-Ray System	Medical Device	Recall for Product Correction	Class II	Hospital
25/06/2014	IntelliVue MX40	Medical Device	Recall for Product Correction	Class I	Hospital
24/06/2014	BOC Medical E.P. Grade Oxygen Compressed supplied in Size D Cylinders	Medicine	Recall	Class III	Hospital
24/06/2014	CARESCAPE Monitor B850, B650 or B450 Monitors with V2 software versions (Multiparameter patient monitors)	Medical Device	Recall for Product Correction	Class II	Hospital
24/06/2014	Skin Graft Knife Blades for use with Thackray Watson Cobbett and Braithwaite Skin Graft Knife (Pack of 10 blades)	Medical Device	Recall	Class II	Hospital
23/06/2014	500 Series Vertical Rails	Medical Device	Recall	Class II	Retail
23/06/2014	ACUSON S Family Ultrasound Systems with software versions VC25D, VC30A, VC30B	Medical Device	Recall for Product Correction	Class I	Hospital
23/06/2014	Cardioxyl Sutures	Medical Device	Recall	Class II	Hospital
23/06/2014	INTELEPACS Version 3.8.1 and up (Radiology picture archiving and communication system)	Medical Device	Recall for Product Correction	Class II	Hospital
23/06/2014	Logical Ceramic Liner	Medical Device	Recall	Class II	Sponsor

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18/06/2014	BD FACSCanto 10 colour configuration (Cytometer). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
18/06/2014	HeartSineTechnologies Pad-Pak/ Pedi-Pak (contains non-rechargeable battery and defibrillation electrodes for use with the HeartSine Samaritan PAD 350P and 500P Defibrillators)	Medical Device	Recall	Class III	Wholesale
18/06/2014	Multi Lumen and Pressure Injectable Central Venous Catheters	Medical Device	Recall for Product Correction	Class II	Hospital
18/06/2014	Muro 128 5% Ointment (Sodium Chloride Hypertonicity Ophthalmic Ointment, 5%) Tube 3.5g	Medicine	Recall	Class II	Hospital
18/06/2014	Puritan Bennett 840 Ventilator with 9.4 inch graphical user interface (GUI) assembly	Medical Device	Recall for Product Correction	Class I	Hospital
18/06/2014	Thermablate Endometrial Ablation System (EAS)	Medical Device	Recall for Product Correction	Class II	Hospital
17/06/2014	Anspach Attachments and Handpieces (reusable surgical devices)	Medical Device	Recall for Product Correction	Class II	Hospital
17/06/2014	Axiom Artis and Artis Zee Systems with hand switch (Fluoroscopic angiographic X-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
17/06/2014	Cortex Screw Ø 1.5 mm, self-tapping, length 8 mm (non-biodegradable orthopaedic bone screw)	Medical Device	Recall	Class II	Hospital
17/06/2014	Pulmonary Valve Allograft	Biological	Hazard Alert	Class I	Hospital
13/06/2014	Medtronic Duet External Drainage and Monitoring System (Cerebrospinal fluid drainage system)	Medical Device	Recall	Class I	Hospital
13/06/2014	SOLIRIS eculizumab (rmc) Concentrated Solution for Infusion 300mg/30mL	Medicine	Recall	Class II	Hospital
12/06/2014	Proteus XR/a X-ray imaging systems and Revolution XR/d X-ray imaging systems	Medical Device	Recall for Product Correction	Class II	Hospital
11/06/2014	Ingenia MR FlexTrak Trolley	Medical Device	Recall for Product Correction	Class II	Hospital
11/06/2014	Medtronic Navigation Planning Station	Medical Device	Recall for Product Correction	Class III	Hospital
11/06/2014	RIA Coat-A-Count Androstenedione	Medical Device	Recall for Product Correction	Class II	Hospital

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6/06/2014	Alere Triage BNP Calibrator for Beckman Coulter	Medical Device	Recall	Class II	Hospital
6/06/2014	Guide Wire diameter 3.2mm, length 400mm (Fixation nail guidewire)	Medical Device	Recall	Class II	Hospital
6/06/2014	Single-width Airway Module E-miniC and Extension Modules N-FC & N-FCREC	Medical Device	Recall for Product Correction	Class I	Hospital
5/06/2014	ADVIA Centaur, ADVIA Centaur XP and ADVIA Centaur CP - Troponin Ultra ReadyPack. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class I	Hospital
5/06/2014	Digital Linear Accelerators of type ARTISTE, ONCOR and PRIMUS with Automatic Sequenced Treatment Delivery Option	Medical Device	Recall for Product Correction	Class II	Hospital
5/06/2014	Fludeoxyglucose F18, sterile injectable solution, multidose vial	Medicine	Recall	Class II	Hospital
5/06/2014	Puritan Bennett 840 Ventilator	Medical Device	Recall for Product Correction	Class I	Hospital
4/06/2014	MENTOR Gel Sizers (Sizer for mammary prosthesis)	Medical Device	Recall	Class II	Hospital
3/06/2014	AGA Medical Amplatzer Septal Occluder	Medical Device	Recall	Class II	Hospital
3/06/2014	DCP 2.0, 7 holes, length 37 mm, Stainless Steel, Sterile (Non-biodegradable orthopaedic fixation plate)	Medical Device	Recall	Class III	Hospital
3/06/2014	HexaPOD evo RT Systems running iGUIDE 2.0.0 - 2.0.2 (used for accurate patient positioning within a radiation therapy treatment environment)	Medical Device	Recall for Product Correction	Class I	Hospital
3/06/2014	Horizon Medical Imaging products versions 4.5 up to and including 11.9 and McKesson Radiology 12.0 (Radiology picture archiving and communication system)	Medical Device	Recall for Product Correction	Class II	Hospital
3/06/2014	RAPIDPoint 500 Measurement Cartridges. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
3/06/2014	Tytin Regular Set (Dental amalgam)	Medical Device	Recall	Class II	Retail
3/06/2014	VTI Bayonet 20 MHz Doppler Probe (used for the intraoperative and transcutaneous critical evaluation of blood flow)	Medical Device	Recall	Class I	Hospital

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30/05/2014	5mm Round Fluted Bur Aggressive, Round Fluted Soft Touch 3.0mm, Round Fluted Bur 6.0mm, 3mm Round Fluted Bur Aggressive, Neuro Drill 3.0mm, 6mm Round Fluted Bur Aggressive, Round Fluted Bur 1.0mm and 5.0mm Egg Bur (Orthopaedic bur used for soft tissue debridement and bone abrasion and removal)	Medical Device	Recall	Class II	Hospital
30/05/2014	Accu-Chek Spirit Combo insulin pump	Medical Device	Recall	Class II	Consumer
30/05/2014	BBL Crystal Enteric/Nonfermenter ID Kit. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
30/05/2014	Orbital Rim Plate 1.3, curved, 9 holes, Pure Titanium (Craniofacial fixation plate)	Medical Device	Recall for Product Correction	Class III	Hospital
29/05/2014	ACUSON S2000 and ACUSON S3000 Ultrasound Systems (software version VC25) or with HELX Evolution (software version VC30A)	Medical Device	Recall for Product Correction	Class II	Hospital
29/05/2014	CARESCAPE Monitor B650	Medical Device	Recall for Product Correction	Class I	Hospital
29/05/2014	HAMILTON G5 / S1 ICU ventilators	Medical Device	Recall for Product Correction	Class I	Hospital
29/05/2014	Hamilton Galileo Ventilator when used with Flexport Communication Interface Protocol version 1.2	Medical Device	Recall for Product Correction	Class II	Hospital
28/05/2014	Accu-Chek Mobile Blood Glucose Meter	Medical Device	Recall for Product Correction	Class I	Consumer
28/05/2014	Hamilton Medical G5 / S1 Ventilator, software versions between V2.00 and V2.31	Medical Device	Recall for Product Correction	Class I	Hospital
27/05/2014	Disposable Ventstar 180cm Circuit (used in connection with the Drager Oxylog 2000 Transport Ventilator)	Medical Device	Recall	Class I	Hospital
26/05/2014	ThermoCool SF NAV Catheter Family	Medical Device	Recall for Product Correction	Class I	Hospital
23/05/2014	Axiom Neurostimulator Leads (MN20450-50AU, MN20450-90AU)	Medical Device	Recall for Product Correction	Class II	Hospital
23/05/2014	HYGROTON Chlorthalidone 25mg Tablets	Medicine	Recall	Class III	Wholesale
23/05/2014	SmartMonitor 2 Professional Series	Medical Device	Recall for Product Correction	Class II	Hospital

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23/05/2014	Tecnis CL Foldable Silicone IOL with OptiEdge Design	Medical Device	Recall	Class II	Hospital
22/05/2014	Baxter Peritoneal Dialysis Transfer Sets, Titanium Adapters, Disconnect Caps and Clamshell	Medical Device	Recall for Product Correction	Class I	Hospital
22/05/2014	Ingenia, Intera and Achieva MR Systems on software version R5.1.1 and R5.1.2	Medical Device	Recall for Product Correction	Class I	Hospital
22/05/2014	Polyurethane Nasogastric Feeding Tube	Medical Device	Recall	Class II	Hospital
22/05/2014	syngo Lab Data Manager. Middle-ware for use with in vitro diagnostic medical devices (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
22/05/2014	Synthes Trauma External Fixation System (Small, Medium, Distraction Osteogenesis (DO) Ring and Large)	Medical Device	Recall for Product Correction	Class II	Hospital
21/05/2014	Ultrasonic Transducer Kits used with the Access Family of Immunoassay Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
20/05/2014	MGuard Prime Coronary Stent System Embolic Protective Stent (EPS)	Medical Device	Recall	Class I	Hospital
20/05/2014	Mobile Shower and Toilet Commode Aquatec Ocean VIP	Medical Device	Recall for Product Correction	Class II	Consumer
20/05/2014	MobileDiagnost wDR (Mobile x-ray imaging system)	Medical Device	Recall for Product Correction	Class II	Hospital
20/05/2014	MOSAIQ Versions 1.40 through 2.50, inclusive (Oncology information system used to manage workflows for treatment planning and delivery)	Medical Device	Recall for Product Correction	Class I	Hospital
20/05/2014	Nifehexal (Nifedipine) 20mg Tablets 60 Blister	Medicine	Recall	Class III	Retail
20/05/2014	Tenor without scale (Mobile patient transfer lift)	Medical Device	Recall for Product Correction	Class I	Hospital
20/05/2014	Wireless Footswitch used in conjunction with AXIOM Artis, Artis Zee and Artis Q Systems	Medical Device	Recall for Product Correction	Class II	Hospital
16/05/2014	Ysio Systems (X-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
15/05/2014	Multiple Krill Oil Capsules Sponsored by Nature's Care	Medicine	Recall	Class III	Retail

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15/05/2014	Single-width Airway Module E-miniC and Extension Modules N-FC & N-FCREC (used with CARESCAPE Monitors B850, B650 and B450, S/5 modular monitors, Engstrom Carestation, Patient Monitor B30, S/5M and FML monitors)	Medical Device	Recall for Product Correction	Class I	Hospital
13/05/2014	ACUSON SC2000 Ultrasound Systems with Software Version 3.5 (VA35)	Medical Device	Recall for Product Correction	Class II	Hospital
13/05/2014	G7 Positioning Guide Rod & G7 Positioning Guide Post	Medical Device	Recall	Class II	Hospital
13/05/2014	Hill-Rom MC700 General Ward Bed	Medical Device	Recall for Product Correction	Class II	Retail
13/05/2014	MAGNETOM Aera (Full Body MRI System)	Medical Device	Recall for Product Correction	Class II	Hospital
13/05/2014	MiniCap Extended Life PD Transfer Set with Twist Clamp (Peritoneal dialysis tubing set)	Medical Device	Recall	Class I	Consumer
12/05/2014	Intuitive Surgical Inc. – 5mm Curved Cannula for Single-Site Instruments for da Vinci Surgical Systems	Medical Device	Recall for Product Correction	Class II	Hospital
12/05/2014	MIBG I-131 Therapy Injection (metaiodobenzylguanidine labelled as iodine- 131)	Medicine	Recall	Class I	Hospital
9/05/2014	ConMed MacroLyte Premie Dispersive Electrode	Medical Device	Recall	Class I	Hospital
9/05/2014	PentaRay Nav Catheter (used for multiple electrode electrophysiological mapping of cardiac structures in the heart)	Medical Device	Recall	Class I	Hospital
9/05/2014	Sidhil Inspiration Cot	Medical Device	Recall for Product Correction	Class I	Hospital
9/05/2014	Tension Band Pins (Internal fixation pins)	Medical Device	Recall	Class III	Hospital
8/05/2014	Flexi-Seal CONTROL Faecal Management System	Medical Device	Recall	Class I	Hospital
8/05/2014	Model 5348 Single-Chamber External Pulse Generator	Medical Device	Recall for Product Correction	Class I	Hospital
8/05/2014	Receptal System Liners and Canisters	Medical Device	Recall for Product Correction	Class I	Hospital
7/05/2014	GLUMA Desensitizer Power Gel (Polymer based dental bonding agent)	Medical Device	Recall	Class II	Retail
7/05/2014	PATH Thread Cup Adaptor	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
7/05/2014	Synapse Cardiovascular (CV) Client application, version 4.0.8 (Picture archiving and communication system)	Medical Device	Recall for Product Correction	Class II	Hospital
7/05/2014	VITROS ALT, ALKP, AST, CHE, CK, GGT and LDH results generated on VITROS 4600 Chemistry System, VITROS 5600 Integrated System and VITROS 5,1 FS Chemistry System	Medical Device	Recall for Product Correction	Class II	Hospital
6/05/2014	Lithium Ion Batteries, M4605A and M4607A for use with IntelliVue Patient Monitors	Medical Device	Recall for Product Correction	Class II	Hospital
5/05/2014	Alere INRatio2 PT/INR Heparin Insensitive Test Strips	Medical Device	Recall for Product Correction	Class I	Hospital
5/05/2014	FOLFusor SV 0.5mL/hr used for infusing patient specific compounded Fluorouracil (Fluorouracil compounded for treatment of cancer)	Medicine	Recall	Class II	Hospital
5/05/2014	HeartWare Ventricular Assist System batteries	Medical Device	Recall for Product Correction	Class I	Hospital
5/05/2014	Medtronic Navigation Sterile Devices (used in a variety of imaged guided, navigated surgical procedures)	Medical Device	Recall	Class II	Hospital
5/05/2014	Oxoid Antimicrobial Susceptibility Testing Penicillin (P1) Discs (an in vitro diagnostic medical device (IVD))	Medical Device	Recall	Class II	Hospital
29/04/2014	12 Instrument Sterilisation Tray (used for the Conquest Manual Instrument line)	Medical Device	Recall for Product Correction	Class II	Hospital
29/04/2014	ACUSON SC2000 Ultrasound Systems with software version 3.5 (VA35)	Medical Device	Recall for Product Correction	Class II	Hospital
29/04/2014	Compact Airway Modules E-CO, E-COV, E-COVX, E-CAiO, E-CAiOV & E-CAiOVX (used with CARESCAPE Monitors B850 and B650, Avance and Aisys Anesthesia Carestations, Engstrom Respiratory Carestation, or S/5 Anesthesia and Critical Care Monitors)	Medical Device	Recall for Product Correction	Class I	Hospital
29/04/2014	enGen Laboratory Automation Systems (enGen) with TCAutomation Software v2.6, v3.2 and v3.5 Configured with Bypass Modules for ADVIA Centaur, Abbott Architect, VITROS and/or Tosoh AIA Systems (an in vitro diagnostic medical device (IVD))	Medical Device	Recall for Product Correction	Class II	Hospital

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29/04/2014	RaySearch RayStation, version 4.0.3 (Radiation therapy treatment planning system)	Medical Device	Recall for Product Correction	Class I	Hospital
28/04/2014	Percutaneous Sheath Introducer Kits	Medical Device	Recall	Class I	Hospital
28/04/2014	Philips HeartStart XL+ Defibrillator/Monitor	Medical Device	Recall for Product Correction	Class I	Hospital
28/04/2014	SynFix-LR Surgical Implant Holder	Medical Device	Recall for Product Correction	Class II	Hospital
24/04/2014	Bond Ready-To-Use Primary Antibody Thyroglobulin (1D4) (An in vitro Diagnostic Medical Device (IVD))	Medical Device	Recall	Class I	Hospital
24/04/2014	Brilliance CT 16, 64, Big Bore iCT, Ingenuity CT, Ingenuity Core, Ingenuity Core128, Ingenuity Flex	Medical Device	Recall for Product Correction	Class I	Hospital
24/04/2014	Brilliance CT series (6, 10, 16, 16 Power, 40, 64, Big Bore, iCT, iCT SP), Ingenuity CT, Ingenuity Core, Ingenuity Core128, Ingenuity Flex, MX8000 Dual v. EXP	Medical Device	Recall for Product Correction	Class I	Hospital
24/04/2014	Corneo-scleral Disc (Normothermic)	Biological	Hazard Alert	Class II	Hospital
24/04/2014	Craniomaxillofacial (CMF) Distraction System (modular family of internal distraction devices to lengthen the mandibular body and ramus)	Medical Device	Hazard Alert	Class I	Hospital
24/04/2014	Discovery MR450w, Discovery MR750, Optima MR450w, Optima MR450w equipped with the GEM option, Discovery MR750w and Discovery MR750w equipped with the GEM option products (Full body magnetic resonance imaging (MRI) systems)	Medical Device	Recall for Product Correction	Class I	Hospital
24/04/2014	FUJIFILM FDR-1000AWS / FDR-2000AWS / FDR-3000AWS V5.1.0001-0007 with Biopsy unit (a component of FUJIFILM Digital Mammography System)	Medical Device	Recall for Product Correction	Class II	Hospital
23/04/2014	HexaPOD evo RT Couchtop (X-ray powered radiation therapy table)	Medical Device	Recall for Product Correction	Class I	Hospital
23/04/2014	Otto Bock A200 Power Wheelchair, SKIPPI and SKIPPI PLUS Power Wheelchairs	Medical Device	Recall for Product Correction	Class II	Consumer
23/04/2014	Xyntha (moroctocog alfa) 500IU Dual-Chamber Syringe	Medicine	Recall	Class II	Consumer

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17/04/2014	550 TxT Treatment Table used with PRIMUS, ONCOR and ARTISTE Digital Linear Accelerators (LINAC)	Medical Device	Recall for Product Correction	Class I	Hospital
17/04/2014	Accu-Chek Mobile Blood Glucose Monitoring System	Medical Device	Recall for Product Correction	Class II	Consumer
17/04/2014	ADVIA Centaur, ADVIA Centaur XP and ADVIA Centaur CP	Medical Device	Recall for Product Correction	Class II	Hospital
17/04/2014	AQURE Data Management System	Medical Device	Recall for Product Correction	Class II	Hospital
17/04/2014	Colied-Tube INFUSOR System	Medical Device	Recall for Product Correction	Class II	Hospital
17/04/2014	FOLFusor SV 0.5 ml/hr	Medical Device	Recall for Product Correction	Class II	Hospital
17/04/2014	IMPAX RIS 5.8 and higher (Picture archiving and communication system software)	Medical Device	Recall for Product Correction	Class II	Hospital
17/04/2014	Luminos dRF (Fluoroscopic diagnostic x-ray systems)	Medical Device	Recall for Product Correction	Class I	Hospital
17/04/2014	MDC PACS Release R2.x and IntelliSpace PACS DCX r3.x (picture archiving and communication system)	Medical Device	Recall for Product Correction	Class I	Hospital
17/04/2014	Mueller Hinton-HTM (culture media). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
17/04/2014	SOMATOM Emotion 6 / 16 Slice Configuration and SOMATOM Spirit/Spirit Power Systems (Full-body computed tomography (CT) diagnostic x-ray system)	Medical Device	Recall for Product Correction	Class I	Hospital
17/04/2014	syngo Dynamics v9.5 with Sensis-syngo Dynamics Integration (Radiology picture archiving and communication system)	Medical Device	Recall for Product Correction	Class II	Hospital
16/04/2014	Cochlear Baha Soft Tissue Gauge (included in the Cochlear Baha Attract surgical tool kit)	Medical Device	Recall	Class II	Hospital
16/04/2014	Panda iRes Warmers integrated with Nellcor SpO2	Medical Device	Recall for Product Correction	Class I	Hospital
15/04/2014	Centricity PACS RA1000 Workstation versions 3.2 and higher (Picture archiving and communication system)	Medical Device	Recall for Product Correction	Class II	Hospital
14/04/2014	ExacTrac 5.5.5 (Image guided radiation therapy patient positioning system)	Medical Device	Recall for Product Correction	Class I	Hospital

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14/04/2014	Infant Nasal CPAP Prongs and Bubble CPAP Starter Kits	Medical Device	Recall	Class I	Hospital
11/04/2014	DigitalDiagnost (Digital X-ray System)	Medical Device	Recall for Product Correction	Class II	Hospital
11/04/2014	Extension Tubing in Refill Kits for use with Synchronised pumps	Medical Device	Recall	Class II	Hospital
11/04/2014	MEDRAD Continuum Infusion Pump	Medical Device	Recall	Class I	Hospital
10/04/2014	Bayer CANESTEN clotrimazole thrush treatment 6 day cream 35g	Medicine	Recall	Class II	Consumer
10/04/2014	EverCross .035" OTW PTA Catheter (Balloon dilatation angioplasty catheter)	Medical Device	Recall	Class II	Hospital
10/04/2014	LenSx Laser System (used for femtosecond cataract surgery)	Medical Device	Recall for Product Correction	Class II	Hospital
9/04/2014	Edwards Lifesciences Fem-Flex II Cannulae	Medical Device	Recall	Class I	Hospital
9/04/2014	Lipase Reagent (diagnostic good for the quantitation of lipase in human serum or plasma)	Medical Device	Recall for Product Correction	Class II	Hospital
8/04/2014	ACUSON X700 Ultrasound System with software versions 1.0.00, 1.0.01, 1.0.02, 1.1.00 or 1.1.02	Medical Device	Recall for Product Correction	Class II	Hospital
8/04/2014	Cavafix (used for the catheterisation of vena cava)	Medical Device	Recall	Class I	Hospital
8/04/2014	Dynabeads HLA (Human Leucocyte Antigen) Class II (an in vitro diagnostic medical device)	Medical Device	Recall	Class II	Hospital
8/04/2014	Potassium 10mmol in 0.225% Sodium Chloride and 10% Glucose (500ml)	Medical Device	Recall	Class I	Hospital
7/04/2014	enGen Laboratory Automation Systems configured with Data Innovation, LLC Instrument Manager (IM) v8.06	Medical Device	Recall for Product Correction	Class II	Hospital
7/04/2014	ICS G2 Clinical Access (used for acquiring 24-72 hours of standard patient waveforms for analysis)	Medical Device	Recall	Class III	Hospital
7/04/2014	Monitor AC2000 Spring Arm	Medical Device	Recall	Class II	Hospital
7/04/2014	Philips Ingenuity Core128 with Software Version 3.5.5 (whole body Computed Tomograph (CT) x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital

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7/04/2014	VITROS Chemistry Products Specialty Diluent and VITROS Chemistry Products FS Diluent Pack 3	Medical Device	Recall for Product Correction	Class II	Hospital
4/04/2014	FELDENE (piroxicam) 10mg Capsules Blister packs of 50s	Medicine	Recall	Class III	Retail
4/04/2014	Kenex suspension arm with radiation shield and/or surgical lamp	Medical Device	Recall for Product Correction	Class I	Hospital
4/04/2014	Pipeline Embolization Device and Alligator Retrieval Device	Medical Device	Recall	Class I	Hospital
4/04/2014	Vivid E9 Ultrasound Systems, software versions 113.0.1 to 113.0.5 when used with probes C1-5-D, C2-9-D, IC-5-9-D and M5Sc-D	Medical Device	Recall for Product Correction	Class II	Hospital
3/04/2014	Discovery MR450, Discovery MR750, Optima MR450w, Optima MR 450w GEM, Discovery MR750w, and Discovery MR750w GEM products (Full body magnetic resonance imaging systems)	Medical Device	Recall for Product Correction	Class I	Hospital
3/04/2014	Fraxel Dual 1550/1927 Laser Systems	Medical Device	Recall for Product Correction	Class II	Retail
2/04/2014	OEC 9900 Workstation Monitor Spring Arm Screws	Medical Device	Recall for Product Correction	Class II	Hospital
2/04/2014	Technetium-99m Oxidronate HDP (Radioactive Dose prepared as a solution in a syringe for diagnostic imaging)	Medicine	Recall	Class II	Hospital
1/04/2014	ADAC Vertex Classic, Vertex Plus, Vertex V60 and Solus Systems	Medical Device	Recall for Product Correction	Class I	Hospital
1/04/2014	ARTIS Zeego (Fluoroscopic angiographic x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
1/04/2014	Mindray's V Series Monitoring System	Medical Device	Recall for Product Correction	Class II	Hospital
31/03/2014	Alere Triage BNP Test for Beckman Coulter (intended to measure B-type Natriuretic Peptide levels)	Medical Device	Recall for Product Correction	Class II	Hospital
31/03/2014	Colleague Volumetric Infusion Pumps	Medical Device	Recall for Product Correction	Class II	Hospital
28/03/2014	ADVIA Centaur Folate Assay	Medical Device	Recall	Class III	Hospital
28/03/2014	LOVher Herbal Viagra	Medicine	Recall	Class II	Consumer

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27/03/2014	Datascope System 98/98XT, CS100/CS100i and CS300 Intra-Aortic Balloon Pumps (IABP)	Medical Device	Recall for Product Correction	Class I	Hospital
27/03/2014	Guide Wire Ø 3.2 mm, length 400 mm (used for the implantation of intramedullary nails)	Medical Device	Recall for Product Correction	Class II	Hospital
26/03/2014	DePuy S-ROM Noiles Rotating Hinge Femur with Pin (compatible with the MBT revision tibial tray)	Medical Device	Recall for Product Correction	Class II	Hospital
26/03/2014	IntelliSpace Portal with AutoSPECT Pro reconstruction application (image viewing system for diagnostic imaging, x-ray and computed tomography)	Medical Device	Recall for Product Correction	Class I	Hospital
26/03/2014	On-Board Imager (OBI) (used with linear accelerators for verification of correct patient position in relation to isocenter and verification of treatment fields)	Medical Device	Recall for Product Correction	Class I	Hospital
25/03/2014	Philips EPIQ 5 Ultrasound System	Medical Device	Recall for Product Correction	Class II	Hospital
25/03/2014	Philips EPIQ 7 Ultrasound System	Medical Device	Recall for Product Correction	Class II	Hospital
25/03/2014	Shape Arm Kit Left and Shape Arm Kit Right (Mounting/positioning system for flat panel monitors)	Medical Device	Recall for Product Correction	Class I	Hospital
24/03/2014	Cup Removal Instruments (Reusable surgical instrument used to remove an acetabular cup with minimal loss of bone)	Medical Device	Recall for Product Correction	Class II	Wholesale
24/03/2014	Threaded Reduction Tool, 2.4mm diameter, self-drilling, 78mm length, with Hexagonal coupling	Medical Device	Recall	Class II	Hospital
20/03/2014	Expression Information Portal - IP5 (secondary display control unit for Expression MRI patient monitoring system)	Medical Device	Recall for Product Correction	Class II	Hospital
20/03/2014	H LED and PowerLED Ambient Light Modules (Surgical light)	Medical Device	Recall for Product Correction	Class II	Hospital
20/03/2014	Stainless Steel Scissor, Universal Shear, Blue Handle	Medical Device	Recall	Class III	Hospital
20/03/2014	Zoll X Series Defibrillators with system software version 02.10.02.00 or higher	Medical Device	Recall for Product Correction	Class I	Hospital

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18/03/2014	Dimension Vista Cyclosporine (CSA) Flex Reagent Cartridge and Dimension Vista Cyclosporine (CSAE) Flex Reagent Cartridge	Medical Device	Recall for Product Correction	Class I	Hospital
18/03/2014	Endo-Scrub2 Sheaths and Tubing Set	Medical Device	Recall for Product Correction	Class III	Hospital
18/03/2014	HOTLINE Fluid Warming Sets	Medical Device	Recall	Class II	Hospital
18/03/2014	Latex Test Lungs and Latex Rebreathing Bags	Medical Device	Recall for Product Correction	Class I	Hospital
17/03/2014	Natural-Knee II System with Metal-Backed Patella	Medical Device	Hazard Alert	Class II	Hospital
17/03/2014	Philips HeartStart Home and OnSite (HS1) Automated External Defibrillators	Medical Device	Recall	Class I	Hospital
17/03/2014	Symbia T and Symbia T2 Camera System (CT imaging system)	Medical Device	Recall for Product Correction	Class II	Hospital
17/03/2014	Teleflex Medical CAPIO Sutures	Medical Device	Recall	Class II	Hospital
17/03/2014	Unomedical Feeding Tubes	Medical Device	Recall for Product Correction	Class II	Hospital
14/03/2014	Sysmex CS-2100i and CS-5100 Automated blood coagulation analysers	Medical Device	Recall for Product Correction	Class I	Hospital
13/03/2014	CUSA Excel+ Sterile Torque Disposable Wrench (23kHz)	Medical Device	Recall for Product Correction	Class II	Hospital
13/03/2014	FB Reagent, ZYM B Reagent, API Listeria and API NH	Medical Device	Recall for Product Correction	Class II	Hospital
13/03/2014	HomeChoice PRO Automated Peritoneal Dialysis (PD) System	Medical Device	Recall for Product Correction	Class I	Consumer
12/03/2014	Brain and Spinal Cord Stimulators	Medical Device	Hazard Alert	Class I	Hospital
12/03/2014	INTELEVIEWER Versions 3.8.1 P355 and up (radiology picture archiving and communication system)	Medical Device	Recall for Product Correction	Class II	Hospital
12/03/2014	Liaison Biotrin Control Parvovirus B19 IgM	Medical Device	Recall for Product Correction	Class II	Hospital
12/03/2014	Spinal Cord Stimulation Neurostimulators, Spinal Cord Stimulation Leads, Kits and Patient Programmers	Medical Device	Hazard Alert	Class I	Hospital
12/03/2014	UltraClean Antarctic Krill 1500mg	Medicine	Recall	Class II	Retail

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11/03/2014	Pinnacle3 Radiation Treatment Planning System, software version 9.0	Medical Device	Recall for Product Correction	Class I	Hospital
7/03/2014	syngo Dynamics software version v9.5 using Sensis Integration (Radiology picture archiving and communication system)	Medical Device	Recall for Product Correction	Class I	Hospital
6/03/2014	Cereform Silicone Gel filled Breast Implants and Corresponding Sizers	Medical Device	Recall	Class II	Hospital
5/03/2014	Thymoglobuline (rabbit anti-human thymocyte immunoglobulin) 25mg powder for infusion	Medicine	Recall	Class II	Hospital
4/03/2014	D-10 Haemoglobin Testing System. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
4/03/2014	ExacTrac 6.0.3 Patient Positioning System (Image guided radiation treatment therapy patient positioning system)	Medical Device	Recall for Product Correction	Class I	Hospital
4/03/2014	Head Positioning Devices	Medical Device	Recall	Class II	Hospital
4/03/2014	Philips HeartStart FR3	Medical Device	Recall for Product Correction	Class I	Hospital
4/03/2014	STERRAD 100S Cassettes	Medical Device	Recall	Class III	Hospital
3/03/2014	INNOVA 2121IQ (Cardiovascular X-ray imaging system)	Medical Device	Recall for Product Correction	Class I	Hospital
3/03/2014	Philips HeartStart MRx Monitor/Defibrillator	Medical Device	Recall for Product Correction	Class I	Hospital
3/03/2014	Samaritan PAD 500P (Public Access Defibrillator)	Medical Device	Recall for Product Correction	Class I	Retail
3/03/2014	VerifyNow IIb/IIIa 25 Test and VerifyNow IIb/IIIa 10 Test (An in vitro Diagnostic Medical Device (IVD))	Medical Device	Recall	Class II	Hospital
3/03/2014	XiO Software build versions 4.1 and higher (Radiation therapy treatment planning system)	Medical Device	Recall for Product Correction	Class I	Hospital
27/02/2014	Alaris SmartSite Needlefree Connector	Medical Device	Recall	Class II	Hospital
27/02/2014	Philips HeartStart MRx Monitor/Defibrillator	Medical Device	Recall for Product Correction	Class I	Hospital
26/02/2014	Edi Catheter (nasogastric feeding tube)	Medical Device	Recall for Product Correction	Class II	Hospital

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26/02/2014	Indiko and Indiko Plus Chemistry Analysers	Medical Device	Recall for Product Correction	Class I	Hospital
26/02/2014	Tri-Flex II Bed	Medical Device	Recall for Product Correction	Class II	Hospital
25/02/2014	Philips HeartStart XL, Defibrillator/Monitor	Medical Device	Recall for Product Correction	Class I	Hospital
25/02/2014	Wireless Link for HeartStart MRx Monitor/Defibrillator	Medical Device	Recall for Product Correction	Class III	Hospital
24/02/2014	HINTEGRA Standard and Revision tibial and talar components (Total Ankle Prosthesis)	Medical Device	Recall for Product Correction	Class II	Hospital
24/02/2014	Lithium Ion batteries used with Philips HeartStart MRx Monitor/Defibrillator	Medical Device	Recall for Product Correction	Class I	Hospital
24/02/2014	Philips HeartStart MRx Monitor/Defibrillator with Q-CPR	Medical Device	Recall for Product Correction	Class I	Hospital
24/02/2014	Proceed Surgical Mesh	Medical Device	Recall	Class II	Hospital
24/02/2014	RayStation 3.5 and 4.0 (Radiation therapy treatment planning system)	Medical Device	Recall for Product Correction	Class I	Hospital
24/02/2014	SPAPLuS Analysers. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
21/02/2014	Aquarius Regional Citrate Anticoagulation (RCA) Haemofiltration Device	Medical Device	Recall for Product Correction	Class I	Hospital
21/02/2014	Philips HeartStart MRx Monitor/Defibrillator	Medical Device	Recall for Product Correction	Class I	Hospital
21/02/2014	Philips HeartStart MRx Monitor/Defibrillator	Medical Device	Recall for Product Correction	Class I	Hospital
20/02/2014	ADVIA Centaur XP Immunoassay System (an in vitro diagnostic medical device (IVD))	Medical Device	Recall for Product Correction	Class II	Hospital
20/02/2014	Ding Chuan Wan (Ginkgo Nut & Apricot Seed Formula), Xiao Qing Long Tang (Minor Blue Dragon Combination) & Fang Feng Tong Shen Wan (Siler & Platycodon Formula)	Medicine	Recall	Class III	Retail
20/02/2014	FreeStyle Papillon Mini Blood Glucose Monitoring System	Medical Device	Recall	Class I	Consumer
20/02/2014	OPMI Pentero surgical microscope system (PC 2.1)	Medical Device	Recall for Product Correction	Class II	Hospital

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19/02/2014	Neuromuscular Transmission Module used with CareScape and Datex-Ohmeda S/5 Anaesthesia monitors	Medical Device	Recall for Product Correction	Class II	Hospital
19/02/2014	VDR Proximal Targeting Guide in Acu-Loc 2 Loan sets	Medical Device	Recall for Product Correction	Class II	Hospital
18/02/2014	Oxylog Transport Ventilator	Medical Device	Recall for Product Correction	Class I	Hospital
18/02/2014	PS500 External Power Supply Unit used with Dräger V Series Ventilators	Medical Device	Recall for Product Correction	Class I	Hospital
17/02/2014	GemStar 7 Therapy Pump and GemStar Pain Management Pump (Phase 3 pumps)	Medical Device	Recall for Product Correction	Class II	Hospital
17/02/2014	Peristeen Anal Irrigation System	Medical Device	Recall for Product Correction	Class II	Consumer
14/02/2014	ACE Control. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
14/02/2014	ARCHITECT Intact Parathyroid (PTH) Assay. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
14/02/2014	Communication Engine in Plum A+ and A+3 Infusion Pump	Medical Device	Recall for Product Correction	Class III	Hospital
13/02/2014	Calibrator BRAHMS Free beta-hCG KRYPTOR CAL. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
13/02/2014	DePuy CMW 2 Gentamicin Bone Cement 20 g	Medical Device	Recall for Product Correction	Class III	Hospital
13/02/2014	Etest Ertapenem Foam and Single Blister Packs (antibiotic susceptibility test). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
12/02/2014	550 TxT Treatment Table used with PRIMUS, ONCOR and ARTISTE Digital Linear Accelerators	Medical Device	Recall for Product Correction	Class II	Hospital
12/02/2014	NICABATE nicotine 2mg/4mg lozenge blister pack and NICABATE MINIS MINT nicotine 1.5mg/4mg lozenge tube	Medicine	Recall	Class III	Wholesale
12/02/2014	RayStation software versions 2.5, 3.0, 3.5, and 4.0 (radiation therapy treatment planning system)	Medical Device	Recall for Product Correction	Class I	Hospital
11/02/2014	LUTONIX 014 and 035 OTW Drug Coated PTA Dilatation Catheter	Medical Device	Recall	Class I	Hospital

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11/02/2014	Neptune 2 Rover Ultra (Mobile unit used as surgical fluid/smoke waste management system)	Medical Device	Recall for Product Correction	Class I	Hospital
11/02/2014	The Binding Site SPAPLuS analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
10/02/2014	Aerius/Aerial and Aerius/Aerial Active Wheelchair Cushion	Medical Device	Recall	Class III	Consumer
10/02/2014	AMO Tecnis CL Foldable Silicone IOL (Intraocular lens) with OptiEdge Design (Intraocular lenses indicated for primary implantation for the visual correction of aphakia in adults)	Medical Device	Hazard Alert	Class II	Hospital
10/02/2014	Infinia, Infinia Hawkeye, Millenium VG, VG Hawkeye and VariCam Nuclear Medicine Systems, All configurations	Medical Device	Recall for Product Correction	Class I	Hospital
10/02/2014	Kodak 2100 & 2200 Intraoral X-ray System (dental x-ray)	Medical Device	Recall for Product Correction	Class II	Retail
10/02/2014	Ponstan Mefenamic Acid 250mg Capsule Bottle and Capsule Blister Pack	Medicine	Recall	Class III	Wholesale
7/02/2014	AXIOM Artis Systems (fluoroscopic angiographic x-ray system)	Medical Device	Recall for Product Correction	Class I	Hospital
7/02/2014	Multiple Patient Specific Oncology Medicine Compounded by Fresenius Kabi	Medicine	Recall	Class I	Hospital
7/02/2014	VersaCell connected to IMMULITE 2000/IMMULITE 2000 XPI analysers	Medical Device	Recall for Product Correction	Class I	Hospital
6/02/2014	Oxoid Legionella Latex Test and Oxoid Legionella Penumophila Serogroup 2-14 Test Reagent (an in vitro diagnostic medical device (IVD))	Medical Device	Recall	Class II	Hospital
5/02/2014	MRI-Stretcher non-magnetic	Medical Device	Recall for Product Correction	Class II	Hospital
5/02/2014	Powerheart G5s & G5A Automatic External Defibrillators (AEDs)	Medical Device	Recall for Product Correction	Class I	Retail
5/02/2014	Precision 500D and Proteus XR/a with Wireless Digital Radiography Option (WDR1) (fluoroscopic x-ray system)	Medical Device	Recall for Product Correction	Class I	Hospital
5/02/2014	Solar 8000M and Solar 8000i Patient Monitor software version 5.4, 5.5 or 5.6 (multi-function patient monitor)	Medical Device	Recall for Product Correction	Class II	Hospital

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5/02/2014	Spectra Optia Apheresis machine	Medical Device	Recall for Product Correction	Class I	Hospital
5/02/2014	T-Adaptation Plate 1.3, head 3 holes, shaft 8 holes, Stainless Steel, and T-Adaptation Plate 1.3, head 4 holes, shaft 8 holes, Stainless Steel (orthopaedic fixation plates)	Medical Device	Recall	Class III	Hospital
5/02/2014	Zimmer Segmental System Polyethylene Insert-Size B & Size C (Intended to replace the proximal femur, mid-shaft femur, distal femur, proximal tibia and/or total knee in cases that require extensive resection and restoration)	Medical Device	Recall for Product Correction	Class II	Hospital
4/02/2014	Philips HeartStart XL+ Defibrillator/Monitor	Medical Device	Recall for Product Correction	Class III	Hospital
3/02/2014	Samaritan PDU 400 (automated external defibrillator)	Medical Device	Recall	Class II	Retail
31/01/2014	balanSys Knee System (CR, UC, PS and RP)	Medical Device	Recall for Product Correction	Class II	Hospital
31/01/2014	IMUKIN interferon gamma-1b recombinant human 2 million IU (100 micrograms)/0.5mL injection vial	Medicine	Recall	Class II	Retail
29/01/2014	LCP Condylar Plate 2.4 Shaft, 7 Hole Head, 2 Hole (fixation plate used to treat orthopaedic fractures)	Medical Device	Recall	Class III	Hospital
29/01/2014	LCP Plate 2.4, straight, 8 holes, length 68 mm, Stainless Steel (fixation plate used to treat orthopaedic fractures)	Medical Device	Recall	Class III	Hospital
29/01/2014	Tytin – Regular Set, Double Spill 50 and 500 capsules (self activating capsules of dental alloy used as a dental restorative)	Medical Device	Recall	Class III	Retail
28/01/2014	Horizon Medical Imaging (HMI) products software versions 4.5 to and including 11.9 (Radiology picture archiving and communication system)	Medical Device	Recall for Product Correction	Class I	Hospital
28/01/2014	Zoo Master Pack 3D 1/4" M/H Fox (elastomeric component for orthodontic applications)	Medical Device	Recall	Class III	Retail
24/01/2014	Holding Forceps for SynReam Reaming Rod 2.5 mm (used during surgery to retain an instrument, reduce a fracture, spread an osteotomy, or hold an implant in place)	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
24/01/2014	Puritan Bennett 840 Ventilator and 700 Series (740 and 760) Ventilators	Medical Device	Recall for Product Correction	Class II	Hospital
23/01/2014	Activa PC, Activa RC and Activa SC Implantable Deep Brain Stimulators and RestoreUltra and RestoreSensor Implantable Spinal Cord Stimulators	Medical Device	Hazard Alert	Class I	Hospital
23/01/2014	ACUSON SC2000 Ultrasound Systems	Medical Device	Recall for Product Correction	Class II	Hospital
23/01/2014	St. Jude Medical ICD/CRT-D devices programmed to a single VF detection zone with Merlin Programmer software version 17.2.2 rev. 0	Medical Device	Hazard Alert	Class I	Hospital
23/01/2014	SynchroMed II Implantable Infusion Pump	Medical Device	Hazard Alert	Class I	Hospital
23/01/2014	Vented Spike with Clearlink (fluid transfer set)	Medical Device	Recall	Class I	Hospital
22/01/2014	Anspach Short Carbide Cranial Cutting Burrs - 1.5 mm x 7.5 mm Cylindrical Carbide Drum used with Short Attachments	Medical Device	Recall	Class II	Hospital
22/01/2014	Mosaic Porcine Aortic Bioprosthesis Model 305 and Medtronic Aortic Obturators/Sizers and iOEA Charts	Medical Device	Hazard Alert	Class I	Hospital
22/01/2014	Multiple Manual Pulmonary Resuscitators (Single Use)	Medical Device	Recall	Class II	Hospital
21/01/2014	Xia 3 Titanium Torque Wrench, Mantis Redux Torque Wrench & Xia Torque Wrench (used for final tightening of the blocker on the head of the pedicle screw during posterior spinal fusion surgery)	Medical Device	Recall	Class II	Hospital
20/01/2014	BrightView SPECT, BrightView X and BrightView XCT (SPECT/CT diagnostic imaging system)	Medical Device	Recall for Product Correction	Class II	Hospital
20/01/2014	Osteocalcin assay run on IMMULITE 2000 & IMMULITE 2000 XPI analysers. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
20/01/2014	Sorin Perceval S Post-Dilation Catheter Size M (indicated for in situ post-dilation of the valve after implantation)	Medical Device	Recall for Product Correction	Class I	Hospital
17/01/2014	Elecsys HIV combi PT assay. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
17/01/2014	Kodak DirectView DR 7500 System with software version 5.3 (diagnostic x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital

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16/01/2014	Ceiling mounted rail systems for Liko Overhead Lifts	Medical Device	Recall for Product Correction	Class I	Consumer
16/01/2014	Novocastra Liquid Mouse Monoclonal Antibody. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class I	Hospital
16/01/2014	Oxoid Antimicrobial Susceptibility Discs with Vancomycin (VA30). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
15/01/2014	Magnetom Spectra 3.0 T System (MRI system)	Medical Device	Recall for Product Correction	Class I	Hospital
15/01/2014	Thermo Scientific MAS Omni-IMMUNE PRO. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
13/01/2014	Desktop Pro R7.01 SP2 and Desktop Pro R4.2, R5.0, R5.1, R6.0, R6.1 (Linear accelerator system)	Medical Device	Recall for Product Correction	Class I	Hospital
13/01/2014	Matrix Surgical Laparoscopic Spatula with Cable (Active endotherapy device)	Medical Device	Recall	Class II	Hospital
10/01/2014	Zymed Holter Converter (Cardiology information system designed for the collection and management of electrocardiography data)	Medical Device	Recall for Product Correction	Class II	Hospital
9/01/2014	Innova 3100, Innova 3100IQ and Innova 2100IQ Cardiovascular X-ray Imaging Systems	Medical Device	Recall for Product Correction	Class I	Hospital
9/01/2014	PET Discovery 600 and PET Discovery 690, with software versions pet_mict_plus.44 and pet_velocity.53 (Nuclear medicine diagnostic system)	Medical Device	Recall for Product Correction	Class I	Hospital
9/01/2014	Precision RXI X-ray Imaging Systems equipped with LCD Video Monitor	Medical Device	Recall for Product Correction	Class II	Hospital
8/01/2014	Integrity R1.1, R3.0 and R3.1(digital linear accelerator)	Medical Device	Recall for Product Correction	Class I	Hospital
8/01/2014	Oxford Advance only manufactured prior to July, 2010 (Prior to serial number 1007L0001)	Medical Device	Recall for Product Correction	Class II	Hospital
7/01/2014	CILAMOX Sugar Free (Amoxycillin) 250mg/5mL Syrup	Medicine	Recall	Class II	Retail
3/01/2014	ACUSON SC2000 Ultrasound Systems	Medical Device	Recall for Product Correction	Class II	Hospital
3/01/2014	Journey BCS Knee Replacement System - Femoral Implant	Medical Device	Hazard Alert	Class II	Hospital

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3/01/2014	Total IgE for use with Immulite, Immulite 1000, Immulite 2000, Immulite 2000 XPi analysers. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
2/01/2014	Androstenedione assay run on Immulite, Immulite 1000, Immulite 2000, Immulite 2000XPi analysers. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
24/12/2013	Citrate Activated Partial Thromboplastin Time (APTT) Cuvettes. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class I	Hospital
24/12/2013	cobas 4800 PCR Media Kit, cobas 4800 PCR Urine Sample Kit and cobas PCR Female Swab Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
23/12/2013	STERRAD 100S, STERRAD 50 and STERRAD NX Sterilisation Systems	Medical Device	Recall for Product Correction	Class II	Hospital
23/12/2013	Trident Tritanium Acetabular Window Trials Case	Medical Device	Recall	Class II	Hospital
20/12/2013	Artis systems running software version VC21B in conjunction with a Large Display	Medical Device	Recall for Product Correction	Class II	Hospital
20/12/2013	RAPIDLyte Arterial Blood Sampling Line Draw Syringes	Medical Device	Recall for Product Correction	Class II	Hospital
19/12/2013	EVOTECH Endoscope Cleaner and Reprocessor (ECR)	Medical Device	Recall for Product Correction	Class II	Hospital
19/12/2013	Laparoscopic inserts with tube, 3.00mm	Medical Device	Recall	Class II	Hospital
19/12/2013	Pregnancy Iron (30's)	Medicine	Recall	Class II	Retail
19/12/2013	VITEK 2 System	Medical Device	Recall for Product Correction	Class III	Hospital
18/12/2013	Brilliance iCT with Software Version 4.1.0.19260	Medical Device	Recall for Product Correction	Class II	Hospital
18/12/2013	Giraffe Stand Alone Resuscitation Systems with Blender, Giraffe Warmer Integrated Resuscitation systems with Blender, Panda Warmer Integrated Resuscitation systems with Blender, Panda Freestanding Warmer Integrated Resuscitation Systems with Blender, Resuscitation System field upgrade kits with Blender	Medical Device	Recall for Product Correction	Class I	Hospital

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18/12/2013	HeartWare Ventricular Assist System (intended for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end stage heart failure)	Medical Device	Recall for Product Correction	Class I	Hospital
18/12/2013	SuperElastic NiTi Archwires (intended to provide force to the teeth to effect movement in order to alter their position)	Medical Device	Recall	Class II	Retail
17/12/2013	CompoStop Flex 3F T&B - 100/600/1300 - PLT Pooling - processing and leuko reduction system (Blood donor set)	Medical Device	Recall	Class II	Hospital
17/12/2013	Essenta DR X-ray System (Digital diagnostic X-Ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
16/12/2013	GEMINI TF 64 PET/CT Systems, software versions 3.5.1 and 3.5.2.1	Medical Device	Recall for Product Correction	Class II	Hospital
16/12/2013	Nova StatStrip and StatSensor Blood Monitoring Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
16/12/2013	Philips Expression Information Portal (IP5) (secondary display control unit for the Expression MRI Patient Monitoring System)	Medical Device	Recall for Product Correction	Class I	Hospital
13/12/2013	Acuity Central Monitoring Systems	Medical Device	Recall for Product Correction	Class II	Hospital
13/12/2013	AQURE Data Management System, Version 1.54. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
13/12/2013	BD BACTED FX - Top Unit and Bottom Unit (used to detect bacteria and fungi in clinical specimens)	Medical Device	Recall for Product Correction	Class II	Hospital
13/12/2013	KAMRA Corneal Inlay (inserted into the natural cornea to treat presbyopia ie, age related hyperopia (far sightedness))	Medical Device	Recall for Product Correction	Class II	Hospital
13/12/2013	Optima XR 220amx, Optima XR200amx with Digital Upgrade Mobile X-ray Systems	Medical Device	Recall for Product Correction	Class I	Hospital
12/12/2013	APPESE 0.5 ropinirole (as hydrochloride) 0.5mg tablets	Medicine	Recall	Class II	Wholesale
11/12/2013	MEDRAD Veris MR Vital Signs Monitor	Medical Device	Recall for Product Correction	Class I	Hospital
11/12/2013	SOMATOM CT System	Medical Device	Recall for Product Correction	Class I	Hospital

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10/12/2013	CEM Nosecone for use with CUSA Excel/Excel+ Ultrasonic Aspirator	Medical Device	Recall for Product Correction	Class II	Hospital
10/12/2013	Eclipse Treatment Planning System, ARIA Radiation Oncology (treatment plan and image management application) and Acuity Radiation Therapy Simulator	Medical Device	Recall for Product Correction	Class I	Hospital
10/12/2013	PLUM LifeCare 5000 Series and PLUM XL Family of Infusers	Medical Device	Recall for Product Correction	Class I	Hospital
9/12/2013	DRX Revolution Mobile X-Ray System	Medical Device	Recall for Product Correction	Class II	Hospital
9/12/2013	Inflation bulbs used with Safescope Sigmoidoscopes	Medical Device	Recall for Product Correction	Class III	Hospital
9/12/2013	Large and Mega Needle Driver Endowrist Instruments for da Vinci Surgical Systems	Medical Device	Recall	Class II	Hospital
9/12/2013	Precision 500D, Legacy, Prestilix, Monitrol, RFX, SFX, Tilt-C, Prestige VH, Prestige SI, and Prestige SII (diagnostic fluoroscopic x-ray systems)	Medical Device	Recall for Product Correction	Class I	Hospital
6/12/2013	D-10 Dual Program Reorder Pack (used with D-10 Haemoglobin Testing System). An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
6/12/2013	Viscocol and Viscocol Plus (Hydromethylpropcellulose) 2% Prefilled Syringes 1.5mL and 2.0mL	Medical Device	Recall	Class I	Hospital
5/12/2013	Dimension Vista Systems - Cyclosporine (CSA) Flex reagent cartridge. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class I	Hospital
5/12/2013	Sorin Perfusion System - S5/C5 Heart Lung Machine	Medical Device	Recall for Product Correction	Class I	Hospital
4/12/2013	Carestream DRX Evolution with Full Featured Wall Stand, Carestream DRX Evolution with Carestream Premium Wall Stand and Kodak DirectView DR 7500 System with Full Featured Wall Stand	Medical Device	Recall for Product Correction	Class II	Hospital

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4/12/2013	Giraffe Stand Alone Resuscitation Systems with Blender, Giraffe Warmer Integrated Resuscitation systems with Blender, Panda Warmer Integrated Resuscitation systems with Blender, Panda Freestanding Warmer Integrated Resuscitation systems with Blender and Resuscitation System field upgrade kits with Blender (infant radiant warmers)	Medical Device	Recall for Product Correction	Class I	Hospital
3/12/2013	Integrity, software version R1.1, 3.0, and R3.1 (Linear Accelerator)	Medical Device	Recall for Product Correction	Class I	Hospital
3/12/2013	SANGOFIX IV Administration Set and HEIDELBERG EXTENSION TUBING	Medical Device	Recall for Product Correction	Class I	Hospital
3/12/2013	Volume Imaging System (XVI), software versions 4.2.1 (Electronic Imaging Device (EID) used with radiation therapy treatment)	Medical Device	Recall for Product Correction	Class I	Hospital
2/12/2013	Gemstar Docking Station (Used as an alternate power source for the GemStar infusion pumps and to charge a GemStar battery pack)	Medical Device	Recall for Product Correction	Class I	Hospital
2/12/2013	LH 750 and LH 780 Haematology System. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
2/12/2013	Slimming Factor (also known as Easy Trim, Que She and Chinese Herbal Diet Pills)	Medicine	Recall	Class I	Consumer
2/12/2013	VITROS Mixing Cup Arrays on VITROS 250 Chemistry Systems & VITROS 350 Chemistry Systems. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
2/12/2013	X-ray Volume Imaging System (XVI), software versions R4.5, R4.5.1, R4.6 and R5.0 (Electronic Imaging Device (EID) used with radiation therapy treatment)	Medical Device	Recall for Product Correction	Class I	Hospital
29/11/2013	Children's Panadol 1-5 years Suspension (paracetamol 24mg/mL) Orange 100 ml and Strawberry 200 ml	Medicine	Recall	Class II	Retail
29/11/2013	Instrument Star Unit ML (Calibration with ICM4) (part of Brainlab Spine & Trauma Navigation System)	Medical Device	Recall	Class II	Hospital
29/11/2013	Leica M525 F50 Surgical Microscope with XY-Unit (surgical light microscope)	Medical Device	Recall for Product Correction	Class II	Hospital

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29/11/2013	Plum A+ Infusion Pump and Software Module	Medical Device	Recall for Product Correction	Class III	Hospital
29/11/2013	UniCel DxH 600 & 800 Coulter Cellular Analysis System. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
29/11/2013	XiO versions 4.50 and higher (Radiation therapy treatment planning system)	Medical Device	Recall for Product Correction	Class I	Hospital
28/11/2013	BrainLab Navigation Software Spine and Trauma 3D 2.0 (intra-operative image guided stereotactic localisation system to enable precision spine and trauma surgeries)	Medical Device	Recall for Product Correction	Class I	Hospital
28/11/2013	Calibration Diskette and Assay Data Disks used with VITROS chemistry instruments. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
28/11/2013	Monitor AC3000 Spring Arm (component of Draeger ceiling pendant and light systems)	Medical Device	Recall for Product Correction	Class I	Hospital
27/11/2013	HT Connect Peripheral Guide Wires (used for percutaneous transluminal Angioplasty (PTA) in peripheral arteries)	Medical Device	Recall	Class I	Hospital
27/11/2013	Patient Data Module (PDM) used with B850, B650, B450, Solar 8000i, MacLab / ComboLab (Multifunction patient monitoring)	Medical Device	Recall for Product Correction	Class I	Hospital
27/11/2013	Patient Side Manipulators - da Vinci S, Si, Si-e Surgical System (robotic surgical unit)	Medical Device	Recall for Product Correction	Class II	Hospital
27/11/2013	PET Discovery 610 and Discovery 710 with software version pet_coreload.44 and pet_mfk.44	Medical Device	Recall for Product Correction	Class I	Hospital
26/11/2013	CoreValve AccuTrak Delivery Catheter System (DCS) (Intended to deliver CoreValve Transcatheter Aortic Valve, which is designed to treat severe aortic valve stenosis without open-heart surgery or surgical removal of the native valve)	Medical Device	Recall for Product Correction	Class I	Hospital
26/11/2013	Patient Data Module (PDM) used with B850, B650, B450, Solar 8000i and MacLab / ComboLab (multifunction patient monitor module)	Medical Device	Recall for Product Correction	Class I	Hospital
26/11/2013	Sysmex Automated Blood Coagulation Analyzer CS-2100i and 2000i. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital

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26/11/2013	THUNDERBEAT TB Series Hand Instrument (used in general, laparoscopic and endoscopic surgeries)	Medical Device	Recall for Product Correction	Class II	Hospital
26/11/2013	Zimmer Periarticular Femoral Cond Buttress Plate and Zimmer Periarticular Distal Lateral Femoral Locking Plate	Medical Device	Recall	Class II	Hospital
25/11/2013	Micro Well Shuttle Weight used in VITROS 3600 Immunodiagnostic Systems and VITROS 5600 Integrated Systems	Medical Device	Recall for Product Correction	Class II	Hospital
25/11/2013	Zimmer Trabecular Metal Reverse Shoulder System Glenosphere & Base Plate (Total shoulder replacement prosthesis)	Medical Device	Recall for Product Correction	Class II	Hospital
22/11/2013	Children's Panadol (paracetamol 100mg/mL) Baby Drops Syringe	Medicine	Recall for Product Correction	Class II	Retail
22/11/2013	Modular Finishing Instrument Tray Assembly (used to store, transport and organise instrumentation for the Restoration Modular Instruments Set)	Medical Device	Recall	Class II	Hospital
22/11/2013	Oncaspar (Pegaspargase) 3750IU/5mL Injection Solution (Pack of 1 injection)	Medicine	Recall for Product Correction	Class II	Hospital
22/11/2013	REPLY and ESPRIT Pacemakers interrogated using Orchestra and Orchestra Plus Programmers	Medical Device	Hazard Alert	Class I	Hospital
22/11/2013	STERRAD 100NX (Gas Plasma Steriliser)	Medical Device	Recall for Product Correction	Class III	Hospital
22/11/2013	TWISTER PLUS Rotatable Retrieval Device 22mm and 26mm (used in flexible endoscopes as a retrieval device for foreign bodies, such as polyps and food boluses)	Medical Device	Recall	Class II	Hospital
21/11/2013	A-642100 fixed offset adaptor (used in external prosthesis)	Medical Device	Recall for Product Correction	Class II	Hospital
21/11/2013	LIKO SlingBar 350, SlingBar 360, SlingBar Wide 670 and SideBar Standard	Medical Device	Recall	Class II	Consumer
21/11/2013	Medfusion 4000 Syringe Infusion Pump	Medical Device	Recall for Product Correction	Class II	Hospital
21/11/2013	VITROS 3600, 4600, 5600, 5,1 FS Chemistry Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital

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21/11/2013	VITROS Chemistry Products K+ Slides. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class I	Hospital
20/11/2013	Ceiling system for Artis Zee System (Fluoroscopic angiographic digital x-ray system)	Medical Device	Recall for Product Correction	Class I	Hospital
20/11/2013	FreeStyle Lite Blood Glucose Test Strips (used with FreeStyle Papillon Mini Blood Glucose Meters). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Consumer
19/11/2013	Gemstar Infusion System	Medical Device	Recall for Product Correction	Class I	Hospital
15/11/2013	Atrium Chest drains that contain an Autotransfusion (ATS) System access line (for re-infusion of autologous blood in postoperative and trauma blood loss management)	Medical Device	Recall	Class I	Hospital
15/11/2013	Human IgM Kit for use on SPA Plus. An in vitro Diagnostic Medical Device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
15/11/2013	ONCASPAR (pegaspargase) injection, 750 IU/mL, 5mL vial	Medicine	Recall for Product Correction	Class II	Hospital
15/11/2013	STERRAD Boosters and Adaptors (used in STERRAD NX steriliser and contains hydrogen peroxide sterilant)	Medical Device	Recall for Product Correction	Class I	Hospital
14/11/2013	Star Drive Frame Adapters and Positioners (intended to be used with stereotactic systems for neurosurgical procedures for accurate positioning of microelectrodes, stimulating electrodes or other instruments in the brain or nervous system)	Medical Device	Recall for Product Correction	Class II	Hospital
14/11/2013	Vessix Generator System (portable RF generator used with percutaneous angioplasty balloon catheter to deliver low frequency RF energy into the renal artery)	Medical Device	Recall	Class I	Hospital
14/11/2013	ZYM B, API Listeria and API NH (bacterial identification reagents and kits). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
13/11/2013	BFT II Analyser	Medical Device	Recall for Product Correction	Class II	Hospital
12/11/2013	Infinity Acute Care System (IACS) Monitoring Solution (Patient monitoring system)	Medical Device	Recall for Product Correction	Class I	Hospital

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12/11/2013	IS3000 HD Lamp Modules with metal finish (endoscopic illumination system used with the da Vinci Si Vision Cart System which is a robotic surgical system)	Medical Device	Recall for Product Correction	Class II	Hospital
11/11/2013	ADVIA Chemistry Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
11/11/2013	Stryker NV Excelsior (used to assist in the delivery of diagnostic agents) SL-10 90deg 2-Tip, NV Neuroform 3EZ-3.0x15mm and 3EZ-3.5x15mm Microcatheters (used with occlusive devices in the treatment of intracranial aneurysms)	Medical Device	Recall	Class II	Hospital
8/11/2013	ADAC ARGUS Gamma Camera Systems (Nuclear medicine system)	Medical Device	Recall for Product Correction	Class I	Hospital
8/11/2013	Ansell Sandel Weighted Safety Scalpel	Medical Device	Recall	Class II	Hospital
8/11/2013	Boston Scientific 13F/15F Navigator HD Ureteral Access Sheath Set (used to facilitate the passage of endoscopes, urological instruments and for the injection of fluids into the urinary tract)	Medical Device	Recall	Class I	Hospital
8/11/2013	Epidural Minipack Systems (Epidural anaesthesia kit)	Medical Device	Recall for Product Correction	Class II	Hospital
8/11/2013	Fresofol 1% MCT/LCT (propofol) 500mg/50mL Emulsion for Intravenous Injection/Infusion Pre-Filled Syringe	Medicine	Recall	Class II	Hospital
8/11/2013	Imigran Mk II sumatriptan 6mg/0.5mL (as succinate) Injection Syringe	Medicine	Recall	Class II	Consumer
8/11/2013	IN.PACT Amphirion Drug-Eluting Balloon (DEB) (used for percutaneous transluminal angioplasty of small peripheral arteries)	Medical Device	Recall	Class I	Hospital
8/11/2013	ONCASPAR (pegaspargase) injection, 750 IU/mL, 5mL vial	Medicine	Recall	Class II	Hospital
8/11/2013	Teflon Tube T2 Humerus, Sterile (Intended to support the exchange of the Ball Tip Guide Wires for Smooth Tip Guide Wires for nail insertion)	Medical Device	Recall	Class II	Hospital
8/11/2013	Welch Allyn Propaq LT / Propaq 802 with Nellcor SpO2 (multifunction patient monitor)	Medical Device	Recall for Product Correction	Class II	Hospital

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6/11/2013	ABL90 FLEX Analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
6/11/2013	Clinac, Trilogy, Trilogy Tx, Novalis Tx and Unique accelerators, software versions 7.x, 8.x and 9.0. (Linear accelerator system)	Medical Device	Recall for Product Correction	Class I	Hospital
6/11/2013	PDM module with Frame F5-01 used with CARESCAPE Monitor B850	Medical Device	Recall for Product Correction	Class II	Hospital
4/11/2013	ClinActiv and ClinActiv Plus Therapy Surface (used to provide pressure relief to aid in the prevention and treatment of pressure ulcers)	Medical Device	Recall for Product Correction	Class II	Hospital
1/11/2013	AxSYM Valproic Acid Reagent (An in vitro diagnostic medical device IVD)	Medical Device	Recall	Class II	Hospital
1/11/2013	Homechoice Pro APD System (peritoneal dialyser)	Medical Device	Recall	Class II	Consumer
1/11/2013	i-STAT PT/INR Cartridge (prothrombin time test used for monitoring patients receiving oral anticoagulation therapy) (An in vitro diagnostic medical device (IVD))	Medical Device	Recall	Class I	Hospital
1/11/2013	Weinmann Medumat Transport Ventilator	Medical Device	Recall for Product Correction	Class I	Hospital
31/10/2013	CARESCAPE Monitor B850 (with software versions 1.0.12 and earlier) and CARESCAPE Monitor B650 (with software version 1.1.12 and earlier)	Medical Device	Recall for Product Correction	Class I	Hospital
31/10/2013	MIBGen - Iobenguane [I-123] Injection 2mL and 4mL	Medicine	Recall for Product Correction	Class II	Hospital
30/10/2013	E.cam and Symbia E systems (diagnostic nuclear medicine imaging system)	Medical Device	Recall for Product Correction	Class II	Hospital
30/10/2013	KABIVEN G 19% 1540mL injection bag	Medicine	Recall	Class II	Hospital
30/10/2013	TRUEtrack and TRUEbalance Blood Glucose Monitoring Systems	Medical Device	Recall for Product Correction	Class I	Consumer
29/10/2013	MDC PACS R2.3 SP2 HF6 and MDC PACS R2.3 SP2 HF7 (Picture, archiving and communication system)	Medical Device	Recall for Product Correction	Class II	Hospital
28/10/2013	Vygon Nutrisafe Syringe Feeding Pumps	Medical Device	Recall for Product Correction	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
25/10/2013	Luminos dRF and Urooskop Omnia systems with Software Version VD10	Medical Device	Recall for Product Correction	Class II	Hospital
25/10/2013	OCTREOTIDE SUN octreotide (as acetate) solution for injection ampoule	Medicine	Recall for Product Correction	Class II	Hospital
25/10/2013	Panbio Barmah Forest Virus IgM ELISA (An in vitro diagnostic medical device (IVD))	Medical Device	Recall	Class II	Hospital
25/10/2013	RayStation 3.0, 3.5, or 4.0 (Radiation therapy treatment planning system)	Medical Device	Recall for Product Correction	Class I	Hospital
25/10/2013	Reliance Endoscope Processing System (EPS) used with FUJINON G5 and G8 Type Flexible GI Endoscopes	Medical Device	Recall for Product Correction	Class II	Hospital
25/10/2013	Star Excimer Laser System (used to surgically correct visual refractive error in corneal surgery)	Medical Device	Recall for Product Correction	Class II	Hospital
25/10/2013	SynReam Medullary Reamer Head Ø 8.5 mm (part of the Adolescent Lateral Femoral Nail and SynReam Reaming System Instrument Trays)	Medical Device	Recall	Class II	Hospital
25/10/2013	VITROS Chemistry Products Na+ Slides and Calibrator Kit 2 (used on VITROS 250/350/5, 1 FS, 4600 Chemistry Systems, VITROS 5600 Integrated System). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class I	Hospital
24/10/2013	Basin Liner within Molnlycke ProcedurePak (surgical procedure packs)	Medical Device	Recall for Product Correction	Class II	Hospital
24/10/2013	CEDIA Tobramycin II Assay(used for quantitative determination of tobramycin in human serum or plasma) (an in vitro diagnostic medical device (IVD))	Medical Device	Recall for Product Correction	Class II	Hospital
24/10/2013	Inzii 12/15mm Retrieval System (used as a receptacle for the collection and extraction of tissues, organs and calculi during laparoscopic procedures)	Medical Device	Recall for Product Correction	Class II	Hospital
24/10/2013	Novacell Battery Charger supplied with the BLS-1000 Light Source set (light source for endoscopic procedures)	Medical Device	Recall for Product Correction	Class II	Hospital
24/10/2013	Trinica Ratchet Handles (included in the Anterior Lumbar Plate (ALP) Instrument Tray)	Medical Device	Recall for Product Correction	Class II	Hospital
24/10/2013	Vivid E9 with Software versions 112.1.0, 112.1.1, and 112.1.3	Medical Device	Recall for Product Correction	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
23/10/2013	Aequalis Reversed II and Reversed Fracture Impactors (supplied as part of Aequalis Reversed II and Reversed Fracture Instrument sets, YKAD83 & YKAD95)	Medical Device	Recall	Class II	Hospital
23/10/2013	Brivo CT315/325, Brivo CT385, Optima CT520 and Optima CT540 (all configurations)	Medical Device	Recall for Product Correction	Class II	Hospital
22/10/2013	ATTAIN HYBRID Guide Wires (used to aid the placement of Medtronic transvenous left ventricular leads in the coronary vasculature)	Medical Device	Recall	Class I	Hospital
22/10/2013	EPIQ 7 Diagnostic Ultrasound System (software version 1.0, 1.0.1)	Medical Device	Recall for Product Correction	Class II	Hospital
22/10/2013	OPTEASE Retrievable Vena Cava Filter	Medical Device	Recall	Class I	Hospital
22/10/2013	Transradial Artery Access Kits	Medical Device	Recall	Class II	Hospital
21/10/2013	Getinge 46-Series Washer Disinfector with PACS 300 module	Medical Device	Recall for Product Correction	Class II	Retail
21/10/2013	Straight Adjustable Gastric Band	Medical Device	Recall	Class II	Hospital
17/10/2013	GSI Viewer, prior to version 2.00-0M on AW and prior to version 2.20-0B in AW Server (Picture archiving and communication system, PACS)	Medical Device	Recall for Product Correction	Class I	Hospital
17/10/2013	IntelliSpace PACS 4.4 (Picture archiving and communication system)	Medical Device	Recall for Product Correction	Class I	Hospital
17/10/2013	IOLMaster (used for the treatment of axial length, corneal curvature, anterior chamber depth and for the determination of the white-to-white distance (WTW) of the human eye, as well as for the calculation of the required intraocular lens)	Medical Device	Recall for Product Correction	Class II	Hospital
17/10/2013	Optimys Opening Broach Bent (Reusable surgical instrument used for opening the medullary canal)	Medical Device	Recall	Class I	Hospital
16/10/2013	Crocodile Size 3 Walker (walking aid)	Medical Device	Recall for Product Correction	Class II	Consumer
16/10/2013	TDL6000MC Disposable Diathermy - Spatula tip with handle (Electrosurgical electrode)	Medical Device	Recall	Class II	Hospital
15/10/2013	da Vinci S Surgical System, IS2000; da Vinci Si Surgical System IS3000	Medical Device	Recall for Product Correction	Class II	Hospital

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14/10/2013	Discovery NM/CT 670, Optima NM/CT 640, Discovery NM630 and Brivo NM615 (all configurations) (Nuclear Medicine System)	Medical Device	Recall for Product Correction	Class II	Hospital
14/10/2013	Single-Site Bipolar Maryland and Single-Site Curved Needle Driver (Reusable endotherapy device with an endoscope)	Medical Device	Recall for Product Correction	Class III	Hospital
14/10/2013	TISSUE-GUARD Family of Products - VASCU-GUARD, DURA-GUARD, PERI-GUARD and SUPPLE PERI GUARD (Xenograft)	Medical Device	Recall	Class II	Wholesale
14/10/2013	Volumed VP7000 Premium, Volumed VP7000 Classic Plus, Syramed SP6000 Premium and Syramed SP6000 Classic Plus	Medical Device	Recall for Product Correction	Class II	Hospital
14/10/2013	Vygon Purple Nutrisafe Feeding Tube 10 FR	Medical Device	Recall	Class II	Hospital
11/10/2013	Philips Expression Information Portal - IP5 (Multiparameter patient monitor)	Medical Device	Recall for Product Correction	Class I	Hospital
11/10/2013	VITEK MS, firmware version 3.10 and 3.13 (bacterial and fungal identification system which uses the matrix-assisted laser desorption / ionization (MALDI) mass spectrometry method) (an in vitro diagnostic medical device (IVD))	Medical Device	Recall for Product Correction	Class II	Hospital
10/10/2013	Lifestent Vascular Stent System (200 mm stent length)	Medical Device	Recall	Class I	Hospital
10/10/2013	PEB01H Diathermy Pencil (Electrosurgical electrode)	Medical Device	Recall	Class II	Hospital
10/10/2013	Sapphire Multi Therapy Pump with software Rev09Ver07 (Infusion Pump)	Medical Device	Recall for Product Correction	Class I	Hospital
10/10/2013	TPS MicroDriver (used for surgical procedures involving drilling, reaming, driving wires or pins, cutting bone and hard tissue)	Medical Device	Recall	Class II	Hospital
9/10/2013	Avance, Amingo, Aisys Anaesthesia Devices (software version 8.00) and Avance CS Anaesthesia Devices (with software version 10.00)	Medical Device	Recall for Product Correction	Class I	Hospital
9/10/2013	Contoura 1000 and 1080 Beds (used to facilitate management of very obese patients)	Medical Device	Recall for Product Correction	Class II	Hospital
9/10/2013	Ysio, Luminos Agile, Luminos dRF and Uroskop Omnia Systems with software Versions VB10 and VC10 (diagnostic digital x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital

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4/10/2013	ADM/MDM Ball Impactor Tip and ADM Rim Impactor Tip (reusable surgical instrument used to implant Stryker's Automatic Dual Mobility (ADM) and/or the Modular Dual Mobility (MDM) Acetabular Systems)	Medical Device	Recall for Product Correction	Class II	Hospital
4/10/2013	Invacare Power Wheelchairs with affected SPJ+ Joysticks and MK6i Driver Controls	Medical Device	Recall for Product Correction	Class II	Consumer
3/10/2013	BD SoloMed 3-piece syringe with breakable plunger.	Medical Device	Recall for Product Correction	Class III	Wholesale
3/10/2013	Carestream PACS Client Workstation version 11.3.2.0 / 11.3.2.4 / 11.4	Medical Device	Recall for Product Correction	Class II	Hospital
3/10/2013	Magstim 90mm High Power Coil (used for diagnostic and therapeutic purposes by stimulating the cortical and peripheral nerves using the magnetic field)	Medical Device	Recall	Class II	Hospital
3/10/2013	Medtronic CareLink 2090 Programmer (Implantable pacemaker programmer)	Medical Device	Recall for Product Correction	Class III	Hospital
2/10/2013	B20, B30, B40 Patient Monitors (used for ECG monitoring)	Medical Device	Recall for Product Correction	Class I	Hospital
1/10/2013	ISE Reference Solenoid Valve for AU400, AU480, AU640, AU680, AU2700, AU5400 and AU5800 Chemistry Analysers. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
1/10/2013	TomoFix Plate Medial Tibia 4 Hole Standard and TomoFix Small Proximal Medial Tibia 4 Hole 112 mm Titanium Sterile	Medical Device	Recall for Product Correction	Class II	Hospital
1/10/2013	UniCel DxH 800 and UniCel DxH 600 Coulter Cellular Analysis Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
1/10/2013	Xia 3 Titanium Torque Wrench & Xia 3 Titanium Torque Wrench Short (used for final tightening of the blocker on the head of the pedicle screw during posterior spinal fusion surgery)	Medical Device	Recall	Class II	Hospital
27/09/2013	Beckman Coulter LH 750 & 780 Hematology Analysers (An in vitro diagnostic device (IVD))	Medical Device	Recall for Product Correction	Class I	Hospital
27/09/2013	PICATO ingenol mebutate 0.015% / 0.05% (w/w) gel tube	Medicine	Recall for Product Correction	Class III	Wholesale
25/09/2013	EPIQ 7 Ultrasound system version 1.0 (Intended for diagnostic ultrasound imaging)	Medical Device	Recall for Product Correction	Class II	Hospital

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25/09/2013	HIV Ag/Ab Combo (CHIV) Assay (used with ADVIA Centaur, ADVIA Centaur XP and ADVIA Centaur CP) (an in vitro diagnostic medical device (IVD))	Medical Device	Recall for Product Correction	Class III	Hospital
25/09/2013	Muliple Zimmer Highly Polished Implants (packaged in a Low Density Polyethylene (LDPE) Bag)	Medical Device	Recall for Product Correction	Class II	Hospital
25/09/2013	RAPIDPoint 400 Series, RAPIDPoint 500, and RAPIDLab 1200 Series Analysers (diagnostic blood gas analyser)	Medical Device	Recall for Product Correction	Class II	Hospital
20/09/2013	Stryker Standard Video Cart and Vision Mounting Arm	Medical Device	Recall for Product Correction	Class II	Hospital
18/09/2013	NX3 Try-In Gel Syringe Refills, Bleach (dental material used to preview the expected shade of a tooth restoration before final cementation)	Medical Device	Recall	Class II	Retail
18/09/2013	Sodium Iodide (I-131) Therapy Capsule	Medicine	Recall	Class II	Hospital
17/09/2013	BBL MGIT Mycobacteria Growth Indicator Tube	Medical Device	Recall	Class II	Hospital
16/09/2013	LOCI Cardiac Troponin I Calibrator (used with Dimension EXL Clinical Chemistry Systems)	Medical Device	Recall	Class II	Hospital
16/09/2013	NC Sprinter RX Balloon Dilatation Catheter (Angioplasty balloon dilatation catheter)	Medical Device	Recall	Class II	Hospital
16/09/2013	VERSA-FX II Femoral Fixation System	Medical Device	Recall	Class II	Hospital
13/09/2013	Argyle Single Lumen Polyurethane Umbilical Vessel Catheter	Medical Device	Recall for Product Correction	Class II	Hospital
13/09/2013	Artis Systems running Artis VC1x software (Fluoroscopic angiographic diagnostic x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
13/09/2013	Crocodile Size 3 Walker (walking aid)	Medical Device	Recall for Product Correction	Class II	Consumer
13/09/2013	DRX Revolution Mobile, DRX Mobile Retrofit & DRX Transportable X-ray Systems	Medical Device	Recall for Product Correction	Class II	Hospital
13/09/2013	Grifols Australia AHG Cards. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class I	Hospital
13/09/2013	Panbio Barmah Forest Virus IgM ELISA. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
13/09/2013	Ureterorenoscope 8703-524 (rigid ureteroendoscope)	Medical Device	Recall	Class II	Hospital

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12/09/2013	Thermocool SmartTouch Bi-Directional Navigation Catheter and Thermocool SmartTouch Uni-Directional Navigation Catheter (used to facilitate electrophysiological mapping of the heart and to undertake RF ablations)	Medical Device	Recall	Class I	Hospital
11/09/2013	Cobas b 101 HbA1c Test (used to test for diabetes)	Medical Device	Recall	Class II	Hospital
11/09/2013	Engstrom Ventilator & Aespire View, Aisys and Avance Anaesthesia Machines	Medical Device	Recall for Product Correction	Class II	Hospital
11/09/2013	FMS Intermediary Tubing with One-Way Valve (used with FMS Fluid Management Systems in a surgical setting by personnel trained in arthroscopy)	Medical Device	Recall	Class I	Hospital
11/09/2013	Vented Spike Adaptor	Medical Device	Recall	Class I	Hospital
10/09/2013	CARDIOHELP-I (Heart-lung bypass system)	Medical Device	Recall for Product Correction	Class I	Hospital
9/09/2013	Bellatek Zirconia Abutments	Medical Device	Recall	Class II	Retail
9/09/2013	Biomet 3i Dental Implants	Medical Device	Recall	Class II	Retail
9/09/2013	Standard SlingBar 450	Medical Device	Recall for Product Correction	Class II	Consumer
6/09/2013	BD Epilor Plastic BD Luer-Lok Loss of Resistance (LOR) Syringe (7mL) (Used in conjunction with an epidural needle for identifying epidural space)	Medical Device	Recall for Product Correction	Class II	Hospital
6/09/2013	BrightView XCT	Medical Device	Recall for Product Correction	Class I	Hospital
6/09/2013	Brilliance CT Big Bore Oncology, Brilliance CT Big Bore Radiology and Brilliance CT 16 (Air), software version 3.6.0	Medical Device	Recall for Product Correction	Class II	Hospital
6/09/2013	Howard Wright Limited Hospital Beds and Stretchers	Medical Device	Recall for Product Correction	Class II	Hospital
6/09/2013	Leica Ceiling Mounts MSF-1, MS-1F and MC-1F (Used for mounting surgical microscopes)	Medical Device	Recall for Product Correction	Class II	Hospital
5/09/2013	ADVIA 1200, 1650, 1800 and 2400 Clinical Chemistry Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
5/09/2013	Paclitaxel suspension (Abraxane) 150mg in Bag Viaflex	Medicine	Recall	Class I	Hospital

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5/09/2013	Robicomb Liceguard Comb	Medical Device	Recall	Class III	Retail
4/09/2013	COBAS INTEGRA 800 Software Version 9864.C2. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class I	Hospital
4/09/2013	Easypod Auto Injector, model 5.1 (Used to inject SAIZEN growth hormone under the skin)	Medical Device	Recall	Class II	Consumer
3/09/2013	Application Instrument for Sternal ZipFix	Medical Device	Recall	Class I	Hospital
2/09/2013	Inspira Air Balloon Dilation System (Bronchial balloon catheter)	Medical Device	Recall for Product Correction	Class I	Hospital
30/08/2013	BacT/ALERT PF Plus Culture Bottle. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
30/08/2013	Free T3 Assays for use on the IMMULITE, IMMULITE 1000, IMMULITE 2000 and IMMULITE 2000 XPi analysers. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
30/08/2013	Little Coughs	Medicine	Recall for Product Correction	Class II	Retail
29/08/2013	COGNIS Implantable Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) and TELIGEN DR & VR Implantable Cardioverter-Defibrillators (ICDs)	Medical Device	Hazard Alert	Class I	Hospital
29/08/2013	GENESIS II PS Articular Inserts (internal tibial component for knee prosthesis)	Medical Device	Recall	Class II	Hospital
28/08/2013	DigitalDiagnost - EasyUpgrade DR (Diagnostic digital x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
28/08/2013	Gas/Water Feeding Valve – PTX-OF-B194 (Used with PENTAX GI Video Endoscopes - 90i/90K series and i10/K10 series)	Medical Device	Recall	Class I	Hospital
27/08/2013	Navigator Surgical Kit/Tray, Tapered Navigator Surgical Kit/Tray, Contra-Angle Torque Driver Kit, Prosthetic Instrumentation Kit, Prosthetic System Driver Tray (Instrument kits which contains reusable dental instruments/ trays used to hold dental instruments during lab sterilization)	Medical Device	Recall for Product Correction	Class II	Hospital
26/08/2013	Berichrom Heparin (used in the quantitative and/or qualitative determination of tests associated with the coagulation cascade) (An in vitro diagnostic medical device (IVD))	Medical Device	Recall	Class I	Hospital

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26/08/2013	Centricity PACS RA1000 Workstation (Picture Archiving and Communication System)	Medical Device	Recall for Product Correction	Class I	Hospital
26/08/2013	Zimmer Trabecular Metal Reverse Glenosphere Distractor	Medical Device	Recall	Class II	Hospital
26/08/2013	Zimmer Trabecular Metal Reverse Glenosphere Helmet, 36mm/40mm	Medical Device	Recall	Class II	Hospital
23/08/2013	Advantx, Innova 2000, Innova 2100 IQ, Innova 3100, Innova 3100 IQ, Innova 4100, Innova 4100 IQ Cardiovascular X-ray imaging systems equipped with Video Monitor Suspension (Fluoroscopic, angiographic x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
23/08/2013	SLE 5000 Ventilator	Medical Device	Recall for Product Correction	Class I	Hospital
22/08/2013	Endowrist Instruments and Accessories for the da Vinci Surgical Systems (Used in endoscopic procedures)	Medical Device	Recall for Product Correction	Class II	Hospital
22/08/2013	Sterile K-Wire and Steinmann Pin Products (Typically used for temporary fixation of bones in the extremities)	Medical Device	Recall	Class I	Hospital
21/08/2013	Colleague P1.7 CXE Single Channel Pump and Colleague P1.7 CXE Triple Channel Pump (Infusion Pump)	Medical Device	Recall for Product Correction	Class II	Hospital
21/08/2013	EasyLink Data Management System, all versions (used for connecting multiple IVD instruments to Laboratory Information System (LMS))	Medical Device	Recall for Product Correction	Class II	Hospital
21/08/2013	OtisMed ShapeMatch Cutting Guides (used to assist in the positioning of knee arthroplasty components and in guiding the marking of bone before cutting)	Medical Device	Hazard Alert	Class II	Hospital
21/08/2013	Sterile Chlorohexidine Gluconate/Alcohol Swabs, Sterile Alcohol Swabs and Sterile Povidine Iodine Swabs	Medical Device	Recall	Class II	Wholesale
20/08/2013	Ingenuity TF PET/CT	Medical Device	Recall for Product Correction	Class II	Hospital
20/08/2013	Of Spiggle & Thesis PTFE Ventilation Tubes - Fluoroplastic shepard button and Fluoroplastic collar button (Tympanostomy tubes used to ventilate the middle ear subsequent to otitis media)	Medical Device	Recall	Class II	Hospital

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19/08/2013	Discovery MR450, MR750 and Optima MR450w MRI System	Medical Device	Recall for Product Correction	Class II	Hospital
19/08/2013	SIGMA Fixed Bearing Tibial Inserts - PLI, Cruciate Retaining, Posterior Stabilised (used as part of SIGMA Knee System)	Medical Device	Recall for Product Correction	Class II	Hospital
16/08/2013	Ceiling Supply Units (CSU) 80xx/CSU60xx (Used for positioning of medical gas and vacuum systems)	Medical Device	Recall for Product Correction	Class II	Hospital
16/08/2013	Phosphorus Reagent. An in vitro diagnostic medical device (IVD). (Used for the quantitation of phosphorus in human serum, plasma or urine)	Medical Device	Recall for Product Correction	Class II	Hospital
16/08/2013	Vitamin D3 Streuli 300,000IU/mL Ampoules (pack of 10)	Medicine	Recall	Class I	Hospital
15/08/2013	Oxoid Antimicrobial Susceptibility Discs with Augmentin (Amoxycillin and Clavulanic acid - AMC3). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
14/08/2013	Tec 6 and Tec 6 Plus Vaporizers (Used to vaporize anaesthetic agent Desflurane)	Medical Device	Recall for Product Correction	Class II	Hospital
13/08/2013	LifeCycle for Prenatal Screening software. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
12/08/2013	3M Scotchcast Wet or Dry Cast Padding	Medical Device	Recall	Class II	Hospital
12/08/2013	E-Z Clean, L-Wire Laparoscopic Electrode Split Stem, 45cm (Single use electrosurgical electrode)	Medical Device	Recall	Class I	Hospital
12/08/2013	Liquichek Sedimentation Rate Control, Level 2. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
12/08/2013	MX 16-Slice (Full body CT system)	Medical Device	Recall for Product Correction	Class II	Hospital
9/08/2013	4.0mm x15mm Small Peripheral Cutting Balloon (Monorail & Over-the-Wire) Microsurgical Dilatation Device (used for Percutaneous Transluminal Angioplasty of obstructive lesions in peripheral vessels) and 4.00mm x15mm Flextome Cutting Balloon (Monorail & Over-the-Wire) Microsurgical Dilatation Device (used in patients with coronary vessel disease)	Medical Device	Recall	Class II	Hospital
9/08/2013	Abraxane nanoparticle albumin-bound paclitaxel 100 mg powder for injection (suspension) vial	Medicine	Recall	Class I	Hospital

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9/08/2013	Fluoprep (Mounting medium for immunofluorescence microscopy) - An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class III	Hospital
9/08/2013	Secondary 19" Touchscreen - TEGRIS System (Operating room device management system)	Medical Device	Recall for Product Correction	Class II	Hospital
8/08/2013	Bio-Absorbable Suture Anchors (Soft tissue fixation device)	Medical Device	Recall	Class I	Hospital
8/08/2013	Fabius Anaesthesia Machine	Medical Device	Recall for Product Correction	Class II	Hospital
8/08/2013	General Purpose 9 French Temperature Probe, Disposable, 400 Series	Medical Device	Recall for Product Correction	Class II	Hospital
8/08/2013	HemoCue Hb 201 Microcuvettes (an in vitro diagnostic medical device (IVD))	Medical Device	Recall for Product Correction	Class III	Hospital
8/08/2013	Portex Blue Line Disposable Inner Cannula, 7mm (Reusable tracheostomy tube)	Medical Device	Recall	Class II	Hospital
8/08/2013	PyroTITAN Humeral Resurfacing Arthroplasty (CHRA)	Medical Device	Hazard Alert	Class II	Hospital
8/08/2013	Zoo Master Pouch 15 5H 3/8" Heavy Elephant Elastics (Elastomeric component used with orthodontic brackets)	Medical Device	Recall	Class III	Retail
7/08/2013	8mm Vector TAS Screw and Vector TAS Starter Kit (Orthodontic anchoring screw)	Medical Device	Hazard Alert	Class II	Retail
6/08/2013	ORTHO BioVue System Cassettes (blood typing and compatibility tests). An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class I	Hospital
5/08/2013	Allura Xper FD10 F and Allura FD10/10 (diagnostic, fluoroscopic x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
5/08/2013	Bond Polymer Refine Red Detection System. An in vitro diagnostic medical device (Immunohisto chemical staining kit)	Medical Device	Recall	Class II	Hospital
5/08/2013	HemoCue Glucose 201 RT Microcuvettes, single pack. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class I	Hospital
5/08/2013	Phenocell C 0.8% and Phenocell C 3%. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
2/08/2013	STERRAD 100NX Cassette (Used to provide hydrogen peroxide sterilant used in the STERRAD NX Steriliser)	Medical Device	Recall for Product Correction	Class II	Hospital

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2/08/2013	ViewPoint 6 Versions 6.2, 6.2.1, 6.3 and 6.31 including OB Pro-Expert Reporting (Ultrasound image management software)	Medical Device	Recall for Product Correction	Class II	Hospital
1/08/2013	Anastaflo Intravascular Shunt (Carotid artery shunt)	Medical Device	Recall	Class I	Hospital
1/08/2013	Medtronic Xomed Instrument Trays	Medical Device	Recall	Class II	Hospital
31/07/2013	ACL Top Family of analysers used with HemosIL APTT reagent (an in vitro diagnostic medical device (IVD))	Medical Device	Recall for Product Correction	Class II	Hospital
31/07/2013	Durolane 3ml (synovial fluid supplementation substance)	Medical Device	Recall	Class II	Hospital
31/07/2013	Oxoid Antimicrobial Susceptibility Testing Discs MEM10 (Meropenem), CT0774B (An in vitro diagnostic medical device (IVD))	Medical Device	Recall	Class II	Hospital
30/07/2013	ADVIA Centaur Folate ReadyPack, Lot 071218 Kit Lots (an in vitro diagnostic medical device (IVD))	Medical Device	Recall for Product Correction	Class II	Hospital
30/07/2013	LPS (Limb Preservation System) Lower Extremity Dovetail Intercalary Component (internal femoral component)	Medical Device	Hazard Alert	Class I	Hospital
30/07/2013	VITROS Chemistry Products MicroSlides (an in vitro diagnostic medical device (IVD))	Medical Device	Recall for Product Correction	Class II	Hospital
29/07/2013	Cell Marque CDX-2 (EPR2864Y*) antibody 7ml - an in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class I	Hospital
29/07/2013	FujiFilm Digital Mammography System AMULET (FDR MS-1000)	Medical Device	Recall for Product Correction	Class II	Hospital
29/07/2013	HypoMon Alarm System (alarm for sleep time hypoglycemic episodes)	Medical Device	Recall	Class II	Consumer
29/07/2013	VariVac InLine Adjustable Vacuum Wound Drainage System with bottle	Medical Device	Recall for Product Correction	Class II	Hospital
26/07/2013	C-Qur, C-Qur TacShield and C-Qur V-Patch (used for tissue reinforcement during surgery)	Medical Device	Recall for Product Correction	Class II	Hospital
26/07/2013	Octagam 5% 10g/200mL	Medicine	Recall	Class II	Hospital
24/07/2013	Brilliance iCT and iCT SP up to and including Software Version 3.2.5	Medical Device	Recall for Product Correction	Class I	Hospital
24/07/2013	Compat Nasogastric Feeding Tube 8Fr, 10Fr and 12Fr	Medical Device	Recall	Class II	Hospital

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24/07/2013	Contoura 380 and 480 Bed	Medical Device	Recall for Product Correction	Class II	Hospital
24/07/2013	Fluorocore 2+ Fast Set Core Build Up Dental Material, Syringe- Blue Coloured	Medical Device	Recall	Class III	Retail
24/07/2013	HemoCue Urine Albumin Microcuvettes (an in vitro diagnostic medical device (IVD))	Medical Device	Recall	Class II	Hospital
24/07/2013	Optimark (gadoversetamide) Injection bottle 5mL (Used in magnetic resonance imaging)	Medicine	Recall for Product Correction	Class III	Hospital
24/07/2013	Sterile Disposable Syringe 3mL - Luer Slip	Medical Device	Recall	Class II	Retail
23/07/2013	Cobas 4800 HPV Amplification/Detection Reagents, 240 tests and 960 tests	Medical Device	Recall	Class III	Hospital
23/07/2013	Dimension Vista RF Flex Reagent Cartridge (an in vitro diagnostic medical device (IVD))	Medical Device	Recall for Product Correction	Class II	Hospital
22/07/2013	MX8000 IDT 16 Slice CT Scanner	Medical Device	Recall for Product Correction	Class II	Hospital
22/07/2013	PROMUS Element Plus MONORAIL Everolimus-Eluting Coronary Stent System	Medical Device	Hazard Alert	Class I	Hospital
19/07/2013	Clearlink System Solution Set (Infusion administration set)	Medical Device	Recall	Class I	Hospital
19/07/2013	D788 pCO2 Membrane (catalogue number 942-063) used with Radiometer ABL700 and ABL800 series analysers (An in vitro diagnostic medical device (IVD))	Medical Device	Recall for Product Correction	Class I	Hospital
19/07/2013	Medtronic Navigation Framelink (used with Medtronic Navigation StealthStation S7 and i7 systems or a Medtronic Planning Station for image guided surgery)	Medical Device	Recall for Product Correction	Class I	Hospital
19/07/2013	Normal Saline with Phenol (NSP) in 4.5mL fill	Medicine	Recall	Class II	Hospital
19/07/2013	PTFE GRAFTS – ADVANT VXT, FLIXENE, FLIXENE w/IFG, ADVANTA SST with expiration between April 2017 and May 2018	Medical Device	Recall for Product Correction	Class II	Hospital
19/07/2013	RaySearch RayStation 3.0 and 3.5 (software versions 3.0.0.251, 3.5.0.16, 3.5.1.6) (Radiation treatment planning and analysis software)	Medical Device	Recall for Product Correction	Class I	Hospital
18/07/2013	Air Liquide Medical Oxygen	Medicine	Recall	Class III	Retail

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
18/07/2013	Febridol Paracetamol 500mg, 100 tablet bottle	Medicine	Recall	Class I	Consumer
17/07/2013	Disposable Breathing Circuit Kit	Medical Device	Recall	Class II	Hospital
17/07/2013	Frameless SRS QA Target Pointer (Component of Brainlab Stereotactic System used for patient positioning during stereotactic radiosurgery or radiotherapy procedures using a linear accelerator)	Medical Device	Recall	Class I	Hospital
16/07/2013	Active Care 1015-1 Swivel Sliding Transfer Bench	Medical Device	Recall for Product Correction	Class II	Hospital
16/07/2013	Fine-Medium Buchanan Pluggers (Dental instrument used during endodontic procedures)	Medical Device	Recall for Product Correction	Class III	Retail
16/07/2013	Monaco RTP System (Radiation Treatment Planning System Software)	Medical Device	Recall for Product Correction	Class I	Hospital
16/07/2013	Mullins Transseptal Catheter Introducer 7 French Sheath	Medical Device	Recall	Class II	Hospital
15/07/2013	Life Standard Package Cavity Liner (Calcium Hydroxide)	Medical Device	Recall	Class III	Retail
15/07/2013	Medrad Hand Controller Sheaths (used with Avanta Pedestal Mount Injection System and Avanta Table Mount Injection System)	Medical Device	Recall	Class II	Hospital
12/07/2013	Alaris System PC Unit (PCU) model 8015, software version 9.12	Medical Device	Recall for Product Correction	Class I	Hospital
11/07/2013	Medline Cardiac Pack (which includes Edwards LifeSciences Suction Wand)	Medical Device	Recall	Class I	Hospital
11/07/2013	Olympus OFP-2 Flushing Pump (used with endoscopic irrigation)	Medical Device	Recall for Product Correction	Class II	Hospital
10/07/2013	Locking Screw Stardrive 2.4mm and 2.7mm (self-tapping, 12 mm length, stainless steel. Orthopaedic bone screw)	Medical Device	Recall	Class II	Hospital
10/07/2013	Triathlon Tibial Alignment Ankle Camp Extramedullary (Referencing Instrument supplied with Triathlon Total Knee Arthroplasty procedure kit)	Medical Device	Recall for Product Correction	Class III	Hospital
10/07/2013	Zimmer NexGen Micro Knee Implants (Femur, Patella, Articular Surface) and Provisionals	Medical Device	Recall	Class II	Hospital
9/07/2013	ADVIA Chemistry Systems, Alkaline Phosphate (ALPAMP) Reagent Kits	Medical Device	Recall	Class III	Hospital

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9/07/2013	CT0003B AMP10 Ampicillin Antimicrobial Susceptibility Testing Discs (An in vitro diagnostic medical device (IVD))	Medical Device	Recall	Class II	Hospital
9/07/2013	HemoCue Glucose 201 Microcuvettes, single packed (an in vitro diagnostic medical device (IVD))	Medical Device	Recall	Class II	Hospital
9/07/2013	Liaison Control Mumps IgG (an in vitro diagnostic medical device (IVD))	Medical Device	Recall	Class II	Hospital
5/07/2013	AirSep Impulse Elite OCD (oxygen conserving device)	Medical Device	Recall	Class II	Consumer
5/07/2013	Infinia Nuclear Medicine Systems, VG and VG Hawkeye Nuclear Medicine systems, Helix nuclear medicine systems, Brivo NM615, Discovery NM630, Optima NM/CT640, Discovery NM/CT670	Medical Device	Recall for Product Correction	Class I	Hospital
5/07/2013	Medtronic MiniMed Insulin Reservoirs	Medical Device	Recall	Class I	Consumer
5/07/2013	Riata and Riata ST Silicone Endocardial Defibrillation Leads	Medical Device	Hazard Alert	Class I	Hospital
4/07/2013	iPlan CMF 3.0, iPlan Cranial 3.0, iPlan ENT 3.0, iPlan Flow 3.0, iPlan spine 3.0, iPlan Stereotaxy 3.0 (including all subversions)	Medical Device	Recall for Product Correction	Class I	Hospital
4/07/2013	NordiPen used with 5mg, 10mg and 15mg Norditropin SimpleXx cartridges	Medical Device	Recall for Product Correction	Class II	Consumer
4/07/2013	SynchroMed II and SynchroMed EL Implanted Infusion Pump	Medical Device	Hazard Alert	Class I	Hospital
4/07/2013	SynchroMed II and SynchroMed EL Implanted Infusion Pump	Medical Device	Recall for Product Correction	Class I	Hospital
4/07/2013	SynchroMed II and SynchroMed EL Implanted Infusion Pump	Medical Device	Hazard Alert	Class I	Hospital
4/07/2013	Thymoglobuline (rabbit anti-human thymocyte immunoglobulin) 25 mg powder for infusion vial	Medicine	Recall	Class II	Hospital
3/07/2013	ADVIA Centaur Homocysteine (HCY) Assay used with the ADVIA Centaur, Centaur XP, and Centaur CP systems	Medical Device	Recall for Product Correction	Class III	Hospital
3/07/2013	Aliquot Syringe Delivery System Kits (orthopaedic surgical kit, used to place injectable synthetic cortical bone void filler in weak or diminished bone)	Medical Device	Recall for Product Correction	Class II	Hospital
3/07/2013	All Digital Accelerators with Electrons and Beam Modulator, MLCi/MLCi2, Agility or Asymmetric Heads	Medical Device	Recall for Product Correction	Class I	Hospital

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3/07/2013	GEHC Discovery NM/CT 670 Nuclear Medicine System	Medical Device	Recall for Product Correction	Class I	Hospital
3/07/2013	GNV Slimming Pills - MSV Strong Version Capsules, ESV Extra Strong Capsules & RL Rapid Loss Capsules	Medicine	Recall	Class I	Consumer
3/07/2013	Medisafe Scope Pre-Clean Sponge Kit	Medical Device	Recall	Class III	Hospital
3/07/2013	OASYS Midline Occipital Plate(Intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (Occiput –T3))	Medical Device	Hazard Alert	Class II	Hospital
2/07/2013	Edwards Lifesciences Suction Wand (Used during cardiac surgery for the suction of excessive fluid from the pericardium)	Medical Device	Recall	Class I	Hospital
28/06/2013	BD MAX Instruments. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
28/06/2013	Dimension Vista 500 and Dimension Vista 1500 using software versions 3.5.1 and 3.6 - Clinical chemistry analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
28/06/2013	PSA Assays for use on Immulite, Immulite 1000, Immulite 2000 and Immulite 2000 XPI analysers (an in vitro diagnostic medical device)	Medical Device	Recall	Class II	Hospital
28/06/2013	Red Blood Cell Antibody Identification Reagent - Phenocell C 0.8% and Phenocell C 3%. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class III	Hospital
27/06/2013	Cementless Columbus Knee System	Medical Device	Hazard Alert	Class II	Hospital
27/06/2013	Niti-S Biliary Covered Stent (Flare-Type) Nagi/Pseudocyst 10mm x 3cm	Medical Device	Recall	Class II	Hospital
26/06/2013	Consulta CRT-P (Implantable cardiac pacemaker)	Medical Device	Hazard Alert	Class I	Hospital
26/06/2013	Herbs of Gold Olive Leaf Oral Liquid	Medicine	Recall	Class II	Wholesale
26/06/2013	Liposomal Amphotericin (AMBISOME) 50mg in 50ml 5% glucose infuser device	Medicine	Recall	Class I	Hospital
26/06/2013	Maquet Heater Unit	Medical Device	Recall for Product Correction	Class II	Hospital
26/06/2013	OSSEOTITE Certain PREVAIL 2 Implant 5/4 x 11.5mm	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
25/06/2013	Aquarius GEF08200 Device, V4 Software	Medical Device	Recall	Class I	Hospital
25/06/2013	Mini RPE Screw Assembly (Orthodontic Appliance System)	Medical Device	Recall	Class II	Retail
25/06/2013	Morphine Sulphate solution, 50mg in 50mL 0.39% Sodium Chloride Syringe (Compounded patient specific medicine)	Medicine	Recall	Class II	Hospital
25/06/2013	Reduction Instrument for Spondylolisthesis, standard, for Matrix 5.5	Medical Device	Recall	Class II	Hospital
24/06/2013	Cholestahealth Powder	Medicine	Recall	Class II	Consumer
21/06/2013	BD Stem Cell Control Kit (used with BD FACSCanto flow cytometers). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class I	Hospital
20/06/2013	Infinia, VG, VG Hawkeye and Helix nuclear medical systems	Medical Device	Recall for Product Correction	Class I	Hospital
20/06/2013	Perfect Pool 10x10ml, an in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
19/06/2013	AMBISOME (amphotericin B) 50 mg powder for injection vial	Medicine	Recall	Class I	Hospital
19/06/2013	AMH Gen II ELISA Kit. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
19/06/2013	Biograph mCT systems running the VG40A or VG40B software	Medical Device	Recall for Product Correction	Class II	Hospital
19/06/2013	Transpedicular Schanz Screw (Bone screw for internal spinal fixation system)	Medical Device	Recall	Class II	Hospital
18/06/2013	Dynamic Locking Screw Stardrive 3.7mm self tapping, length 22-70mm and 5.0mm, length 32-90 mm, Cobalt Chrome (CoCrMo) sterile	Medical Device	Hazard Alert	Class II	Hospital
18/06/2013	HeartStart MRx Monitor / Defibrillator	Medical Device	Recall for Product Correction	Class I	Hospital
18/06/2013	V60 Non-invasive Ventilators	Medical Device	Recall for Product Correction	Class I	Hospital
17/06/2013	Ceftriaxone (as Sodium) Powder for Injection 1g	Medicine	Recall	Class I	Hospital
17/06/2013	Deep Brain Stimulation (DBS) Leads (implantable, neurological electrode stimulator)	Medical Device	Recall	Class I	Hospital
14/06/2013	Abbott Medical Optics (AMO) STAR Excimer Laser System	Medical Device	Recall for Product Correction	Class II	Hospital

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14/06/2013	Alaris GP, GP Guardrails, GP Plus & GP Plus Guardrails Infusion Pumps	Medical Device	Recall for Product Correction	Class I	Hospital
14/06/2013	EZTest steam and Smart-Read EZTest steam Biological Indicators	Medical Device	Recall	Class II	Retail
14/06/2013	Medtronic Consulta CRT-P (Implantable cardiac pacemaker)	Medical Device	Recall	Class I	Hospital
13/06/2013	5L and 10L Prolystica Ultra Concentrate Alkaline Detergent	Medical Device	Recall for Product Correction	Class II	Hospital
13/06/2013	IH-1000. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
13/06/2013	INFUSE/LT Cage Bone Graft Kit (Used for spinal fusion procedures)	Medical Device	Hazard Alert	Class I	Hospital
13/06/2013	Intuitive Surgical 5mm Cannula and 5mm Flared Cannula (Reusable endotherapy cannula)	Medical Device	Recall for Product Correction	Class II	Hospital
12/06/2013	Allura Systems: FD10, FD20, FD10/10, Allura Systems with OR table: FD10, FD10/10, FD20/20 (Fluoroscopic x-ray systems used for diagnostic/interventional procedures in cardiovascular and vascular imaging applications)	Medical Device	Recall for Product Correction	Class II	Hospital
12/06/2013	Diclocil (dicloxacillin sodium) 500mg capsules	Medicine	Recall	Class II	Retail
12/06/2013	Elements Motor and TF Adaptive Starter Kit (Dental motor used with endodontic rotary instruments)	Medical Device	Recall for Product Correction	Class III	Retail
12/06/2013	Medtronic Paradigm Insulin Infusion Sets	Medical Device	Recall for Product Correction	Class I	Consumer
6/06/2013	APEX Arthroscopy Tubing Set, One Connection	Medical Device	Recall	Class II	Hospital
6/06/2013	CAPD Solution Transfer Set with Locking Connector, Minicap Extended Life PD Transfer Set with Twist Clamp, Minicap Extended Life PD Transfer Set with Twist Clamp (Extra Short and Extra Long)	Medical Device	Recall for Product Correction	Class II	Hospital
6/06/2013	Coiled Tube Baxter Infusors (Portable Elastomeric Infusion Systems)	Medical Device	Recall	Class I	Hospital
6/06/2013	MEVATRON, PRIMUS, ONCOR and ARTISTE Digital Linear Accelerators	Medical Device	Recall for Product Correction	Class I	Hospital
6/06/2013	Sonopet Console (Ultrasonic Surgical Aspirator System)	Medical Device	Recall for Product Correction	Class I	Hospital

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4/06/2013	DePuy ReClaim Reamer Extension (Supplied as part of the ReClaim modular revision hip system kit)	Medical Device	Recall for Product Correction	Class II	Hospital
4/06/2013	DX-D 100 (Mobile diagnostic x-ray generator)	Medical Device	Recall for Product Correction	Class II	Hospital
3/06/2013	Elekta XVI X-Ray Volume Imager (Electronic Portal Imaging Device (EPID) used with radiation therapy treatment)	Medical Device	Recall for Product Correction	Class I	Hospital
3/06/2013	SYNCHRON Systems Lactate (LACT). An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class I	Hospital
3/06/2013	Vitamin A Ampoules	Medicine	Recall	Class II	Retail
31/05/2013	Bone Fragments - Milled irradiated femoral head	Biological	Hazard Alert	Class II	Hospital
31/05/2013	Brilliance CT Systems and Gemini & Precedence Systems utilising Brilliance CT	Medical Device	Recall for Product Correction	Class II	Hospital
31/05/2013	Monaco RTP System (Radiation Treatment Planning System Software)	Medical Device	Recall for Product Correction	Class I	Hospital
30/05/2013	Glenosphere Orientation Guide Instrument used with the Delta EXTEND Reverse Shoulder System.	Medical Device	Hazard Alert	Class II	Hospital
30/05/2013	Medrad Veris MR Vital Signs Monitor - Power cable	Medical Device	Recall for Product Correction	Class II	Hospital
30/05/2013	Neptune 2 Rover Ultra and Neptune Bronze Rover (Mobile unit used as surgical fluid/smoke waste management system)	Medical Device	Recall for Product Correction	Class I	Hospital
29/05/2013	8 mm Fenestrated Bipolar Forceps used with da Vinci Standard System (IS1200)	Medical Device	Recall	Class II	Hospital
29/05/2013	ECHELON 60mm Endoscopic Linear Cutter Reloads, Black (Reload cartridge with two 60mm long triple-staggered lines of staples)	Medical Device	Recall	Class I	Hospital
29/05/2013	Edwards Lifesciences QuickDraw Venous Cannula	Medical Device	Recall	Class I	Hospital
29/05/2013	G-6-PDH Control Kits, Normal. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
29/05/2013	Intuitive Surgical EndoWrist Instrument Hot Shears Monopolar Curved Scissors	Medical Device	Recall	Class II	Hospital
29/05/2013	MIA16 Minimally Invasive Attachment used with the Anspach	Medical Device	Recall for Product Correction	Class II	Hospital

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28/05/2013	Medacta Femoral Stems	Medical Device	Recall for Product Correction	Class II	Hospital
24/05/2013	Checking Dilator 24-492-15-01 (Dilator, De Bakey, 0 1.5mm, 19cm)	Medical Device	Recall	Class II	Hospital
24/05/2013	DBL Metronidazole Intravenous Infusion, Infusion bag 500mg in 100mL	Medicine	Recall	Class II	Hospital
24/05/2013	Dimension Vista 500 & Dimension Vista 1500 Analysers with Software versions 3.4 or 3.5.1 (An in vitro diagnostic medical device (IVD))	Medical Device	Recall for Product Correction	Class II	Hospital
24/05/2013	GlideScope Video Laryngoscope Blades GVL3, GVL4 and GVL5	Medical Device	Recall	Class I	Hospital
24/05/2013	MammoDiagnost DR with software release 2.1 (mammography system)	Medical Device	Recall for Product Correction	Class III	Hospital
24/05/2013	PET VCAR Application Software (installed on Advantage Workstation and AW Server versions: Advantage Workstation 4.6, Volume Share 5 enhanced - vx11.11.3, vx11.11.3 ext1, or vx11.11.3 ext2 AW Server 2.0, Volume Share 5 enhanced - vx11.11.3, vx11.11.3 ext1, or vx11.11.3 ext2)	Medical Device	Recall for Product Correction	Class I	Hospital
24/05/2013	PYRENEES Constrained plate 2 Level 36mm	Medical Device	Recall	Class II	Wholesale
22/05/2013	ADVIA Chemistry Total Protein_2 reagent (Urine) (UPRO_2). An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
22/05/2013	Alere DDS2 Test Kits (Drug screening test system). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
22/05/2013	syngo Lab Data Manager Version VA11B and VA12A. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
21/05/2013	CT0003B AMP10 Ampicillin Antimicrobial Susceptibility Testing Discs. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
20/05/2013	Blackmax, Micromax, Xmax Anspach Pneumatic Drill Systems / Hoses without a pressure relief valve (PRV)	Medical Device	Recall for Product Correction	Class I	Hospital
20/05/2013	GAMMA3 Long Nail Kit R2.0 LEFT (Intramedullary Nail for fracture fixation)	Medical Device	Recall	Class II	Hospital

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20/05/2013	Zimmer Air Dermatome (Air powered surgical skin grafting device)	Medical Device	Recall for Product Correction	Class II	Hospital
17/05/2013	Access 2 Immunoassay System with Software Version 3.4. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
17/05/2013	ARCHITECT STAT High Sensitive Troponin-I Calibrators and Controls	Medical Device	Recall for Product Correction	Class III	Hospital
17/05/2013	Codman Certas Programmable Valves (Hydrocephalic valve)	Medical Device	Hazard Alert	Class I	Hospital
17/05/2013	Dimension Chemistry Wash	Medical Device	Recall	Class II	Hospital
17/05/2013	Integra Ojemann Cortical Stimulator (Electrical antiseizure brain stimulator)	Medical Device	Recall for Product Correction	Class II	Hospital
17/05/2013	Receptal 1000 mL liner and canister used with the Laerdal Suction Unit	Medical Device	Recall for Product Correction	Class II	Hospital
16/05/2013	1.5T Signa HDxt, 3.0T Signa HDxt, Signa Vibrant MR Systems (Magnetic Resonance Imaging Systems)	Medical Device	Recall for Product Correction	Class II	Hospital
16/05/2013	Berichrom PAI (Plasmin activator inhibitors). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
16/05/2013	Carbon dioxide absorbent canister for use with the Aespire, Aespire View, Avance, Avance CS2, Aisys, ADU, 9100, M900, M904, 9300 anaesthesia systems	Medical Device	Recall for Product Correction	Class II	Hospital
16/05/2013	IH-1000 Immunohaematology Analyser. An in vitro Diagnostic Medical Device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
16/05/2013	LifeCare P5 Premium Bed with side rails	Medical Device	Recall for Product Correction	Class II	Hospital
15/05/2013	HeartWare Controller	Medical Device	Recall for Product Correction	Class I	Hospital
15/05/2013	Viper & Viper Plus Powerchairs	Medical Device	Recall for Product Correction	Class III	Hospital
13/05/2013	BrightView SPECT (single photon emission computed tomography system)	Medical Device	Recall for Product Correction	Class I	Hospital
13/05/2013	Epix and Direct Drive Laparoscopic Grasper	Medical Device	Recall	Class II	Hospital
10/05/2013	1000mL Receptal System (waste disposable suction system)	Medical Device	Recall	Class II	Hospital

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10/05/2013	BioMend Absorbable Collagen Membrane/Wound Dressing	Medical Device	Recall	Class II	Retail
10/05/2013	Medtronic NIM Flex EMG Endotracheal Tube	Medical Device	Recall	Class I	Hospital
10/05/2013	Sterile Adapter for use with the da Vinci S, da Vinci Si, da Vinci Si-e (robotic surgical system)	Medical Device	Recall for Product Correction	Class II	Hospital
10/05/2013	Versaport Bladeless Optical 5mm Trocar with Fixation Cannula (Abdominal and thoracic trocar)	Medical Device	Recall	Class II	Hospital
9/05/2013	Brilliance CT 64, Ingenuity Core, Ingenuity Core 128 systems using software versions 2.6.1 or 3.5.4 (Computed tomography full-body x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
9/05/2013	CoaguChek XS, CoaguChek XS Plus and CoaguChek XS Pro. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Consumer
9/05/2013	Cortex Screw 3.5mm, self-tapping, length 60mm, Stainless Steel, sterile (Orthopaedic non-biodegradable bone screw)	Medical Device	Recall	Class III	Hospital
9/05/2013	Guide Wire 2.5mm, with drill tip, length 300mm Cobalt-Chrome Alloy (Orthopaedic fixation nail guidewire)	Medical Device	Recall	Class II	Hospital
9/05/2013	Soft Tissue Retractor, small, extendible	Medical Device	Recall	Class II	Hospital
9/05/2013	STF Load Check Indicators (ultrasonic bath efficacy indicator)	Medical Device	Recall	Class II	Hospital
9/05/2013	T4 Zipper Toga (XL - Tall) (Operating room gown)	Medical Device	Recall	Class II	Hospital
7/05/2013	A-dec 311 Chair and A-dec 361 Support Centre	Medical Device	Recall for Product Correction	Class II	Retail
7/05/2013	AU2700/AU2700 Plus and AU5400 Clinical Chemistry Analysers, an in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
7/05/2013	Aurum Amiodarone 30mg/mL Pre-Filled Syringe	Medicine	Recall	Class II	Hospital
7/05/2013	Cautery Pen Push Button PTFE Coated blade	Medical Device	Recall	Class III	Hospital
7/05/2013	ProcedurePak - Mater Day Hip Arthroscopy Pack	Medical Device	Recall	Class II	Hospital
6/05/2013	Hill-Rom VersaCare VC 755 Bed	Medical Device	Recall for Product Correction	Class II	Hospital

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3/05/2013	BariAir Therapy System (Provides low air-loss pressure management therapy, pulsation, percussion, turn-assist, flexible patient positioning capabilities and built-in scales for large patients)	Medical Device	Recall for Product Correction	Class II	Hospital
3/05/2013	Brainlab Cranial Navigation System, all versions	Medical Device	Recall for Product Correction	Class I	Hospital
3/05/2013	Elecsys Beta-CrossLaps. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
3/05/2013	Mini C-arm, models InSight and InSight 2 (Fluoroscopic x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
2/05/2013	Dimension TACR (Tacrolimus) Flex Reagent Cartridge (DF107), An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class I	Hospital
1/05/2013	LIGACLIP 10mm M/L Endoscopic Rotating Multiple Clip Applier (metal ligating clip applier)	Medical Device	Recall	Class I	Hospital
30/04/2013	Elekta Integrity R3.0 Digital Linear Accelerator	Medical Device	Recall for Product Correction	Class II	Hospital
30/04/2013	Masimo Rad-8 Pulse Oximeters	Medical Device	Recall for Product Correction	Class II	Hospital
30/04/2013	PANTA Arthrodesis Nail & PANTA XL Arthrodesis Nail (Intramedullary tibial nail)	Medical Device	Recall for Product Correction	Class II	Hospital
30/04/2013	Tensioner (Instrument used for general orthopaedic repairs using implants like cerclage wires, cables and crimps/clamps)	Medical Device	Recall for Product Correction	Class II	Hospital
30/04/2013	VIDAS D-Dimer Exclusion II (An in vitro medical device (IVD))	Medical Device	Recall for Product Correction	Class I	Hospital
29/04/2013	Discovery MR450, MR750, MR750w and Optima MR450w products, running software versions DV22.0_V02, DV22.1_V01, DV23.0_V01 (MRI System)	Medical Device	Recall for Product Correction	Class II	Hospital
29/04/2013	Electrosurgery Probe Plus II (Electrosurgical electrodes) & Laparoscopic Banding Kit	Medical Device	Recall	Class II	Hospital
29/04/2013	Trima Accel Automated System (Apheresis unit)	Medical Device	Recall for Product Correction	Class I	Hospital
26/04/2013	Zilver PTX Drug-Eluting Peripheral Stent	Medical Device	Recall	Class I	Hospital

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24/04/2013	ACUSON SC2000 System (Ultrasound cardiovascular imaging system) when used with V5M Transducer (which includes revision 4 of the MPI board)	Medical Device	Recall for Product Correction	Class II	Hospital
24/04/2013	LOGIQ S8 with software revisions R1.1.1 and R1.5.1, and LOGIQ S7 with software revisions R1.0.1, R1.0.2 and R1.0.3 (Diagnostic ultrasound system)	Medical Device	Recall	Class II	Hospital
24/04/2013	RPM Respiratory Gating System, version v1.7.5 with 3D Option (Patient respiratory monitoring system used with radiation therapy systems)	Medical Device	Recall for Product Correction	Class II	Hospital
23/04/2013	BBL DrySlide Oxidase Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
23/04/2013	BD Vacutainer Multiple Sample Luer Adapter	Medical Device	Recall for Product Correction	Class II	Hospital
23/04/2013	Flexible Handle for Simplified Universal Nail System (SUN) and the Universal Nail System (UNI) (Re-usable surgical instrument supplied as part of internal fixation system implantation kit)	Medical Device	Recall	Class I	Hospital
23/04/2013	LCP Distal Femoral Plate 4.5/5.0, right, 19 holes, length 436 mm, Titanium Alloy (TAN), sterile (Orthopaedic fixation plate)	Medical Device	Recall	Class III	Hospital
23/04/2013	VITROS Immunodiagnostic Products CK-MB Calibrators. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
22/04/2013	Biograph mCT Systems with VG40 Software (Diagnostic imaging system)	Medical Device	Recall for Product Correction	Class II	Hospital
22/04/2013	Confidence Spinal Cement System Kit	Medical Device	Recall	Class II	Hospital
22/04/2013	Constellation Pneumatic Handpiece, DSP (Ophthalmic surgical instrument handle)	Medical Device	Recall	Class II	Hospital
22/04/2013	DuraGen Dural Graft Matrix, DuraGen Plus Dural Regeneration Matrix & DuraGen Suturable Dural Regeneration Matrix (Dura mater grafts indicated for the repair or primary closure of dura (brain and spinal chord) for regeneration)	Medical Device	Recall	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
22/04/2013	NeuraGen Nerve Guide (Indicated for the repair of peripheral nerve discontinuities); NeuraWrap Nerve Protector (Indicated to provide nerve protection following peripheral nerve surgery)	Medical Device	Recall	Class I	Hospital
22/04/2013	OxyCap Adult CO2 Sampling Oxygen Mask	Medical Device	Recall	Class II	Hospital
22/04/2013	Panbio Dengue IgM Capture ELISA, An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
22/04/2013	SYNCHRON Systems Lactate (LACT), An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
19/04/2013	iPlan RT Dose version 4.0 and 4.1 (including all subversions) (Radiation therapy treatment planning system)	Medical Device	Recall for Product Correction	Class II	Hospital
19/04/2013	Liquichek ToRCH Plus IgM Control - Positive (An in vitro diagnostic medical device (IVD))	Medical Device	Recall	Class I	Hospital
19/04/2013	MatrixORTHOGNATHIC Screws; MatrixMANDIBLE Screws; MatrixMIDFACE; MatrixNEURO Screws (Non-sterile and sterile screws supplied as part of a craniofacial fixation plate kit)	Medical Device	Recall	Class I	Hospital
19/04/2013	Nicolet EEG Wireless Amplifier	Medical Device	Recall	Class II	Hospital
19/04/2013	PCA LifeCare Infusion System	Medical Device	Recall	Class I	Hospital
19/04/2013	Respond Wires (Orthodontic wire)	Medical Device	Recall for Product Correction	Class III	Retail
19/04/2013	Streptex Group D Latex agglutination reagent R30950901, An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
19/04/2013	Tissue Liberator Blade Up (Forceps)	Medical Device	Recall	Class II	Hospital
18/04/2013	IMPAX 5.2 DB Server, version 5.2 (Picture archiving and communication system, PACS)	Medical Device	Recall for Product Correction	Class I	Hospital
18/04/2013	Optima MR430s and MSK 1.5T Extreme (MRI System)	Medical Device	Recall for Product Correction	Class II	Hospital
18/04/2013	Philips HeartStart MRx Monitor/Defibrillator	Medical Device	Recall for Product Correction	Class I	Hospital
18/04/2013	YUNO Table Extension device	Medical Device	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
17/04/2013	Dimension Tacrolimus (TACR) Flex Reagent Cartridge (An in vitro diagnostic medical device used with Dimension Clinical Chemistry Systems)	Medical Device	Recall	Class I	Hospital
17/04/2013	Elekta Integrity Digital Linear Accelerator, version 1.1	Medical Device	Recall for Product Correction	Class II	Hospital
17/04/2013	EnSeal G2 SuperJaw (Used for bipolar coagulation and mechanical transection of tissue during laparoscopic and open procedures)	Medical Device	Recall for Product Correction	Class I	Hospital
17/04/2013	Pulmonary Valve Transplant	Biological	Hazard Alert	Class I	Hospital
17/04/2013	SAFETY Blood Collection Sets	Medical Device	Recall	Class II	Hospital
16/04/2013	Optima CT660, Brivo CT385, Discovery PET/CT 610 and Discovery PET/CT 710 Systems	Medical Device	Recall for Product Correction	Class II	Hospital
16/04/2013	Torix Disposable Toric IOL Marking and Alignment System	Medical Device	Recall	Class III	Hospital
15/04/2013	ADVIA Chemistry Systems Liquid Specific Protein Calibrator (an in vitro diagnostic medical device (IVD))	Medical Device	Recall for Product Correction	Class III	Hospital
15/04/2013	Dimension Clinical Chemistry Systems HB1C Flex Reagent Cartridge (An in vitro diagnostic medical device (IVD))	Medical Device	Recall	Class II	Hospital
15/04/2013	SJM Confirm External Patient Activator Model DM2100A	Medical Device	Recall	Class III	Consumer
12/04/2013	All GemStar Family of Infusers: GemStar Infusion System - Single Therapy, GemStar 7 Therapy Infusion System	Medical Device	Recall for Product Correction	Class I	Consumer
12/04/2013	All GEMSTAR Family of Infusers; GemStar Infusion System - Single Therapy; GemStar 7 Therapy Infusion System	Medical Device	Recall for Product Correction	Class II	Hospital
12/04/2013	All GEMSTAR Family of Infusers; GemStar Infusion System - Single Therapy; GemStar 7 Therapy Infusion System	Medical Device	Recall for Product Correction	Class II	Consumer
12/04/2013	DHS/DCS Screw, sterile (Orthopaedic bone screw, non bio-degradable)	Medical Device	Recall	Class II	Hospital
12/04/2013	EVOTECH Endoscope Cleaner and Reprocessor (ECR) System (Endoscope disinfecting unit)	Medical Device	Recall for Product Correction	Class II	Hospital
12/04/2013	EVOTECH Endoscope Cleaner and Reprocessor (ECR) System (Endoscope disinfecting unit)	Medical Device	Recall for Product Correction	Class III	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
12/04/2013	FreeStyle InsuLinx Blood Glucose Meter (An in vitro diagnostic medical device (IVD))	Medical Device	Recall for Product Correction	Class I	Consumer
11/04/2013	All GemStar Family of Infusers: GemStar Infusion System - Single Therapy, GemStar 7 Therapy Infusion System	Medical Device	Recall for Product Correction	Class II	Consumer
9/04/2013	ExacTrac (Image guided radiation treatment therapy patient positioning system)	Medical Device	Recall for Product Correction	Class I	Hospital
9/04/2013	HbA1c Flex Reagent Cartridge (An in vitro diagnostic medical device (IVD) used with Dimension Vista Systems)	Medical Device	Recall	Class II	Hospital
8/04/2013	Newport HT70 and HT70 Plus Ventilator	Medical Device	Recall for Product Correction	Class II	Hospital
8/04/2013	PSV Sets (Scalp Vein), Hard, 27Gx 3/4" ISO CE	Medical Device	Recall	Class II	Wholesale
5/04/2013	AcrySof CACHET Phakic Lens (Used for the reduction or elimination of myopia)	Medical Device	Recall for Product Correction	Class I	Hospital
5/04/2013	Imagine Instant Pregnancy Test	Medical Device	Recall	Class II	Retail
5/04/2013	syngo WorkFlow MLR with version VB30C_FP1, VB30E, VB35A, VB36A and "Portal Radiologist" license (radiology information system used to process data)	Medical Device	Recall for Product Correction	Class II	Hospital
4/04/2013	cobas 8000 modular analyser series, control unit software version 03-03 (An in vitro diagnostic medical device (IVD))	Medical Device	Recall for Product Correction	Class II	Hospital
4/04/2013	DASH, PDM and Tram models (Multiparameter patient monitor)	Medical Device	Recall for Product Correction	Class II	Hospital
4/04/2013	Locking screw 3.5mm, self tapping, length 55mm, stainless steel, sterile (Orthopaedic bone screw, non-biodegradable)	Medical Device	Recall	Class II	Hospital
4/04/2013	STERRAD 100NX and STERRAD 200 Sterilisation Systems	Medical Device	Recall for Product Correction	Class II	Hospital
4/04/2013	Stryker Suction Irrigation Tips (general purpose irrigation/aspiration units)	Medical Device	Recall for Product Correction	Class II	Hospital
3/04/2013	epoc BGEM Test Card (blood gas, electrolyte and metabolite test card panel), An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
28/03/2013	AQUIRE POC Management System, software versions 1.4.0 to 1.5.3 (An in vitro diagnostic medical device (IVD))	Medical Device	Recall for Product Correction	Class II	Hospital

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28/03/2013	AU5800 Clinical Chemistry Analyser; all instrument serial numbers with software version 4.11 and prior (An in vitro diagnostic medical device (IVD))	Medical Device	Recall for Product Correction	Class II	Hospital
28/03/2013	Biomet Oxford Uni Toffee Hammer (Reusable surgical instrument used to insert or remove pins, nails etc)	Medical Device	Recall	Class II	Hospital
28/03/2013	Blue Free Strand ORTHOCORD Sutures: Orthocord Blue without needles; Orthocord Blue & Violet without needles; Orthocord Blue & Violet with needles; Orthocord Violet/Blue W/ MO 06 NDLE PK12; Orthocord Violet/Blue W/ OS 06 NDLE PK12 (Sutures used in general soft Tissue approximation and or ligation, including orthopaedic procedures	Medical Device	Recall for Product Correction	Class III	Hospital
28/03/2013	CARDIOHELP-1, software version 3.3.0 (Heart-lung bypass system)	Medical Device	Recall for Product Correction	Class I	Hospital
28/03/2013	cobas 4800 - z 480 (Real time PCR sample preparation, amplification and detection instrument). An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
28/03/2013	Fluoron Gas Tamponades (Intraocular injection of ophthalmic gases)	Medical Device	Recall	Class II	Hospital
28/03/2013	HemoCue Glucose 201 RT and Glucose 201 DM RT Systems (An in vitro diagnostic medical device (IVD) for the quantitative detection of blood glucose)	Medical Device	Recall for Product Correction	Class I	Hospital
28/03/2013	PROSTIVA RF Model 8930 Generator (Used for minimally invasive treatment for patients with lower urinary tract symptoms due to benign prostatic hyperplasia (BPH))	Medical Device	Recall for Product Correction	Class II	Hospital
28/03/2013	Pulp Canal Sealer EWT Standard, Pulp Canal Sealer EWT Bulk Powder Refill (Root canal sealing material)	Medical Device	Recall	Class III	Retail
27/03/2013	Advantx, Innova 2000, Innova 2100 IQ, Innova 3100, Innova 3100 IQ, Innova 4100, Innova 4100 IQ Cardiovascular X-ray Imaging Systems equipped with Video monitor Suspension model numbers 2236709, 2353620, 2223039-2 and 2270677-2	Medical Device	Recall for Product Correction	Class I	Hospital
27/03/2013	Medtronic Paradigm Insulin Pump	Medical Device	Recall for Product Correction	Class I	Consumer
27/03/2013	One Touch Verio IQ Blood Glucose Monitoring System	Medical Device	Recall	Class I	Consumer

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
25/03/2013	CentraLink Database Management System, version 14.0.4 (An in vitro diagnostic medical device (IVD))	Medical Device	Recall for Product Correction	Class II	Hospital
25/03/2013	Oxoid Antimicrobial Susceptibility Testing discs for Ampicillin (AMP10). An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
25/03/2013	Oxoid Antimicrobial Susceptibility Testing discs for Ertapenem (ETP10). An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
25/03/2013	Reinforced Endotracheal Tubes - Murphy, Magill, Murphy with stylet & Magill with stylet	Medical Device	Recall	Class I	Hospital
22/03/2013	Elekta PreciseTreatment Table (Intended as a universal patient treatment support and positioning table for radiation therapy and simulation use)	Medical Device	Recall for Product Correction	Class I	Hospital
22/03/2013	Take 1 Advanced Medium SuperFast (Dental silicone impression material)	Medical Device	Recall	Class III	Retail
21/03/2013	Kimguard Container Filters 7.5in (19cm) round & 9x9in (23x23cm) square (Used for wrapping medical devices prior to sterilisation)	Medical Device	Recall	Class II	Hospital
21/03/2013	Philips IntelliVue Information Center iX (PIIC iX) software release A.01.XX (Central patient monitoring station)	Medical Device	Recall for Product Correction	Class I	Hospital
20/03/2013	ML 301 Examination Lamp	Medical Device	Recall for Product Correction	Class II	Hospital
19/03/2013	BD HLA-B27 Kit (An in vitro diagnostic medical device (IVD))	Medical Device	Recall	Class II	Hospital
19/03/2013	FEMME-TAB ED 20/100 levonorgestrel 100mcg ethinylestradiol 20mcg film-coated blister pack (Oral contraception)	Medicine	Recall	Class II	Wholesale
19/03/2013	MX PGE2 3/4 Gellhorn Pessary	Medical Device	Recall	Class III	Retail
19/03/2013	RegenerOss Allograft Block Max/Mand Blocks	Biological	Hazard Alert	Class II	Hospital
19/03/2013	VITROS Chemistry Products PHBR Slides (An in vitro diagnostic medical device (IVD) for the quantitative measure of phenobarbital)	Medical Device	Recall	Class I	Hospital
15/03/2013	AMS 800 Artificial Urinary Sphincter Control Pumps	Medical Device	Hazard Alert	Class I	Hospital

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15/03/2013	Avance CS2 Anesthesia Carestation	Medical Device	Recall for Product Correction	Class I	Hospital
15/03/2013	MAQUET QUADROX-i Oxygenators (excluding HLS) and Blood Outlet Connectors	Medical Device	Recall for Product Correction	Class I	Hospital
15/03/2013	Medtronic NIM TriVantage EMG Endotracheal Tube	Medical Device	Recall	Class I	Hospital
14/03/2013	Alere Cholestech LDX ALT-AST Cassette (An in vitro medical device (IVD) used for the quantitative determination of alanine aminotransferase (ALT) and aspartate aminotransferase (AST) in whole blood)	Medical Device	Recall	Class II	Hospital
14/03/2013	Alere Cholestech LDX Multianalyte Control (An in vitro diagnostic medical device used to monitor the performance of total cholesterol (TC), high density lipoprotein (HDL), triglycerides (TRG), glucose (GLU), alanine aminotransferase (ALT), and aspartate aminotransferase (AST) test procedures on the Alere Cholestech LDX System)	Medical Device	Recall	Class II	Hospital
14/03/2013	IMMULITE 2500 IGF-I (An in vitro diagnostic medical device (IVD))	Medical Device	Recall for Product Correction	Class II	Hospital
14/03/2013	ML 301 Examination Lamp	Medical Device	Recall	Class II	Retail
13/03/2013	Alere Cholestech LDX hsCRP Cassette (An in vitro medical device (IVD) used in the quantitative determination of C-reactive protein in whole blood or serum)	Medical Device	Recall	Class II	Hospital
13/03/2013	Archer 0.035 inch (0.89mm) Super Stiff Guidewire	Medical Device	Recall	Class I	Hospital
13/03/2013	D-dimer Test kit for AQT90 Flex (An in vitro diagnostic medical device (IVD) used as an aid in the diagnosis of venous thromboembolism)	Medical Device	Recall	Class I	Hospital
12/03/2013	ConMed Linvatec VP1600 HD Still Capture Image System (Endoscopic video imaging system)	Medical Device	Recall for Product Correction	Class III	Hospital
12/03/2013	IntelliSpace Portal software version 4.0.2 (Used to remotely access data from networked computers for diagnostic viewing) used with URL PACS integration	Medical Device	Recall for Product Correction	Class I	Hospital
8/03/2013	Aquae Dry Mouth Gel Hypromellose Oral gel 20mg/g	Medical Device	Recall	Class III	Wholesale

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8/03/2013	Artis Zeego systems (Angiographic fluoroscopic digital diagnostic x-ray system) with software Artis VC20x/VC21A/VD10x that have a DSA license installed	Medical Device	Recall for Product Correction	Class I	Hospital
8/03/2013	Columbia Ultima Bath Chair	Medical Device	Recall for Product Correction	Class II	Consumer
8/03/2013	ExacTrac versions 6.0.1 and 6.0.2 only (Image Guided Radiation Therapy Patient Positioning System)	Medical Device	Recall for Product Correction	Class I	Hospital
8/03/2013	ISKD – Intramedullary Skeletal Kinetic Distractor (Limb Lengthener)	Medical Device	Recall	Class II	Hospital
8/03/2013	LIFEPAK CR Plus and LIFEPAK EXPRESS Automated External Defibrillators (AED)	Medical Device	Recall	Class I	Retail
7/03/2013	Switch Point Infinity 3 (SPI3) (Computer Interface)	Medical Device	Recall for Product Correction	Class III	Hospital
6/03/2013	Technetium-99m Technescan Sestamibi (Compounded radioactive dose prepared from a kit as a solution in a syringe for diagnostic imaging)	Medicine	Recall	Class II	Hospital
6/03/2013	TRIATHLON Baseplate Impactor/Extractor (Included in the reusable Triathlon primary or revision knee implantation kits)	Medical Device	Recall	Class III	Hospital
5/03/2013	Artis Zeego Systems (Fluoroscopic angiographic x-ray system)	Medical Device	Recall for Product Correction	Class III	Hospital
5/03/2013	Transpedicular Schanz Screw, 6.2mm with dual core, length 190/45mm. Titanium alloy (TAN), dark blue (Bone screw for internal spinal fixation system)	Medical Device	Recall	Class II	Hospital
4/03/2013	Brilliance 64, software version 4.0.0.22621 and Ingenuity CT, software version 4.0.025621 (Whole body computed tomography x-Ray systems)	Medical Device	Recall for Product Correction	Class II	Hospital
4/03/2013	Maxcem Elite (Dental cement)	Medical Device	Recall	Class II	Retail
1/03/2013	Bone Fragments - Milled irradiated femoral head	Biological	Hazard Alert	Class II	Hospital
28/02/2013	BiCision (electrosurgical thermofusion and dissection system)	Medical Device	Recall	Class II	Hospital
28/02/2013	Chlorhexidine 0.5% in Alcohol 70%	Medical Device	Recall	Class III	Wholesale

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28/02/2013	Dash 3000/4000/5000 (multiparameter patient monitor) & Dash Port 2 (docking station for Dash 3000/4000/5000)	Medical Device	Recall for Product Correction	Class II	Hospital
27/02/2013	All Plum A+ Family of Infusers: Plum A+Single Channel Infusion Pump, Plum A+ and A+3 Infusion Pumps with MedNet Software	Medical Device	Recall for Product Correction	Class I	Hospital
27/02/2013	All Plum A+ Family of Infusers: Plum A+Single Channel Infusion Pump, Plum A+ and A+3 Infusion Pumps with MedNet Software	Medical Device	Recall for Product Correction	Class I	Hospital
27/02/2013	All Plum A+ Family of Infusers: Plum A+Single Channel Infusion Pump, Plum A+ and A+3 Infusion Pumps with MedNet Software	Medical Device	Recall for Product Correction	Class I	Hospital
27/02/2013	All Plum A+ Family of Infusers: Plum A+Single Channel Infusion Pump, Plum A+ and A+3 Infusion Pumps with MedNet Software	Medical Device	Recall for Product Correction	Class I	Hospital
26/02/2013	RaySearch RayStation 3.0 (Radiation treatment planning and analysis software)	Medical Device	Recall for Product Correction	Class I	Hospital
25/02/2013	Abbott Molecular m 2000sp instrument. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
25/02/2013	ADEPT 12/14 Modular Head (Used as femoral head component in metal on metal (MoM) total hip arthroplasty)	Medical Device	Hazard Alert	Class II	Hospital
25/02/2013	TREPANOSTIKA TP Recombinant Kit (An in vitro diagnostic medical device (IVD) used for the qualitative determination of specific antibodies to Syphilis (treponema pallidum) in human serum or plasma)	Medical Device	Recall	Class I	Hospital
22/02/2013	Dade Actin FSL Activated Pro Thromboplastin Time (APTT) Reagent. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
22/02/2013	Drug 4 Cal (KC460) & Drug 4 Cal (KC460A) for use with the Dimension Vista System. In vitro diagnostic medical devices (IVD).	Medical Device	Recall	Class II	Hospital
22/02/2013	HOYA One-Piece Intraocular Lenses (IOL)	Medical Device	Recall	Class I	Hospital
22/02/2013	IPAD Defib Pad, CU-CUA0512F (used with I-PAD NF 1200 Defibrillator)	Medical Device	Recall for Product Correction	Class III	Retail

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22/02/2013	Oxoid Antimicrobial Susceptibility Testing Discs for Gentamicin (CN10). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
22/02/2013	Oxoid Antimicrobial Susceptibility Testing Discs for Norfloxacin (NOR10). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
22/02/2013	Restylane SubQ Lidocaine (Used for facial tissue augmentation)	Medical Device	Recall	Class II	Retail
22/02/2013	VITEK 2 60/XL and VITEK 2 Compact systems (In vitro diagnostic medical devices (IVD) used Bacterial identification and antibiotic sensitivity system)	Medical Device	Recall for Product Correction	Class I	Hospital
22/02/2013	Z Hyalin Multipack and Z Hyalin Plus Multipack	Medical Device	Recall	Class II	Retail
21/02/2013	FIAB Ultrasound Transmission and IPL Transparent Gel	Medical Device	Recall	Class II	Retail
21/02/2013	Vitrea Enterprise Suite: Vitrea, Vitrea fX and VitreaCore (Tool for analysis of diagnostic images)	Medical Device	Recall for Product Correction	Class I	Hospital
20/02/2013	DLP Single Stage Venous Cannula with Metal Tip (Intended for the collection of deoxygenated blood from the superior and/or inferior vena cava during cardiopulmonary bypass)	Medical Device	Recall	Class I	Hospital
20/02/2013	MuscleBack Energy Magnesium Complex 150 g Powder	Medicine	Recall	Class II	Consumer
20/02/2013	Oxoid Xpect Legionella Test Kit (R24680), an in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
19/02/2013	Philips HeartStart XL+ Defibrillator / Monitor (manual defibrillator)	Medical Device	Recall for Product Correction	Class I	Hospital
18/02/2013	Enzymatic Creatinine (EZCR) Flex Reagent Cartridge & Phosphorus (PHOS) Flex Reagent Cartridge for use on the Dimension Clinical Chemistry System. In vitro diagnostic medical devices (IVDs)	Medical Device	Recall for Product Correction	Class II	Hospital
18/02/2013	Kinevac (sincalide for injection) 5mcg (5mL vial)	Medicine	Recall	Class III	Retail
15/02/2013	Bone Unprocessed - Whole femoral head non-irradiated allograft	Biological	Hazard Alert	Class II	Hospital
15/02/2013	KWIK-QC Acid Fast Stain Slides (Microbiology quality control slides). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital

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15/02/2013	Thromborel S for use with the Sysmex CS-2000i or Sysmex CS-2100i analysers (Used for the determination of prothrombin time). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
15/02/2013	Vitrea Enterprise Suite : Vitrea, VitreaAdvanced, VitreaCore (VitalConnect) and Vitrea fX (Tool for analysis of diagnostic images)	Medical Device	Recall for Product Correction	Class I	Hospital
14/02/2013	CLOPIDOGREL RBX clopidogrel (as hydrogen sulfate) 75 mg tablets	Medicine	Recall	Class III	Consumer
13/02/2013	LifeCycle for Prenatal Screening, software versions V3.0, v3.1, v3.2, v4.0. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Retail
12/02/2013	Artis Zee/Zeego Systems equipped with A 100 plus generator (Fluoroscopic angiographic digital x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
12/02/2013	Monaco, Release 3.20.00 - 3.20.01 (Radiation Treatment Planning System)	Medical Device	Recall for Product Correction	Class I	Hospital
11/02/2013	Deep Brain Stimulation (DBS) Leads (implantable, neurological electrode stimulator)	Medical Device	Recall for Product Correction	Class I	Hospital
11/02/2013	SureSigns Patient Monitors, Model VS2+	Medical Device	Recall for Product Correction	Class I	Hospital
8/02/2013	HeartWare Ventricular Assist System (intended for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end stage heart failure)	Medical Device	Recall for Product Correction	Class I	Hospital
8/02/2013	Iconos R200 C20, Iconos R200 T20, Iconos R100, Iconos RHD, Luminos RF Classic, Luminos Fusion, Luminos Select (Fluoroscopic diagnostic x-ray systems)	Medical Device	Recall for Product Correction	Class I	Hospital
7/02/2013	Allura Xper FD20 Biplane / FD20 Biplane OR table (Fluoroscopic angiographic digital x-ray system)	Medical Device	Recall for Product Correction	Class I	Hospital
7/02/2013	Ceramic Insertion Tool Assembly (Supplied as part of the reusable orthopaedic surgical procedure kit)	Medical Device	Recall	Class I	Hospital
6/02/2013	Reflotron Hb Test Strips, an in vitro diagnostic medical device (IVD) intended for the quantitative measurement of haemoglobin in venous blood samples	Medical Device	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
6/02/2013	UniCel DxI 800 Access Immunoassay Systems, UniceL DxI 600 Access Immunoassay Systems, UniCel Dx C 660i, 680i, 860i, 880i SYNCHRON Access Clinical System. In vitro diagnostic medical devices (IVDs)	Medical Device	Recall for Product Correction	Class II	Hospital
5/02/2013	MAQUET Heart Lung Machine - HL30 (Heart-lung bypass system)	Medical Device	Recall for Product Correction	Class II	Hospital
5/02/2013	Medtronic Navigation O-Arm Imaging System (Digital fluoroscopic diagnostic portable x-ray system)	Medical Device	Recall for Product Correction	Class I	Hospital
4/02/2013	Eclipse Treatment Planning System, (Radiation therapy treatment planning system), version 11	Medical Device	Recall for Product Correction	Class I	Hospital
1/02/2013	Berman Angiographic Balloon Catheters	Medical Device	Recall for Product Correction	Class II	Hospital
1/02/2013	FCR Go 2 (FCR-MB201) X-Ray System (Digital general purpose mobile diagnostic x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
1/02/2013	Fenwal Transfer Pack 150ml with spike coupler (Blood collection/cell-culture container)	Medical Device	Recall for Product Correction	Class II	Hospital
1/02/2013	Gambro Conventional Bloodlines; BL200 BD Pre Post, BL208 BD & BL223PB (dialysis/haemodialysis tubing set)	Medical Device	Recall for Product Correction	Class II	Hospital
31/01/2013	Artis Zee Systems equipped with a card collimator	Medical Device	Recall for Product Correction	Class II	Hospital
31/01/2013	HeartStart Automated External Defibrillator (AED)	Medical Device	Recall for Product Correction	Class I	Retail
31/01/2013	ISOLINE 2CR6 and 2CT6 Implantable Defibrillation Leads	Medical Device	Hazard Alert	Class I	Hospital
31/01/2013	Level 1 Fast Flow Fluid Warmers with and without Air Detection	Medical Device	Recall for Product Correction	Class I	Hospital
30/01/2013	AcroMetrix PeliSpy Sero Control Type 36 and Type 38. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
30/01/2013	Apex (Multileaf collimator used with Elekta linear accelerators)	Medical Device	Recall for Product Correction	Class I	Hospital
29/01/2013	ACUSON S2000 Automated Breast Volume Scanner (ABVS)	Medical Device	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
29/01/2013	Correct Quick: Refill - Correct Quick Light Body 4pk, Refill - Correct Quick Light Body 32pk, Refill - Correct Quick Medium Body 4pk, Refill - Correct Quick Medium Body 32pk, Refill - Correct Quick Heavy Body 4pk, Refill - Correct Quick Heavy Body 32pk (dental impression material)	Medical Device	Recall	Class III	Retail
25/01/2013	Clopine Suspension - Clozapine 50mg/ml 100ml bottle	Medicine	Recall	Class II	Retail
25/01/2013	Hand Switch for Electric Pen Drive (electrical drive for use with a range of surgical attachments)	Medical Device	Recall	Class II	Hospital
25/01/2013	Razit 20 rabeprazole sodium 20mg enteric coated tablets blister pack of 28's	Medicine	Recall	Class III	Retail
25/01/2013	Ventri and Discovery NM 530c (Full body computed tomography (CT) system)	Medical Device	Recall for Product Correction	Class II	Hospital
25/01/2013	XVI R3.5, R4.0, R4.2 and R4.5 (X-ray volume imager intended to confirm patient positioning and support decision making in response to target displacement resulting from organ deformation and anatomical movement during radiation therapy)	Medical Device	Recall for Product Correction	Class I	Hospital
22/01/2013	Confidence Spinal Cement System 11cc Plus Kit, Confidence Spinal Cement System Kit	Medical Device	Recall	Class II	Hospital
22/01/2013	Corneal Grafts	Biological	Hazard Alert	Class II	Hospital
22/01/2013	Medtronic Ardian Symplicity Catheter System	Medical Device	Recall	Class II	Hospital
22/01/2013	Mizuho OSI 5855 Orthopedic Table Top	Medical Device	Recall for Product Correction	Class II	Hospital
22/01/2013	VITROS Vapor Adsorption Cartridge. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class I	Hospital
21/01/2013	A52103 Navios 10 Colours/3 Lasers, A52102 Navios 8 Colours/2 Lasers, A52101 Navios 6 Colours/2 Lasers (Navios Flow Cytometers). In vitro diagnostic medical devices (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
21/01/2013	XVI R3.5.1, R4.2.1 and R4.5.1 (X-ray volume imager intended to confirm patient positioning and support decision making in response to target displacement resulting from organ deformation and anatomical movement during radiation therapy)	Medical Device	Recall for Product Correction	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
18/01/2013	Albuterex Xtreme, Albutarex Xtreme and Albutarex Femme (promoted as fat-loss product)	Medicine	Recall	Class I	Consumer
18/01/2013	Alkaline Phosphatase (ALPAMP and ALPDEA), An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
18/01/2013	Dimension Tacrolimus (TACR) Flex Reagent Cartridge, An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class I	Hospital
18/01/2013	Fentanyl Intranasal Solution 600 Microgram/2mL (Non sterile aqueous solution)	Medicine	Recall	Class II	Hospital
18/01/2013	Sofia Influenza A+B FIA Kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
17/01/2013	CEM Nosecone for use with CUSA Excel/Excel+ Ultrasonic Aspirator	Medical Device	Recall for Product Correction	Class II	Hospital
17/01/2013	MobileDiagnost wDR (mobile x-ray unit)	Medical Device	Recall for Product Correction	Class II	Hospital
17/01/2013	STA - Liatest vWF: Ag assay used with the STA-R/STA-R EVOLUTION analyser. An in vitro diagnostic medical device (IVD) for the measurement of von Willebrand factor.	Medical Device	Recall for Product Correction	Class II	Hospital
17/01/2013	Swift Mobile Shower Chair (includes Swift Mobile 160 shower chair, Swift Mobile 24" shower chair, Swift Mobile Tilt shower chair, Swift Mobile Tilt 160 shower chair).	Medical Device	Recall for Product Correction	Class II	Retail
16/01/2013	BM Lactate Test Strips for use with the Accutrend Plus, Accutrend GC/GCT/Lactate. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
15/01/2013	Brilliance CT series (6, 10, 16, 16 Power, 40, 64, CT Big Bore and CT Big Bore Oncology), iCT, iCT SP, Ingenuity Core, Ingenuity CT and	Medical Device	Recall for Product Correction	Class II	Hospital
15/01/2013	Tracheal tube	Medical Device	Recall	Class II	Hospital
10/01/2013	HAMILTON-T1 Transport Ventilator, Software version 1.1.2	Medical Device	Recall for Product Correction	Class I	Hospital
10/01/2013	TempSpan CMT Dental Cement (used to take dental impressions)	Medical Device	Recall	Class III	Retail
9/01/2013	MX 16-Slice CT scanner	Medical Device	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
8/01/2013	ARCHITECT Testosterone Reagent, ARCHITECT Testosterone Calibrators and ARCHITECT Testosterone Controls. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
8/01/2013	BBL Crystal Enteric/Non-fermenter ID Kit, An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
8/01/2013	Giraffe Incubator and Giraffe OmniBed with Servo Oxygen Control System	Medical Device	Recall for Product Correction	Class I	Hospital
8/01/2013	QHVB Pulmonary Allograft Conduit (Human cardiovascular tissue)	Biological	Hazard Alert	Class I	Hospital
8/01/2013	SOMATOM CTs: Definition Flash, Definition Edge, Definition AS and Definition (full body CT diagnostic x-ray systems) equipped with software syngo CT2010A, CT2010B, CT2011A and CT2012B	Medical Device	Recall for Product Correction	Class II	Hospital
7/01/2013	Quadra Trial Broach size 0	Medical Device	Recall	Class II	Hospital
4/01/2013	Bunnell Life Pulse Patient Circuits (Used with Life Pulse High Frequency Ventilator)	Medical Device	Recall	Class I	Hospital
4/01/2013	Plum A+ Infusion Pump; Plum A+ Infusion Pump with Hospital MedNet Software; Plum A+3 Infusion Pump with Hospital MedNet Software	Medical Device	Recall	Class I	Hospital
2/01/2013	4" Goldvac UltraClean Blade, Single Use ABC Needle, 1" UltraClean Needle & Blade with extended insulation and 6" UltraClean Blade (Electrosurgical system electrodes & accessories)	Medical Device	Recall	Class II	Hospital
2/01/2013	A.5650.5 LEM non-sterile haemorrhoid suction bander and Latex gravorings	Medical Device	Recall for Product Correction	Class II	Retail
24/12/2012	ADVIA Centaur and ADVIA Centaur XP HBsAg II Assay. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
24/12/2012	AutoTac Delivery Handle 400-200 and AutoTac Titanium Tack Starter Kit 400-270 (Dental membrane fixation kit)	Medical Device	Recall for Product Correction	Class II	Retail
24/12/2012	cobas IT 1000, version 2.00.00.02 to current, ESX 4.1 platform virtual server (Analyser software). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
24/12/2012	ELS Cannulae (Part of intravenous catheterisation kit)	Medical Device	Recall	Class I	Hospital

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24/12/2012	Fill-In Refill A1 and A2 (temporary crown/bridge)	Medical Device	Recall	Class III	Retail
24/12/2012	Lumenis VersaCut Tissue Morcellator (soft tissue extraction)	Medical Device	Recall for Product Correction	Class I	Hospital
24/12/2012	Nobel Replace CC NP 3.5 x 10mm implant (Dental Implant Endosseous)	Medical Device	Recall	Class II	Retail
24/12/2012	Urinary Catecholamines by HPLC Reagent Kits, Automated Method on Gilson ASPEC. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
21/12/2012	A3/A5 Anesthesia Delivery System	Medical Device	Recall for Product Correction	Class II	Hospital
21/12/2012	Cook Medical Zilver PTX Drug-Eluting Peripheral Stent (peripheral artery stent)	Medical Device	Recall for Product Correction	Class I	Hospital
21/12/2012	Ventolin Inhaler CFC-free Salbutamol 100 microgram (as sulphate) pressurised inhaler metered dose, 200 doses, and ASMOL CFC-FREE Inhaler Salbutamol 100 microgram (as sulfate) pressurised inhaler metered dose, 200 doses.	Medicine	Recall	Class I	Retail
20/12/2012	Dimension Clinical Chemistry System, Total Iron Binding Capacity. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
19/12/2012	Animas 2020 Insulin Infusion Pumps (ambulatory infusion pump)	Medical Device	Recall for Product Correction	Class I	Consumer
19/12/2012	cobas Product System Manager (PSM) (Analyser software), all versions. An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
19/12/2012	Liaison Biotrin Parvovirus B19 IgM (testing kit), An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
18/12/2012	MobileDiagnost wDR (digital diagnostic X-ray imaging system)	Medical Device	Recall for Product Correction	Class II	Hospital
18/12/2012	SYNCHRON Systems Glucose (GLU) cartridge Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
17/12/2012	AU5800 Clinical Chemistry Analyzer, software versions 4.05 and prior. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
17/12/2012	LSX Files, 25mm (Powered endodontic rasp)	Medical Device	Recall	Class III	Retail

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14/12/2012	Belmont Instrument Corporation Rapid Infuser (high flow, warming infusion pump).	Medical Device	Recall for Product Correction	Class I	Hospital
14/12/2012	NARDIL phenelzine 15mg (as sulphate) 100 tablet bottle	Medicine	Recall	Class III	Wholesale
14/12/2012	UCFP Flex Reagent Cartridge (Urinary / Cerebrospinal fluid protein assay) used with Dimension Vista Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
13/12/2012	Philips IntelliVue Information Centre and Philips IntelliVue Information Centre iX (Central patient monitor unit)	Medical Device	Recall for Product Correction	Class I	Hospital
10/12/2012	ARCHITECT Active-B12 (Holotranscobalamin). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
10/12/2012	Oxoid Anti-microbial Susceptibility Testing Disc for Nitrofurantoin. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
7/12/2012	ARIA Radiation Oncology System (information system), versions: 11.0 below 11.0.55, Build 11.02.28 and 11.0.34	Medical Device	Recall for Product Correction	Class I	Hospital
7/12/2012	Corpuls Defibrillator (Automated defibrillator). Software version 2.0.0 and 2.0.2	Medical Device	Recall for Product Correction	Class I	Retail
7/12/2012	DigitalDiagnost (Digital diagnostic X-Ray System). All systems with Eleva software version 3.0.x	Medical Device	Recall for Product Correction	Class II	Hospital
7/12/2012	Radiometer TCM4 series analyser base units (Transcutaneous and non invasive blood gas analysers)	Medical Device	Recall for Product Correction	Class I	Hospital
7/12/2012	X-Ray detectable tracer thread included on patient swab / bandage (swabs are included in Sterile Suture, Catheter and Lumbar Puncture Kits)	Medical Device	Recall	Class II	Hospital
6/12/2012	DBB-06, DBB-07 Haemodialysis Device (haemofiltration dialysis unit)	Medical Device	Recall for Product Correction	Class I	Hospital
6/12/2012	DigitalDiagnost (Digital diagnostic X-Ray System) with software version 2.0.2 and 2.0.2SP1	Medical Device	Recall for Product Correction	Class II	Hospital
6/12/2012	MagNA Pure 96. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital

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5/12/2012	AMH Gen II ELISA (clinical chemistry substrate, Anti-Mullerian Hormone assay). An in vitro diagnostic medical device (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
5/12/2012	Crutches - Forearm Ergo Grip Tall and Forearm Ergo Grip Adult (one arm, walking aid crutch)	Medical Device	Recall	Class II	Consumer
5/12/2012	DualHemo Mcable for use with the Infinity Acute Care System (IACS) (Patient monitoring system)	Medical Device	Recall for Product Correction	Class II	Hospital
5/12/2012	Siroclave Dental Sterilisers (moist heat autoclave)	Medical Device	Recall	Class II	Retail
4/12/2012	TumorLOC (intensity projection dataset software) use with: Brilliance CT Big Bore, EBW, GEMINI LXL, GEMINI TF 16, GEMINI TF 64 & GEMINI TF Big Bore (radiology systems)	Medical Device	Recall for Product Correction	Class I	Hospital
4/12/2012	Vatech X-Ray System, models: Pax-500, Pax-Uni3D, pax-Reve3D and Duo3D and Picasso 3D (Dental x-ray system)	Medical Device	Recall for Product Correction	Class II	Retail
4/12/2012	Z Hyalin Multipacks and Z Hyalin Plus Multipacks (aqueous/vitreous (eye) humour replacement medium kit)	Medical Device	Recall	Class II	Retail
3/12/2012	Coverstainer Slide Rack (automated staining instrument). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
3/12/2012	Liko Sabina and Capella Sit-to-Stand Mobile Lifts	Medical Device	Recall for Product Correction	Class II	Hospital
30/11/2012	Artis Zeego Systems (Fluoroscopic diagnostic x-ray system for angiographic procedures) with SW revision VC14, VC20 & VC21 in conjunction with a specific technical configuration	Medical Device	Recall for Product Correction	Class II	Hospital
30/11/2012	IH-Com Kit Full version (Data management and Result Interpretation Software for ABO blood grouping). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class I	Hospital
30/11/2012	Velcade 1mg powder for injection (VELCADE bortezomib 1mg powder for injection vial)	Medicine	Recall for Product Correction	Class II	Hospital
29/11/2012	Advanced Perfusion System 1 (heart-lung bypass machine)	Medical Device	Recall for Product Correction	Class I	Hospital
29/11/2012	Welch Allyn Schiller AG 1500 Monitor (multi parameter patient monitor)	Medical Device	Recall for Product Correction	Class III	Hospital

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28/11/2012	Clinical Chemistry Phenobarbital Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
28/11/2012	DigitalDiagnost (Digital diagnostic X-Ray System) All systems with Eleva software version 2.1.3	Medical Device	Recall for Product Correction	Class II	Hospital
28/11/2012	ENSEAL G2 Curved and Straight Tissue Sealer Devices (used in endoscopic procedures)	Medical Device	Recall	Class II	Hospital
28/11/2012	Phenobarbital Reagent (used with ADVIA Chemistry System). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
27/11/2012	2.7mm Self-Tapping Cortex Screw (internal fixation device)	Medical Device	Recall	Class II	Hospital
27/11/2012	Active Knee System - Patella Insert (Used as a component in total knee replacement)	Medical Device	Hazard Alert	Class II	Hospital
27/11/2012	DR0850M, Oxoid Staphytest plus 100 tests (used for the identification of Staphylococcus aureus). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
26/11/2012	Ardis Inserter (intended for delivery of the Ardis interbody spacer into the prepared disc space)	Medical Device	Recall for Product Correction	Class I	Hospital
23/11/2012	Brilliance 64 system with software version 4.00xx516 and Ingenuity CT system running software version 4.00xx518 (full body CT systems)	Medical Device	Recall for Product Correction	Class II	Hospital
23/11/2012	CLINITEK Atlas and Chek-Stix Positive Urinalysis Control Solutions. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
23/11/2012	GlideScope Video Laryngoscope Blades GVL3, GVL4 and GVL5 (used for intubation)	Medical Device	Recall	Class I	Hospital
23/11/2012	Replace Select Tapered TiU RP 4.6x16mm (fully imbedded dental implant)	Medical Device	Recall	Class III	Retail
23/11/2012	Table pallet for use with Discovery NM/CT 670 & Discovery NM630 (Diagnostic full body CT X-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
22/11/2012	Alaris GP Large Volumetric Pump (general purpose infusion pump)	Medical Device	Recall for Product Correction	Class II	Hospital
22/11/2012	Biomet 2.5MM offset tibial tray adaptor (tibial component of knee joint prosthesis)	Medical Device	Hazard Alert	Class II	Hospital
22/11/2012	Coffee Shape Slimming Green Coffee	Medicine	Recall	Class II	Retail

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22/11/2012	MEDRAD Avanta Hand Controller Sheath (multi-phase contrast medium injection system)	Medical Device	Recall	Class II	Hospital
22/11/2012	Steris Reliance 130L Cart Washer (decontamination washer utensil)	Medical Device	Recall for Product Correction	Class II	Hospital
21/11/2012	Access Immunoassay System, Access 2 Immunoassay System, Synchron LXi 725 Clinical System, UniCel 600i Synchron Access Clinical System. In vitro diagnostic medical devices (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
21/11/2012	Amvisc Plus 0.8mL (Aqueous/vitreous humour replacement medium (eye))	Medical Device	Recall	Class II	Hospital
21/11/2012	Automatic Quality Control (AQC) Cartridge for use with the RAPIDLab 1200 Series, RAPIDPoint 400 Series and RAPIDPoint 500 Analysers. In vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
21/11/2012	Immulite / Immulite 1000 XPi IGF-1 and Immulite 2000 / Immulite 2000 XPi IGF-1. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
21/11/2012	MOBICATH Bi-Directional Guiding Sheath, small curve (used to introduce cardiovascular catheters)	Medical Device	Recall	Class I	Hospital
21/11/2012	Nihon Kohden Defibrillator (semi-automated defibrillator)	Medical Device	Recall for Product Correction	Class I	Hospital
16/11/2012	Adult Circuit Tubing (Oxygen therapy delivery system)	Medical Device	Recall	Class II	Hospital
15/11/2012	"PROFEMUR R" PROX BODY PLASMA SPRAYSTD3 (femoral component of a hip joint prosthesis)	Medical Device	Hazard Alert	Class II	Hospital
15/11/2012	ACL ELITE, ACL ELITE PRO, ACL 8000, ACL 9000 and ACL 10000 (coagulation analysers)	Medical Device	Recall for Product Correction	Class II	Hospital
15/11/2012	A-dec 200 Dental Chair (examination chair)	Medical Device	Recall for Product Correction	Class II	Retail
15/11/2012	SonoSite NanoMaxx Ultrasound System, version 60.80.101.025	Medical Device	Recall for Product Correction	Class II	Hospital
14/11/2012	ADVIA Centaur and Centaur XP Instrument Systems (immunoassay analysers). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital

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14/11/2012	Rayner T-Flex Aspheric 623T Intraocular Lens (Posterior chamber intraocular lenses)	Medical Device	Recall	Class I	Wholesale
14/11/2012	YUNO Extension Device (used to support and stabilise the patient's body during a surgical procedure)	Medical Device	Recall for Product Correction	Class II	Hospital
13/11/2012	DRX-1 System Console (radiation therapy digital imager)	Medical Device	Recall for Product Correction	Class I	Hospital
13/11/2012	VIPER 8, 9 & 10mm Large Diameter Polyaxial Screws, Lengths 70, 80 & 100 mm (To provide immobilisation and stabilisation of spinal segments in the treatment of instabilities or deformities of the thoracic, lumbar, and sacral spine)	Medical Device	Recall	Class II	Hospital
13/11/2012	VITROS Chemistry Products HPT Reagent. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
12/11/2012	Access hLH Calibrators used with Access Immunoassay Systems. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
12/11/2012	Mammomat Inspiration (diagnostic mammography X-Ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
9/11/2012	AU5800 diluted detergent tank used with AU5800 Clinical Chemistry Analyser. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
8/11/2012	ADVIA Centaur/Centaur XP/ Centaur CP HBcTotal (HBcT) Kits. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
8/11/2012	Micro Curved Attachment (MCA) and MCA Cutting Burrs (Intended for use in delicate bone in otologic (ear) procedures such as cochleostomy)	Medical Device	Recall	Class II	Hospital
8/11/2012	Multiple assays used with ADVIA Centaur, ADVIA Centaur XP, ADVIA Centaur CP Systems: Theophylline 2, Procalcitonin, Folate, DHEA-SO ₄ , CA 19-9, BR Assay for CA 15-3, BR Assay for CA 27.29, BNP (B-type Natriuretic Peptide), In vitro diagnostic medical devices (IVDs)	Medical Device	Recall for Product Correction	Class II	Hospital
8/11/2012	Spacelabs Healthcare Qube Compact Monitor (Multi parameter transportable patient monitor)	Medical Device	Recall for Product Correction	Class II	Hospital
8/11/2012	STERRAD CYCLESURE 24 Biological Indicators (sterilisation process indicator)	Medical Device	Recall	Class II	Hospital

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6/11/2012	Haag-Streit International - Tonometer Measuring Prisms (an ophthalmic device used to measure eye ocular pressure/tension).	Medical Device	Recall for Product Correction	Class II	Retail
5/11/2012	BioPlant Curved Syringe, multiple doses, BioPlant Intro Pack (synthetic dental bone grafts)	Medical Device	Recall for Product Correction	Class II	Retail
2/11/2012	PAD 300/PAD 300P Public Access Defibrillators (PAD) (Semi-automated defibrillator)	Medical Device	Recall for Product Correction	Class I	Retail
1/11/2012	Cobas 8000 Patient sample and control recovery on Cobas c 701/702 modules (clinical chemistry analyser). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
1/11/2012	Cobas IT 3000 version 2.03.04 to 2.04.00, Cobas 8000 Data Manager version 1.02.02 to 1.02.05, Cobas INTEGRA 400 and Cobas INTEGRA 400 Plus. In vitro diagnostic medical devices (IVD).	Medical Device	Recall for Product Correction	Class II	Hospital
1/11/2012	Dimension Vista ALP Calibrator (clinical chemistry enzyme). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
1/11/2012	Lactate membrane for ABL700 series and ABL800 series blood gas analysers (Part 942-066, D7077) . An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
31/10/2012	Cordis ExoSeal Vascular Closure Device (femoral artery compression device)	Medical Device	Recall	Class II	Hospital
31/10/2012	FlexiView 8800 Mobile C-Arms (Mobile, general-purpose, diagnostic, fluoroscopic x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
31/10/2012	HeartWare Sterile Surgical Tool Sets (Supplied as part of the HeartWare Ventricular Assist System, artificial heart (HVAS))	Medical Device	Recall	Class III	Hospital
31/10/2012	OEC 6800 MiniView C-arms (Mobile, general-purpose, diagnostic, fluoroscopic x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
31/10/2012	SureSafe Wraps and Drapes	Medical Device	Recall	Class II	Hospital
30/10/2012	Extended Brilliance Workstation with running software versions 4.0.2, V4.5.2 or V4.5.3 (To perform offline measurement and manipulation of CT images, diagnostic X-ray system)	Medical Device	Recall for Product Correction	Class I	Hospital

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30/10/2012	Liquid Assayed Multiqual Premium (multi analyte control material). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
30/10/2012	OriGen Syringe DMSO (Used for Research Use Only)	Medical Device	Recall	Class II	Hospital
29/10/2012	Encore 26 Advantage Kit & Encore 26 Advantage Kit, 5 pack (Used to perform general intravascular procedures)	Medical Device	Recall for Product Correction	Class II	Hospital
29/10/2012	Essenta DR Compact (Digital diagnostic X-Ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
29/10/2012	Monitors B20 or B40 Software version VSP-A_1.10 (or earlier) (Multiparameter Patient Monitor)	Medical Device	Recall for Product Correction	Class I	Hospital
29/10/2012	Muscletech Hydroxystim 3s, 18s, 110s and 200s Capsules	Medicine	Recall	Class I	Consumer
29/10/2012	Nihon Kohden Defibrillator CardioLife, Model Number: TEC 5521 & 5531 (Semi-automated defibrillator)	Medical Device	Recall for Product Correction	Class I	Hospital
26/10/2012	Jurlique Grapefruit Essential Oil 10mL	Medicine	Recall	Class III	Retail
26/10/2012	S500 Hi-Lo Bed (General Purpose Bed)	Medical Device	Recall	Class III	Retail
24/10/2012	ARIA Oncology Information System, version 11 (A suite of software modules designed to manage the entire process of a patient's course of treatment including treatment plans and image management)	Medical Device	Recall for Product Correction	Class I	Hospital
24/10/2012	CD7 Mouse Monoclonal Antibody (MRQ-12) 1ml concentrate and CD7 Mouse Monoclonal Antibody (MRQ-12) 0.5ml concentrate (T-cell markers used in immunohistochemistry). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
24/10/2012	CT0034B Nitrofurantoin 100ug F100 Antimicrobial Susceptibility Discs. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
23/10/2012	Bio-Rad Multispot HIV-1 / HIV-2 Rapid Test. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class I	Hospital
23/10/2012	GE Corometrics Qwik Connect Plus Spiral Electrodes (single use electrodes used for electrocardiographs)	Medical Device	Recall	Class II	Hospital
23/10/2012	ORT100 Neurosurgical Table (for Intra-operative MRI Suites)	Medical Device	Recall for Product Correction	Class II	Hospital

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23/10/2012	PSX Proximate Skin Staple Extractor (staple remover)	Medical Device	Recall	Class II	Hospital
23/10/2012	Resuscitation Systems with blender field upgrade installed in GE Giraffe and Panda Warmers (infant radiant warmer)	Medical Device	Recall for Product Correction	Class I	Hospital
23/10/2012	syngo WorkFlow SLR (Radiology workflow software). Product versions: VA31A SP1, VA31A SP2 & VA31A SP3	Medical Device	Recall for Product Correction	Class II	Hospital
22/10/2012	BacT/ALERT 3D B.40.xx Firmware (Automated blood culture incubator/growth detector). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
22/10/2012	Elecsys Thyroglobulin assay used with the Elecsys Modular Analytics analysers An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
22/10/2012	Quantiferon (QFT) Gold Tubes, QFT Gold Unitised Pack, TB Ag Tubes 100ct, QFT Gold Tubes (Nil & TB & Mitogen) High Altitude. An in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class II	Hospital
22/10/2012	Various mass spectrometers - Quattro micro, ACQUITY TQD, Quattro Premier XE, Xevo TQ; In vitro diagnostic medical devices (IVD's)	Medical Device	Recall for Product Correction	Class II	Hospital
19/10/2012	Blooms Melt (weight loss formula), 60 Vege Capsules	Medicine	Recall for Product Correction	Class III	Retail
18/10/2012	Apex K2 Modular Hip Replacement System (total joint prosthesis)	Medical Device	Hazard Alert	Class II	Hospital
18/10/2012	MOSAIQ (Radiation Oncology Information System). All releases pre version 2.41	Medical Device	Recall for Product Correction	Class I	Hospital
16/10/2012	ChromID Strepto B agar (Used for screening of S. agalactiae carriage in pregnant women and potential infections in newborns). An in-vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
16/10/2012	StreamLAB Automation Solutions (Clinical Chemistry Sample Processors). An in-vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
11/10/2012	Canon CXDI-70C Wireless and CXDI-80C Wireless (Computed Radiographic System)	Medical Device	Recall for Product Correction	Class III	Hospital
11/10/2012	DigitalDiagnost (Digital Diagnostic X-ray System)	Medical Device	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
11/10/2012	Kryptonite Bone Cement / Kryptonite X-Radiopaque Bone Cement (Intended for use as a self-setting bone void filler for bony voids or gaps that are no intrinsic to the stability of the bony structure)	Medical Device	Recall for Product Correction	Class III	Wholesale
11/10/2012	Plum A+ Pump Version 11.6 and Plum A+ Pump Version 13.4 Med Net ABG Driver (general purpose infusion pump)	Medical Device	Recall for Product Correction	Class II	Hospital
11/10/2012	Zoo Pack Elastics Master Pack 2E 3/16 Hvy Kangaroo (Orthodontic elastic bands)	Medical Device	Recall	Class III	Retail
10/10/2012	IMMULITE 1000, 2000, 2000 XPi - IGF-I Control Module (Used for the detection of insulin like Growth Factor hormone). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
10/10/2012	IMMULITE 2000 / IMMULITE 2000 XPi ACTH Control module (Used for the detection of Adrenocorticotrophic hormone). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
10/10/2012	INFANRIX HEXA injection composite pack (pre-filled syringe and vial)	Medicine	Recall	Class II	Retail
10/10/2012	Mobile Detector Holder for DigitalDiagnost System (Digital diagnostic x-ray System). Models: Single Detector, Dual Detector, Release 3	Medical Device	Recall for Product Correction	Class III	Hospital
10/10/2012	Siemens AX System (Digital fluoroscopic x-ray system) fitted with MAVIG PORTEGRA 2 System (Radiation protection system)	Medical Device	Recall for Product Correction	Class II	Hospital
5/10/2012	Expert Tibial Nail PROtect Ø 8.0 – 13.0 mm, cannulated, length 255 – 465 mm, Gentamicin Sulphate, Titanium Alloy (TAN), dark blue, sterile, (Antibiotic coated tibial nail)	Medical Device	Recall	Class II	Hospital
4/10/2012	Cancellous Bone Impactor 6.0mm, Flattened (Supplied as part of the bone internal fixation system implantation kit)	Medical Device	Recall	Class II	Hospital
4/10/2012	Durom Acetabular Component (Used for metal on metal hip replacements)	Medical Device	Hazard Alert	Class II	Hospital
4/10/2012	Surecan Angled Needle (Non-coring needle for access ports)	Medical Device	Recall	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
4/10/2012	Triathlon CR/PS Inserts & ASYM Patella, Brunswik Captive Cemented Cup, Avon Patella Medium & Patella Femoral Joint, HMRS Humerus Bearing, MRH Bumper Neutral/3 Degrees & Tibial Inserts, Scorpio CR Tibial Insert & Medialised Patella, Duracon PCA Femoral, Patella & Constrain Inserts, Scorpio PS Tibial & Flex PS/+PS/+PCS Inserts (total knee, hip, shoulder components) and Artisan Bone Plug	Medical Device	Recall	Class II	Hospital
4/10/2012	Typhim Vi Vaccine 25ug/0.5mL Solution for Injection (Salmonella typhi Vi polysaccharide)	Medicine	Recall	Class III	Retail
3/10/2012	Brilliance CT Big Bore with Software Versions 2.4.7 or 2.4.8 (Full body CT system)	Medical Device	Recall for Product Correction	Class II	Hospital
3/10/2012	Dimension Vista IRON Flex reagent cartridge. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
3/10/2012	Spring Arm (Intended for use as a ceiling mounted device to support or position equipment in the patient area)	Medical Device	Recall for Product Correction	Class I	Hospital
2/10/2012	Birmingham Hip Modular Head (Used as part of a Total Conventional Hip Replacement system)	Medical Device	Hazard Alert	Class II	Hospital
2/10/2012	HLS Cannulae (Used for the cannulation of suitable vessels during extra corporeal circulation as inflow or outflow cannula)	Medical Device	Recall	Class II	Hospital
28/09/2012	Hospira LifeCare 4200 Patient-Controlled Analgesia (PCA) Infuser, PCA with MedNet Software Infusers (general purpose infusion pump).	Medical Device	Recall for Product Correction	Class I	Hospital
28/09/2012	PillCam Express Delivery Device (Indicated for the transendoscopic delivery of the PillCam SB video capsule in patients who are unable to ingest the PillCam capsule or are known to have slow gastric emptying time)	Medical Device	Recall	Class I	Hospital
27/09/2012	MX 16-Slice (Full body CT system) oil accumulator within gantry	Medical Device	Recall for Product Correction	Class II	Hospital
27/09/2012	TempSpan CMT (Temporary composite dental cement)	Medical Device	Recall for Product Correction	Class III	Retail

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
26/09/2012	ARCHITECT HAVAb-IgG Assay (Indicated as an aid in the diagnosis of hepatitis A viral infection or detection of IgG anti-HAV). An in-vitro diagnostic medical device	Medical Device	Recall for Product Correction	Class II	Hospital
26/09/2012	BD MAX (6 channel) Instruments (Automated specimen preparation and PCR amplification/detection instrument). An in-vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
26/09/2012	HeartStart XL Defibrillator Battery / Monitor, model M3516A (manual defibrillator).	Medical Device	Recall for Product Correction	Class I	Hospital
26/09/2012	IMMULITE /IMMULITE 1000 Osteocalcin Control Module (Clinical chemistry hormones). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
26/09/2012	Spectra Optia Apheresis System	Medical Device	Recall for Product Correction	Class II	Hospital
25/09/2012	Osseotite NT Certain Implant 5mm x 10mm (endosseous dental implant)	Medical Device	Recall	Class II	Retail
25/09/2012	VenoCath Drum Cartridge Catheter (intravascular catheter)	Medical Device	Recall	Class I	Hospital
24/09/2012	Standard Cranial Reference Array (used with Vector Vision Cranial Navigation System)	Medical Device	Recall	Class II	Hospital
21/09/2012	Bolton Surgical - Sims Speculum D/E Insulated Large 33 x 38 mm 18.5cm	Medical Device	Recall	Class II	Hospital
21/09/2012	Brilliance CT 6, 16, MX8000 v. EXP and GEMINI Dual Oil Accumulator within the Gantry (combination diagnostic imaging system (PET/CT)	Medical Device	Recall for Product Correction	Class II	Hospital
21/09/2012	Invacare I-Fit Shower Chair	Medical Device	Recall	Class II	Consumer
21/09/2012	Sorin S5/C5 Perfusion System: S5 Single Roller Pump 150 and S5 Double Roller Pump 85 (Heart-lung Bypass System)	Medical Device	Recall for Product Correction	Class I	Hospital
21/09/2012	Zimmer A.T.S. 3000 Automatic Tourniquet System (used to temporarily occlude blood flow during surgery)	Medical Device	Recall for Product Correction	Class II	Hospital
20/09/2012	Patient Labels for Zimmer orthopaedic implants manufactured prior to March 2010.	Medical Device	Recall for Product Correction	Class III	Hospital

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20/09/2012	SIFROL (pramipexole HCl) Tablets 0.125mg 30's, SIFROL (pramipexole HCl) Tablets 0.25mg 100's, SIFROL (pramipexole HCl) Tablets 1mg 100's	Medicine	Recall for Product Correction	Class II	Retail
20/09/2012	Soft-Core Obturators (Warm bonded endodontic obturation system obturator)	Medical Device	Recall	Class III	Retail
19/09/2012	Genscreen HIV Ag/Ab Ultra. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
19/09/2012	Patient Specific Active Medication Rolls containing SERENACE 0.5mg Tablets	Medicine	Recall	Class I	Consumer
14/09/2012	Flex Large 4 Coil for MAGNETOM Skyra, Verio, Spectra and Biograph mMR (Full body MRI System)	Medical Device	Recall for Product Correction	Class II	Hospital
14/09/2012	INHALO CD Cylinder (Medical oxygen), Product Code: 400CD	Medicine	Recall	Class II	Hospital
14/09/2012	SPIRALOK Anchors (suture anchors used to reattach soft tissue to bone in orthopaedic surgery)	Medical Device	Recall	Class II	Hospital
14/09/2012	Stellaris PC Vision Enhancement System (Cataract Extraction/Vitreotomy System)	Medical Device	Recall for Product Correction	Class II	Hospital
14/09/2012	SureSigns VSi/VS2 Patient Monitors (multiparameter patient monitor)	Medical Device	Recall for Product Correction	Class II	Hospital
13/09/2012	B. Braun Infusomat Space Infusion System (infusion pump)	Medical Device	Recall for Product Correction	Class II	Hospital
13/09/2012	Serenace (haloperidol) 0.5mg tablet bottle	Medicine	Recall	Class I	Consumer
12/09/2012	Arthrex and Andreas Hettich Rotofix 32A Centrifuge, An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital
12/09/2012	Immulite 2000, 2000 XPi EBV-EBNA IgG Assay; An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
11/09/2012	V60 Non Invasive Ventilators (adult mechanical ventilator)	Medical Device	Recall for Product Correction	Class I	Hospital
7/09/2012	ClearLink System BURETROL Solution Set with 150ml ClearLink Burette (Ball-Valve Drip Chamber) (Administration sets for the infusion of intravenous solutions and blood)	Medical Device	Recall	Class I	Hospital

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7/09/2012	Eclipse Treatment Planning System, (radiation therapy treatment planning system). Versions: 8.9 and 10	Medical Device	Recall for Product Correction	Class II	Hospital
7/09/2012	GH3 Lifting Hanger (patient lift)	Medical Device	Recall for Product Correction	Class II	Retail
6/09/2012	ADVIA Centaur BR Assay for CA 27.29, ADVIA Centaur BR Assay for CA 15-3. An in vitro diagnostic devices (IVD)	Medical Device	Recall	Class II	Hospital
6/09/2012	Mystic Pump with M-Style Mushroom Cup, Pack Size 1	Medical Device	Recall	Class II	Hospital
6/09/2012	Remel Xpect Clostridium difficile Toxin A/B. An vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
5/09/2012	Equinoxe Reverse Compression Screws, Replicator Plates, Locking Screws, Compression Screw Kit, Fracture Adapter Tray Screws and Octane-C Intervertebral fusion devices (intended for Primary and Reverse Total Shoulder joint Arthroplasty)	Medical Device	Recall	Class II	Hospital
5/09/2012	Multiple Topiramate Sandoz 60 HDPE tablet bottle, various concentrations	Medicine	Recall	Class II	Retail
5/09/2012	Octagam 10% 20g/200mL Human Normal Immunoglobulin (solution for intravenous infusion)	Medicine	Recall	Class II	Hospital
5/09/2012	Water Filters on Cavitron Scalers and Air Polishing Units (ultrasonic peridontic scaler)	Medical Device	Recall for Product Correction	Class III	Retail
4/09/2012	Brilliance 6, 10, 16, 40, 64 and Brilliance CT Big Bore Systems with a Multifunction Footswitch (Full body CT diagnostic system)	Medical Device	Recall for Product Correction	Class II	Hospital
3/09/2012	DBL Irinotecan hydrochloride injection vial 100mg/5ml	Medicine	Recall	Class II	Hospital
3/09/2012	Integra CT-compatible Intubation Head Ring Assembly (HRAIM), (used to stabilise the head during an imaging procedure) Catalogue Number : HRAIM	Medical Device	Recall for Product Correction	Class II	Hospital
3/09/2012	Mahurkar Acute Lumen Catheters, labelled with Non-DEHP Symbol. (Closed loop, haemodialysis catheter)	Medical Device	Recall for Product Correction	Class II	Hospital
3/09/2012	PREVI Isola System. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
3/09/2012	Timesco Laryngoscope Handle Contact Discs (used in intubation procedures)	Medical Device	Recall	Class II	Hospital

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31/08/2012	6.5 Cancellous Bone Screw 35mm (Used in total hip joint arthroplasty when the surgeon elects to use a cluster/multi-hole shell in the acetabulum prosthetic component)	Medical Device	Recall	Class II	Hospital
31/08/2012	ADVIA Centaur and ADVIA Centaur XP (Immuno-assay analysers). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
30/08/2012	Affinity Four Birthing Bed	Medical Device	Recall for Product Correction	Class II	Hospital
30/08/2012	Clear Canal (ear wax removal kit)	Medical Device	Recall	Class III	Retail
30/08/2012	Low Profile Abutment Hexed Castable Cylinder, Model LPCCC1	Medical Device	Recall for Product Correction	Class II	Hospital
30/08/2012	Spacelabs Healthcare Integrated Module Housing (Used for accommodating additional modules to the patient monitor whenever needed)	Medical Device	Recall for Product Correction	Class II	Hospital
30/08/2012	Surecan Safety II (Needles with special bevel for implantable access ports).	Medical Device	Recall	Class II	Hospital
29/08/2012	Sharpoint IQ Geometry Slit Knives (Ophthalmic surgical implement intended to make precise incisions in eye tissue)	Medical Device	Recall	Class II	Hospital
28/08/2012	Protege EverFlex Self-Expanding Peripheral Stent System containing all size variants of 5mm diameter stent in both 80cm and 120cm delivery catheters. Protege EverFlex Self-Expanding Peripheral Stent System containing all size variants of 200mm length stent in 6, 7, 8mm diameter stent in 120cm delivery catheters. (Vascular prosthetic stent)	Medical Device	Recall	Class II	Hospital
28/08/2012	Syntel Vascular Catheters and Syntel Biliary Catheters (embolectomy catheter)	Medical Device	Recall	Class I	Hospital
27/08/2012	Canon CXDA - 70C Wireless Computed radiographic system	Medical Device	Recall for Product Correction	Class II	Hospital
24/08/2012	BiCNU (Carmustine 100mg powder vial for IV injection)	Medicine	Recall	Class I	Hospital
24/08/2012	Duet TRS Universal Straight and Articulating Single Use Loading Units (Internal stapling device used in abdominal, gynaecologic, paediatric and thoracic surgery for resection, transection and creation of anastomosis)	Medical Device	Recall	Class I	Hospital

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23/08/2012	ACTIFUSE ABX Synthetic Bone Substitute (artificial bone graft)	Medical Device	Recall for Product Correction	Class II	Hospital
23/08/2012	DRX Evolution System (digital diagnostic x-ray system)	Medical Device	Recall for Product Correction	Class III	Hospital
23/08/2012	Intuitive Surgical Version 12 Tip Cover for 8mm Monopolar Curved Scissors (endotherapy scissors)	Medical Device	Recall	Class II	Hospital
22/08/2012	GUIDELINER Intravascular Guiding Catheter	Medical Device	Recall	Class II	Hospital
22/08/2012	Thymoglobuline (rabbit anti-human thymocyte immunoglobulin) 25mg Powder for infusion vial	Medicine	Recall	Class II	Hospital
21/08/2012	AEZ Mini Distal Cutter w/ Hold Short (Used to cut archwires during orthodontic treatment)	Medical Device	Recall	Class III	Retail
21/08/2012	Armada 35 and Armada 35LL percutaneous transluminal angioplasty (PTA) catheter (balloon dilation catheter)	Medical Device	Recall	Class I	Hospital
21/08/2012	CANESTEN clotrimazole thrush treatment 6 day cream 1% w/w cream tube	Medicine	Recall	Class III	Wholesale
21/08/2012	Clinac, Trilogy, Novalis Tx and Unique linear accelerators (Intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumours and other conditions requiring radiation therapy)	Medical Device	Recall for Product Correction	Class I	Hospital
21/08/2012	Dimension Clinical Chemistry System - Haemoglobin A1c (HbA1c). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
16/08/2012	Cavitec (A dental material indicated for use as a cavity liner, eg. pulp capping.)	Medical Device	Recall	Class III	Retail
16/08/2012	Xia 3 Torque Wrench and Mantis Redux Torque Wrench (Supplied as part of Xia 3 instrument tray)	Medical Device	Recall	Class II	Hospital
14/08/2012	Digital Linear Accelerators fitted with X-ray Volume Imaging (XVI)	Medical Device	Recall for Product Correction	Class II	Hospital
14/08/2012	Halo Flex Energy Generators (Endotherapy electrosurgical unit)	Medical Device	Recall for Product Correction	Class II	Hospital
14/08/2012	Multiple Suture Anchors: Various models of HEALICOIL, TWINFIX, BIORAPTOR, FOOTPRINT Suture Anchors (Used to attach the end of a synthetic or natural ligament to bone)	Medical Device	Recall	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
14/08/2012	Welch Allyn KleenSpec Disposable Vaginal Speculum	Medical Device	Recall for Product Correction	Class II	Hospital
13/08/2012	Kidwalk Dynamic Mobility System, model number: KW01 (A wheeled support frame intended to assist a disabled child in walking by providing a means of support)	Medical Device	Recall for Product Correction	Class II	Consumer
13/08/2012	Pentax PTX-EG-387UTK Ultrasound Video Gastroscope (flexible gastroduodenoscope)	Medical Device	Recall for Product Correction	Class II	Hospital
13/08/2012	Post Fuse Assembly with Power Wheelchairs (electronic wheelchair)	Medical Device	Recall for Product Correction	Class II	Consumer
10/08/2012	Calibrator B from ADVIA Centaur FSH Assay (used with ADVIA Centaur or ADVIA Centaur XP System). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
10/08/2012	Calibrator B from ADVIA Centaur Prolactin Assay (used with ADVIA Centaur CP System). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
10/08/2012	Jenx Ltd Headrest Brackets (An externally applied orthopaedic frame for standing).	Medical Device	Recall for Product Correction	Class II	Consumer
10/08/2012	L-Gell Ultrasound Transmission Gel – 5ltr & 250mls	Medical Device	Recall	Class II	Retail
10/08/2012	Lomb Scalpel Blade	Medical Device	Recall	Class II	Hospital
10/08/2012	PCA Empty Sterile vials with injector. (Intravenous fluid container).	Medical Device	Recall for Product Correction	Class II	Hospital
10/08/2012	Vital Signs Disposable General Purpose 9 French Temperature probes	Medical Device	Recall	Class I	Hospital
9/08/2012	E1-Tapered 10 degree +3mm Liner 32/39 (hip joint prosthesis, acetabular component)	Medical Device	Hazard Alert	Class II	Hospital
9/08/2012	Eon, Eon Mini and Brio Implantable Pulse Generator (IPG) (Implantable Spinal Cord and Deep Brain Stimulators)	Medical Device	Hazard Alert	Class I	Hospital
9/08/2012	NC and RC screw for Cares Abutment, ZrO2 and IFU	Medical Device	Recall	Class II	Hospital
9/08/2012	TempBond NE (temporary dental cement)	Medical Device	Recall for Product Correction	Class III	Retail
8/08/2012	Brilliance 64 and Ingenuity CT systems with software version 4.0.0.xx379 (Full body diagnostic CT X-ray system)	Medical Device	Recall for Product Correction	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
8/08/2012	Carescape Monitor B650 (Multi parameter patient monitor)	Medical Device	Recall for Product Correction	Class II	Hospital
8/08/2012	Carescape Monitor B850, all software versions (mutliparameter patient monitor)	Medical Device	Recall for Product Correction	Class II	Hospital
8/08/2012	Cobas IT 3000 Haematology Performance Suite, keyboard differential keyboard (with Cobas IT 3000 versions 2.03.08 to 2.04.00). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
8/08/2012	Dash 3000/4000/5000 Patient Monitor with software version 6.0 and later (multiparameter patient monitor).	Medical Device	Recall for Product Correction	Class II	Hospital
8/08/2012	DGPHP RFA High-Power single use grounding pads and Cool-tip RFA Electrode Kits (containing DGPHP RFA High-Power single use grounding pads), Dispersive electrode used during radiofrequency lesioning procedures)	Medical Device	Recall	Class I	Hospital
8/08/2012	Substrate buffer used with LIFECODES PAK12 and LIFECODES PF4IgG Kits. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
6/08/2012	ADVIA Centaur HIV 1/O/2 Enhanced (EHIV) reagent kit. An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
6/08/2012	Agility (An integral beam limiting device used with linear accelerators)	Medical Device	Recall for Product Correction	Class I	Hospital
6/08/2012	Alaris LVP module (model 8100) (General purpose infusion pump)	Medical Device	Recall for Product Correction	Class I	Hospital
6/08/2012	Allersearch Economist Forte Nebuliser (non heated nebuliser)	Medical Device	Recall	Class II	Retail
6/08/2012	Apex Modular Hip Stem Size 4/11.5 (Internal joint prosthesis, femoral component)	Medical Device	Recall	Class II	Hospital
6/08/2012	ARCHITECT Toxo IgG; An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
6/08/2012	Cobas 4800 BRAF V600 Mutation Test (acquired genetic alteration IVD). An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class III	Hospital
6/08/2012	Cobas 8000 'v2' instrument drivers for Cobas IT 3000 (Used with Cobas IT 3000 versions 2.03.08 to 2.04.00); An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital

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6/08/2012	Innova 2121IQ and Innova 3131IQ Cardiovascular X-Ray Imaging Systems (diagnostic fluoroscopic angiography x-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
6/08/2012	Proximate PPH Hemorrhoidal Circular Stapler and Accessories 33mm, Product code PPH03 and Proximate HCS Hemorrhoidal Circular Stapler and Accessories 33mm, Product code PPH01 (Used for treatment of prolapse and hemorrhoids)	Medical Device	Recall	Class II	Hospital
6/08/2012	SMR L2 Metal Back Glenoid Component (part of the total shoulder glenoid replacement)	Medical Device	Hazard Alert	Class II	Hospital
3/08/2012	Captura Disposable Biopsy Forceps (endotherapy forceps, flexible, single use)	Medical Device	Recall	Class II	Hospital
3/08/2012	Eon Mini and Brio Implantable Pulse Generators (IPG) (Implantable Spinal Cord and Deep Brain Stimulators)	Medical Device	Hazard Alert	Class I	Hospital
3/08/2012	Essenta DR Compact (General purpose X-ray system)	Medical Device	Recall for Product Correction	Class II	Hospital
2/08/2012	Access Immunoassay Systems Access Folate Calibrators, Part numbers: A14207, A98033. An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
2/08/2012	Keypad of Alaris LVP module (Component of a general purpose infusion pump); Module Model: 8100	Medical Device	Recall for Product Correction	Class II	Hospital
30/07/2012	ADVIA Centaur Multi-Diluent 1 supplied with ADVIA Centaur BNP kit and ADVIA Centaur TSH-3 Ultra kit; An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
27/07/2012	Afinion AS100 Analyser, CRP and CRP Control; An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
27/07/2012	Extrude Wash (Dental impression material)	Medical Device	Recall for Product Correction	Class III	Retail
27/07/2012	Onyx Liquid Embolic System (LES), (Used for embolization of intracranial aneurysms and lesions in the peripheral and neurovasculature).	Medical Device	Recall for Product Correction	Class I	Hospital
27/07/2012	syngo Dynamics (Radiology picture archiving and communication system); Version 9.5	Medical Device	Recall for Product Correction	Class II	Hospital

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27/07/2012	syngo Imaging XS (Radiology picture archiving and communication system). Version VA70A or higher	Medical Device	Recall for Product Correction	Class II	Hospital
27/07/2012	syngo Plaza (Radiology picture archiving and communication system)	Medical Device	Recall for Product Correction	Class II	Hospital
26/07/2012	GemStar Docking Station (Used as an alternate power source for the GemStar pump and to charge a GemStar battery pack)	Medical Device	Recall	Class I	Hospital
26/07/2012	HemoCue Glucose 201 RT and 201 DM RT Systems. A point of care in vitro diagnostic medical device (IVD).	Medical Device	Recall	Class I	Hospital
24/07/2012	SAIZEN somatropin (rmc) solution for injection multidose cartridge	Medicine	Recall	Class II	Consumer
20/07/2012	44R82 Tube Clamp Adapter (Prosthetic component part)	Medical Device	Recall for Product Correction	Class II	Retail
20/07/2012	AEZ Mini Distal Cutters w/ Hold Long (Used to cut archwires during orthodontic treatment)	Medical Device	Recall	Class III	Retail
20/07/2012	Animas Insulin Infusion Pump (ambulatory insulin infusion pump), models - IR 2020, 1200	Medical Device	Recall	Class I	Consumer
20/07/2012	Birdie, Birdie Compact and Flamingo Lifters (Patient Lifters)	Medical Device	Recall for Product Correction	Class II	Consumer
19/07/2012	4.5mm Dyonics Bonecutter Electroblade (used during arthroscopic procedures for simultaneous soft and osseous tissue resection using mechanical action and coagulation via RF energy)	Medical Device	Recall	Class II	Hospital
19/07/2012	Brilliance series 6, 16, 40, 64, CT Big Bore, iCT and iCT SP (CT systems)	Medical Device	Recall for Product Correction	Class II	Hospital
19/07/2012	CSL Rh(D) IMMUNOGLOBULIN VF (human) 250 IU injection vial	Medicine	Recall	Class II	Sponsor
19/07/2012	Discovery Tray - Child and Small Sizes (A disposable foam tray used for topical oral fluoride applications)	Medical Device	Recall	Class III	Retail
19/07/2012	Philips HeartStart MRx cardiac monitor / defibrillator, model number: M3536A with R.03.03 software and 12 Lead option (manual defibrillator)	Medical Device	Recall for Product Correction	Class II	Hospital
19/07/2012	Philips HeartStart MRx cardiac monitor / defibrillator, model numbers: M3535A, M3536A, M3536M4, M3536M5, and M3536M6 (manual defibrillator)	Medical Device	Recall for Product Correction	Class I	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
19/07/2012	Philips HeartStart MRx cardiac monitor / defibrillators, models:M3535A, M3536A, M3536J, M3536M, M3536MC, M3536M1, M3536M2, M3536M3, M3536M4, M3536M5 and M3536M6 (manual defibrillator)	Medical Device	Recall for Product Correction	Class I	Hospital
19/07/2012	Shiley Reusable Cannula Cuffed Tracheostomy Tubes, Product codes: 8FEN, 8LPC, 8LPC-S	Medical Device	Recall	Class I	Hospital
19/07/2012	Sysmex CS-2100i/2000i Systems (Coagulation Analysers), Software Versions: up to and incl. SW 00-60 (CS-2x00i). An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
16/07/2012	GENTECH molybdenum (99Mo) / technetium (99mTc) sterile generator for production of sodium pertechnetate (99mTc) injection multi dose vial (Used to produce metastable isotope 99mTc from a decaying Molybdenum-99 bound onto a generator column)	Medicine	Recall	Class II	Hospital
13/07/2012	Bowl Surgical Drape	Medical Device	Recall	Class II	Hospital
13/07/2012	Leukine sargramostim (Liquid Injection) 500mcg/mL vial	Medicine	Recall	Class II	Hospital
13/07/2012	Mirage, Silverspeed, X-celerator & X-pedion Guidewires, Hyperform & Hyperglide Occlusion Balloon Catheters and Guidewires (Supplied in Procedure Packs)	Medical Device	Recall	Class II	Hospital
12/07/2012	Alaris PC Unit (General purpose infusion pump)	Medical Device	Recall for Product Correction	Class I	Hospital
12/07/2012	CT1133S Cephalexin 100ug CL100 Antimicrobial Susceptibility Discs (Used for antimicrobial susceptibility testing), An in vitro diagnostic medical device (IVD)	Medical Device	Recall	Class II	Hospital
12/07/2012	Dimension RxL Reagent Management System (RMS) Power Cord Plug; An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital
12/07/2012	Portapres NiMH battery pack (Device to continuously measure blood pressure)	Medical Device	Recall	Class II	Hospital
12/07/2012	Premier C. difficile GDH - Positive Control Lot 6088.011, (Enzyme Immunoassay kit for the detection of C. difficile antigen (GDH)); An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class III	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
11/07/2012	AcrySof CACHET Phakic Lens (Intraocular lens used for the reduction or elimination of myopia)	Medical Device	Hazard Alert	Class II	Hospital
11/07/2012	STERRAD 100S System Cassettes (To provide the hydrogen peroxide sterilant used in the STERRAD Steriliser)	Medical Device	Recall	Class II	Hospital
11/07/2012	ULTRA Fabric Reinforced Surgical Gown, X- Large; MICROCOOL Breathable Gown, with SECURE-FIT, with Towel, X-Large	Medical Device	Recall	Class II	Hospital
6/07/2012	ABGII Modular Stems and ABGII Modular Necks (An exchangeable modular neck, designed to allow intra-operative flexibility for bio mechanical adjustment of offset and anteversion without affecting leg length)	Medical Device	Hazard Alert	Class II	Hospital
5/07/2012	Alginot (dental impression material); All product lots within shelf life	Medical Device	Recall for Product Correction	Class III	Retail
5/07/2012	Elekta Monaco rel. 3.10.00 through 3.20.00 & Focal rel. 4.64.00 through 4.70.00 (Radiation Therapy Treatment Planning System)	Medical Device	Recall for Product Correction	Class II	Hospital
5/07/2012	Indirect (Closed-Tray) Transfer for Internal Hexagon (Used to create the necessary dental suprastructure preparation during the healing and sculpturing period of the soft tissue)	Medical Device	Recall	Class III	Retail
5/07/2012	STERRAD CYCLESURE 24 Biological Indicators within Validation Kits - Product codes: 14324, 20253, 20228, 20232 (sterilisation process indicator)	Medical Device	Recall	Class II	Hospital
5/07/2012	Twinfix Ultra Ti Suture Anchor, 5.5mm (used to attach the end or ends of a synthetic or natural ligament to bone)	Medical Device	Recall	Class II	Hospital
3/07/2012	Matrix Surgical Laparoscopic Spatula with cable (active endotherapy device).	Medical Device	Recall	Class II	Hospital
2/07/2012	Eclipse Treatment Planning System (Radiation treatment planning system); Version 8.5, 8.6, 8.9, 10 & 11	Medical Device	Recall	Class II	Hospital
2/07/2012	Laryngoscope Handles (LED) (Item No 08-100) and Laryngoscope Fibre Optic Blades (Item No 08-101)	Medical Device	Recall for Product Correction	Class II	Hospital

Recall Action Commencement Date ⁱ	Product Name/Description ⁱⁱ	Type of Product ⁱⁱⁱ	Recall Action ^{iv}	Recall Action Classification ^v	Recall Action Level ^{vi}
2/07/2012	SEBIFIN terbinafine (as hydrochloride) 250 mg tablet, blister packs of 42 tablets	Medicine	Recall	Class II	Retail
2/07/2012	VITROS Chemistry Products DGXN Slides; An in vitro diagnostic medical device (IVD)	Medical Device	Recall for Product Correction	Class II	Hospital

Footnotes

ⁱ Recall Action Commencement Date: The date the recall strategy and communication was agreed by the TGA.

ⁱⁱ Product Name/Description: Brand name (including active ingredient for medicines), and may include generic reference for the kind of medical devices.

ⁱⁱⁱ Type of Product: Medicine (including vaccines), Medical Device, or Biological.

^{iv} Recall Action^{**}: A Recall action is an action taken to resolve a problem with a therapeutic good already supplied in the market for which there are issues or deficiencies in relation to safety, quality, efficacy (performance) or presentation. There are four distinct recall actions – recall, product defect correction, hazard alert and product defect alert:

- **Recall** - The permanent removal of an affected therapeutic good from supply or use in the market.
- **Product defect correction** - Repair, modification, adjustment or re-labelling of a therapeutic good. The corrective action may take place at the user's premises or any other agreed location.
- **Hazard alert** - Information issued to healthcare professionals about issues or deficiencies relating to an implanted medical device or biological product and advice about the ongoing management of patients.
- **Product defect alert** - Information issued to raise awareness about issues or deficiencies for a therapeutic good where a recall action will result in interruption of patient treatment or a medicine shortage, including advice to reduce potential risks of using affected goods.

^v Recall Action Classification^{**}: Recall actions of therapeutic goods are classified based on the potential risk the deficiency poses to patients / consumers. They are classified as Class I, Class II or Class III.

- **Class I** - A situation in which there is a reasonable probability that the use of, or exposure to, the deficient therapeutic good(s) will cause serious adverse health consequences or death.
- **Class II** - A situation in which use of, or exposure to, the deficient therapeutic good(s) may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote.
- **Class III** - A situation in which use of, or exposure to, the deficient therapeutic good(s) is not likely to cause adverse health consequences.

^{vi} Recall Action Level: The depth to which the recall action is to be undertaken. This is based on the assessment of the risk to public health and safety, acknowledging the channels through which the goods have been supplied. The recall action levels are given below and are cumulative, e.g. Retail Level, includes Hospital and Wholesale:

- **Wholesale** - includes wholesalers and state purchasing authorities.
- **Hospital** - includes nursing homes and institutions, hospital pharmacists, ambulance services, blood and tissue banks and laboratories as well as wholesale as appropriate.
- **Retail** - includes retail pharmacists, medical, dental and other health care professionals as well as wholesale and hospital as appropriate.
- **Consumer** - includes patients and consumers, as well as wholesale, hospital and retail levels as appropriate.

** These definitions are applicable to the 2017 URPTG (Implemented from Jan 15 2018). Recall Action types and Recall Action Classifications prior to 15 Jan 2018 can be found at:
<https://www.tga.gov.au/sites/default/files/recalls-urptg-170412.pdf>