Recall Action Result Summary

You searched for recall action reports between **01/07/2012 – 14/01/2020**:
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.
- 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.

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## Recall Action Details

Number of recall actions: 4916

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### System for Australian Recall Actions

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<td>Atellica IM NT-proBNP (PBNP) 100 Test Kit and 500 Test Kit. An in vitro diagnostic medical device (IVD)</td>
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<td>QUADROX-iD Paediatric with BIOLINE Coating</td>
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<td>30/10/2019</td>
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<td>Single Use Macintosh 3 Laryngoscope Blades</td>
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<td>Caruso’s Super Collagen Builder</td>
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<td>Alinity c Carbon Dioxide Reagent Kit. An in vitro diagnostic medical device (IVD)</td>
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<td>Arrow MAC Two-Lumen Central Venous Access Kit</td>
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<td>28/10/2019</td>
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<td>17/10/2019</td>
<td>Patient Data Manager</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/10/2019</td>
<td>Roche CARDIAC Pipette 150 µL cobas h 232 POC system. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/10/2019</td>
<td>Surface Temperature Probe</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/10/2019</td>
<td>WECK Auto Endo5 Automatic Hem-o-lok Clip Appliers</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/10/2019</td>
<td>RadiForce RX360 and GX560 Monitors</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/10/2019</td>
<td>Ausran (150mg and 300mg tablets), Chemists' Own Ranitidine and Chemists' Own Ranitidine Forte</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
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<td>Recall Action Level</td>
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<td>15/10/2019</td>
<td>Embryology Heated Plate within the RI Witness</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/10/2019</td>
<td>GSS67H Steriliser (software version earlier than 2.0.1)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/10/2019</td>
<td>UniCel DxH Slidemaker Stainer (DxH SMS) &amp; UniCel DxH Slidemaker Stainer II (DxH SMS II). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/10/2019</td>
<td>Panther Fusion Extraction Reagent-S. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/10/2019</td>
<td>SOMATOM go.Top with software syngo CT VA20A, SP2 and with active &quot;Guide&amp;GO&quot; license</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>11/10/2019</td>
<td>BACT/ALERT VIRTUO system A &amp; B units. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/10/2019</td>
<td>Various SOMATOM Systems with software syngo CT VB20 or syngo CT VB10</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/10/2019</td>
<td>VeriSeq NIPT Sample Prep Kits. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/10/2019</td>
<td>HandyVac</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/10/2019</td>
<td>Various Soul Pattinson Manufacturing (SPM) Ranitidine Tablets</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
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<tr>
<td>10/10/2019</td>
<td>Xpert Xpress Flu/RSV Assay. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/10/2019</td>
<td>Epidural Positioning Device (EPD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>9/10/2019</td>
<td>Monaco version 5.40, 5.50 or 5.51</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>8/10/2019</td>
<td>Cautery Tip Cleaner</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>8/10/2019</td>
<td>Homocysteine. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>8/10/2019</td>
<td>Systems Manager software version 12.0.1 with PCU versions 9.X.</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<td>4/10/2019</td>
<td>Liquid Cardiac Control. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/10/2019</td>
<td>Philips V60 and V80 Ventilators</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>4/10/2019</td>
<td>Prismaflex Control Units with software versions 7.20 and below</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>Recall Action Commencement Date</td>
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<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<td>4/10/2019</td>
<td>TJF / JF Duodenoscope</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>3/10/2019</td>
<td>AERO-AL Revision Housing</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>3/10/2019</td>
<td>CARESCAPE Respiratory Modules</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/10/2019</td>
<td>Coles &amp; Medix Heartburn &amp; Acid Indigestion ranitidine (as hydrochloride) tablets 14s pack</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>3/10/2019</td>
<td>Spacelabs Healthcare Inc. Xhibit Central</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>2/10/2019</td>
<td>Cipla Ranitidine Tablets</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
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<td>2/10/2019</td>
<td>Generic Health Ranitidine Tablets</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
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<td>2/10/2019</td>
<td>Symbion Ranitidine Tablets</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
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<tr>
<td>1/10/2019</td>
<td>iChemVELOCITY Urine Chemistry Strips. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/10/2019</td>
<td>Intellijoint HIP System - (Apple MacBook)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>1/10/2019</td>
<td>Ranitidine 150mg and 300mg (Rani 2)</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>1/10/2019</td>
<td>TherMax, Blood Warmer Unit, ROW</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/10/2019</td>
<td>ZANTAC Ranitidine</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
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<tr>
<td>30/09/2019</td>
<td>Apotex Ranitidine Tablets</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
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<tr>
<td>30/09/2019</td>
<td>Cornea</td>
<td>Biological</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>30/09/2019</td>
<td>Forte Family Gamma Cameras</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/09/2019</td>
<td>Steam Steriliser - HS5510 EC1</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>27/09/2019</td>
<td>Aquilex Fluid Control System (AQL-100CBS)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>26/09/2019</td>
<td>Caesarea Medical Electronics T34 Syringe Pumps</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/09/2019</td>
<td>DTX Safedraw Kits and Meritrans DTXPlus Devices</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/09/2019</td>
<td>Exactamix Empty EVA Bags</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>26/09/2019</td>
<td>F18-FDG</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>26/09/2019</td>
<td>IACS and Stand Alone M540 Monitor. s/w version VG4.1.1 &amp; VG4.0.3 and lower</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>25/09/2019</td>
<td>Atellica CH 930 Analyser – Software versions 1.20.0 and below. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/09/2019</td>
<td>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)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class III</td>
<td>Hospital</td>
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<tr>
<td>25/09/2019</td>
<td>Non-Esterified Fatty Acids (NEFA). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/09/2019</td>
<td>Medisoft FeNO+</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>23/09/2019</td>
<td>AIR LIQUIDE Medical Carbon Dioxide - 16.5m3 G sized cylinder</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
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<tr>
<td>23/09/2019</td>
<td>ATOK Shoulder Anchor</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>23/09/2019</td>
<td>InterVapor System</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/09/2019</td>
<td>LBgard Blood Collection Tubes</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/09/2019</td>
<td>DCFPyL</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/09/2019</td>
<td>Philips HeartStart FRx+ and HS1 OnSite Automated External Defibrillators (AEDs)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/09/2019</td>
<td>ROSA Brain 3.0</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>19/09/2019</td>
<td>Selected Behind-the-Ear hearing aids</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Consumer</td>
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<tr>
<td>18/09/2019</td>
<td>Alinity hq Analyser and Alinity hs Slide Maker Stainer Module. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/09/2019</td>
<td>DC-Screening II. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/09/2019</td>
<td>Radiometer AQURE Data Management System</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class III</td>
<td>Hospital</td>
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<tr>
<td>17/09/2019</td>
<td>Sandoz Ranitidine</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>17/09/2019</td>
<td>VHK and VKMO Adult/Small Adult</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/09/2019</td>
<td>VHK and VKMO(D) Adult/Small Adult Accessories</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
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<td>Recall Action Commencement Date</td>
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<td>Recall Action Classification</td>
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<td>16/09/2019</td>
<td>Atellica UAS 800 Analyser and Atellica 1500 Automated Urinalysis System. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/09/2019</td>
<td>Codan US Corporation Swan-Lock Needle-Free Connector</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
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<td>16/09/2019</td>
<td>GentleCool Pro Cryogen Canister</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>16/09/2019</td>
<td>OriGen Products TissueVault O-Wrap and accessories</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/09/2019</td>
<td>Proxy use in Soluscope Sprint AERs</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>16/09/2019</td>
<td>Shuttle Discovery with 4 Wheel Verve Stroller</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Consumer</td>
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<td>13/09/2019</td>
<td>CereLink ICP Monitor</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>12/09/2019</td>
<td>Alpha Conducting Solution used with Alpha-Stim M &amp; AID devices</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Consumer</td>
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<tr>
<td>12/09/2019</td>
<td>Seca Baby Scale</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>12/09/2019</td>
<td>Serres Suction Bag Liner</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/09/2019</td>
<td>ILED 7 Surgical Light Systems</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class III</td>
<td>Hospital</td>
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<td>11/09/2019</td>
<td>IMMAGE Total Immunoglobulin E (IgE) Reagent. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/09/2019</td>
<td>STRATAFIX Spiral Uni PDS Plus</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
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<td>10/09/2019</td>
<td>Introcan Safety IV Catheter</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
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<td>10/09/2019</td>
<td>SPROTTE Lumbar with Introducer</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/09/2019</td>
<td>Achilles Express and Achilles Insight System Power Cords</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>9/09/2019</td>
<td>Multiple ApexPro Telemetry server hardware platforms</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/09/2019</td>
<td>Philips S7-3t &amp; S8-3t Transesophageal (TEE) Transducers</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>9/09/2019</td>
<td>Thermo Scientific Remel Salmonella paratyphi B-H phase 1 Flagellar antigen b Stained Suspension. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/09/2019</td>
<td>Various Convex Two-Piece Skin Barriers</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Consumer</td>
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<td>6/09/2019</td>
<td>Prima Supercav Fingerswitch Pencils with Smoke Evacuation Tubing</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>Artis zee and Artis Q patient table within a specific production lot</td>
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The TGA publishes Australian recall actions in a searchable database to ensure the public has access to information about therapeutic products that have been recalled from the Australian market. If you are concerned about your health or if you have experienced an adverse event please seek advice from a health professional as soon as possible. Please read all the important information at the beginning of this report.
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<td>Panetti ENT endoscopic ear instruments</td>
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<td>22/07/2019</td>
<td>Radiometer ABL90FLEX blood gas analyser and Radiometer AQT90FLEX immunoassay analyser. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
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<td>19/07/2019</td>
<td>Da Vinci Xi SureForm 60 Stapler Green and Black Reloads</td>
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<td>Recall</td>
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<td>Recall Action Commencement Date</td>
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<td>18/07/2019</td>
<td>Azurion Interventional Fluoroscopic X-ray system with software version 1.2</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class I</td>
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<td>18/07/2019</td>
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<td>18/07/2019</td>
<td>Fluorostar 7900 System</td>
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<td>18/07/2019</td>
<td>HEYEX 2 image management components of SPECTRALIS PC Software</td>
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<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>18/07/2019</td>
<td>Jointrep Cartilage Thermogel Kit - OLM-JR001</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class III</td>
<td>Hospital</td>
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<td>18/07/2019</td>
<td>Monaco version 5.10 or 5.11 using Elekta motorised wedges</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<td>18/07/2019</td>
<td>Pulsavac Plus Wound Debridement System</td>
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<td>Hospital</td>
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<td>18/07/2019</td>
<td>QIAsymphony SP instrument (Software 5.0.3). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>17/07/2019</td>
<td>ImmunoCAP Tryptase Control. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<td>17/07/2019</td>
<td>Mircoaire SmartRelease system</td>
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<td>17/07/2019</td>
<td>MULTIGENT Lithium and Alinity c Lithium Reagents. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>17/07/2019</td>
<td>SYNCHRON Systems Amphetamines (AMPH) Reagent. An in vitro diagnostic medical device (IVD)</td>
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<td>Product Defect Correction</td>
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<td>15/07/2019</td>
<td>Azurion Interventional Fluoroscopic X-ray System, with software version 1.2</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
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<td>Calibration Serum Level 3. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
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<td>Hospital</td>
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<td>12/07/2019</td>
<td>GETINGE Steam Steriliser</td>
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<td>Hospital</td>
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<td>12/07/2019</td>
<td>NEUTROGENA Visibly Clear Light Therapy Acne Mask and Activator</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Consumer</td>
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<tr>
<td>10/07/2019</td>
<td>Individual GRIPPER Needles and PORT-A-CATH Trays containing GRIPPER Needles</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>9/07/2019</td>
<td>Edwards Lifesciences IntraClude Intra-aortic Occlusion Device</td>
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<td>Recall</td>
<td>Class I</td>
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<td>9/07/2019</td>
<td>SOMATOM Confidence, SOMATOM Drive, SOMATOM Definition Edge, SOMATOM Definition AS, SOMATOM Definition Flash, SOMATOM Edge Plus, SOMATOM Force with software syngo CT VB10A</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
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<td>9/07/2019</td>
<td>VIP RIA (Vasoactive Intestinal Polypeptide) kits. An in vitro diagnostic medical device (IVD)</td>
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<td>Class II</td>
<td>Hospital</td>
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<td>8/07/2019</td>
<td>BD Connecta Plus3 White (3 way stopcock)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<td>8/07/2019</td>
<td>Morcher Capsular Tension Rings Type 13 Right, Type 13A Right and Type 13B Right</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<td>8/07/2019</td>
<td>Phadia 1000 instrument. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>8/07/2019</td>
<td>TechnegasPlus Generator</td>
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<td>5/07/2019</td>
<td>MAC VU360 systems</td>
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<td>Product Defect Correction</td>
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<td>5/07/2019</td>
<td>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)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<td>4/07/2019</td>
<td>MAGEC System</td>
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<td>Hazard Alert</td>
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<td>4/07/2019</td>
<td>Mako System SS2U Computer</td>
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<td>Class III</td>
<td>Hospital</td>
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<td>3/07/2019</td>
<td>ADVIA 120/2120/2120i Diff Timepac Assays. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
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<tr>
<td>2/07/2019</td>
<td>AQUIOS IMMUNO-TROL Low Cells. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
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<td>Hospital</td>
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<td>2/07/2019</td>
<td>CT Expres Day Set III</td>
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<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<td>2/07/2019</td>
<td>DRX-Ascend and O-Rad System Overhead Tube Crane (OTC) Assembly</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
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<td>Revolution CT Scanners</td>
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<td>2/07/2019</td>
<td>Spectrum Medical Quantum Perfusion Systems</td>
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<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>28/06/2019</td>
<td>iGUIDE 2.2</td>
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<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>28/06/2019</td>
<td>Stainless Steel Interstitial Needles, 17 Gauge</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<td>27/06/2019</td>
<td>Various Evolutis Femoral Rasps</td>
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<td>Recall</td>
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<td>Hospital</td>
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<td>Recall Action Commencement Date</td>
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<td>24/06/2019</td>
<td>Various GlidePath Standard and Haemodialysis Catheters</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>21/06/2019</td>
<td>Alinity ci-series System Control Module. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>21/06/2019</td>
<td>BD MaxZero Needleless Connector and associated Extension Sets</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>21/06/2019</td>
<td>MID-Tube, Orogastric calibration Tube</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>20/06/2019</td>
<td>cobas 6800 System. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>20/06/2019</td>
<td>Fluoron F-Octane and F-Decalin (syringe delivery format)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<td>20/06/2019</td>
<td>Tenor Passive Floor Lift</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class III</td>
<td>Hospital</td>
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<tr>
<td>19/06/2019</td>
<td>BrightView SPECT, BrightView X, BrightView XCT</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>18/06/2019</td>
<td>ACUSON SC2000 VB20 and VB21 and the eSie Flow software (SW) license</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class III</td>
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<tr>
<td>18/06/2019</td>
<td>ARCHITECT Ceruloplasmin Reagent Kit and Alinity c Ceruloplasmin Reagent Kit. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>18/06/2019</td>
<td>DiaClon Rh-Subgroups + K. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class III</td>
<td>Hospital</td>
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<tr>
<td>18/06/2019</td>
<td>OVC3 16.17L A3 Refills</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
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<tr>
<td>17/06/2019</td>
<td>ACHRAb RIA kits. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<td>17/06/2019</td>
<td>ALT/GPT, Creatine Kinase and Glucose HK assays. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>17/06/2019</td>
<td>Comprehensive Reverse Shoulder Instrument Case – Total (Outer Case Vault Only)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>14/06/2019</td>
<td>6F Sherpa NX Active Catheters</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>14/06/2019</td>
<td>ARTIS zee and AXIOM Artis systems with generator A100</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>14/06/2019</td>
<td>ZOLL AED PRO Product Family</td>
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<td>Product Defect Correction</td>
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<td>Hospital</td>
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<td>12/06/2019</td>
<td>Artis zee and Artis Q systems</td>
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<td>Product Defect Correction</td>
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<td>Recall Action Commencement Date</td>
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<td>12/06/2019</td>
<td>Assayed Bovine Multi-Sera - Level 1. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>12/06/2019</td>
<td>SterilAmp SA/6 Certificate of Analysis</td>
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<td>Class III</td>
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<td>12/06/2019</td>
<td>SYNCHRON Systems Phosphorus Reagent (PHOSm). An in-vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>11/06/2019</td>
<td>BD Microtainer Tubes. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/06/2019</td>
<td>Senographe Pristina with Serena Systems</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>7/06/2019</td>
<td>Spectra Optia Apheresis System</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>5/06/2019</td>
<td>BD Alaris Pump Model 8100 Infusion Sets and Alaris Infusion Sets</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
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<td>5/06/2019</td>
<td>Philips Incisive Computed Tomography X-Ray System</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
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<td>5/06/2019</td>
<td>Rifton Tram and E-Pacer - Standard and Low Leg</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Retail</td>
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<td>5/06/2019</td>
<td>Sheridan Endotracheal Tubes and Connectors, 15mm</td>
<td>Medical Device</td>
<td>Product Defect Alert</td>
<td>Class II</td>
<td>Hospital</td>
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<td>4/06/2019</td>
<td>Elecsys Syphilis 200 tests. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>4/06/2019</td>
<td>Filter-Tips, 1500 µl (1024) used with QIAasympohny SP/AS Instruments. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/06/2019</td>
<td>ECG Trunk Cables and Leadwires</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>31/05/2019</td>
<td>Alinity i BNP Calibrators and Controls. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<td>31/05/2019</td>
<td>ARCHITECT BNP Calibrators and Controls. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>31/05/2019</td>
<td>Sensation Plus 7.5Fr 40cc Intra-Aortic Balloon Catheter with Accessories Kits</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<td>31/05/2019</td>
<td>SenTech Membrane Changer and Insert</td>
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<td>31/05/2019</td>
<td>UniCel DxH 800/600/900 Coulter Cellular Analysis System. An in vitro diagnostic medical device (IVD)</td>
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<td>Product Defect Correction</td>
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<tr>
<td>30/05/2019</td>
<td>Codan Extension Set</td>
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<td>Recall</td>
<td>Class II</td>
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<td>30/05/2019</td>
<td>HeartStart MRx Defibrillator/Monitor</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class I</td>
<td>Retail</td>
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<tr>
<td>29/05/2019</td>
<td>Human Assayed Control Level 2. An in vitro diagnostic medical advice (IVD).</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>29/05/2019</td>
<td>HyLED Surgical Light Series 7, 8 and 9</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
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<td>29/05/2019</td>
<td>J623 Power Wheel Chairs (&quot;Jazzy 623&quot;) fitted with Dynamic Controls Shark Power Module</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Consumer</td>
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<td>28/05/2019</td>
<td>Alinity ci-series System Control Module. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>28/05/2019</td>
<td>DILuent Tubing on the CELL-DYN Emerald Analyser. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<td>28/05/2019</td>
<td>Multiple ARCHITECT Assays. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>20/05/2019</td>
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The TGA publishes Australian recall actions in a searchable database to ensure the public has access to information about therapeutic products that have been recalled from the Australian market. If you are concerned about your health or if you have experienced an adverse event please seek advice from a health professional as soon as possible. Please read all the important information at the beginning of this report.
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<td>11/04/2019</td>
<td>CyberKnife M6 and CyberKnife VSI Secondary Collimation Subsystem with software version 11.0</td>
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<td>11/04/2019</td>
<td>OXOID MICE Strip MA0122 – Ceftriaxone32. An in vitro diagnostic medical device (IVD)</td>
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<td>TactiSys Quartz Equipment operating on Software Version 1.7.0</td>
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<td>Pericardiocentesis Catheter Set</td>
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<td>Femoral Head Allograft</td>
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<td>9/04/2019</td>
<td>Microbore Y-Type Extension Set and Catheter Extension Set with Clearlink - Male Luer Lock Adapter</td>
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<td>Auriga 30 Laser System</td>
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<td>5/04/2019</td>
<td>HeartMate 3 LVAD implant</td>
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<td>5/04/2019</td>
<td>Visiwipe Instrument Wipe 73 x 73mm</td>
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<td>4/04/2019</td>
<td>Alinity hq Analyser. An in vitro diagnostic medical device (IVD).</td>
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<td>Philips Access CT Systems</td>
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<td>4/04/2019</td>
<td>RealTime HBV Control Kit and RealTime CMV Control Kit. An in vitro diagnostic medical device (IVD)</td>
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<tr>
<td>4/04/2019</td>
<td>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</td>
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<td>3/04/2019</td>
<td>Custom Tubing Sets</td>
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<tr>
<td>3/04/2019</td>
<td>Drager Infinity Acute Care System (IACS) and Infinity M540 Stand Alone Patient Monitor</td>
<td>Medical Device</td>
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<td>3/04/2019</td>
<td>G-6-PDH Deficient and Normal Control. An in vitro diagnostic medical device (IVD)</td>
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<td>3/04/2019</td>
<td>Lypochek Specialty Immunoassay Control. An in vitro diagnostic medical device (IVD)</td>
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<td>Product Defect Correction</td>
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## System for Australian Recall Actions

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<th>Product Name/Description</th>
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<tbody>
<tr>
<td>3/04/2019</td>
<td>VariFit Sterile Single Use Adult Thigh Cuffs, Single Port, Single Bladder</td>
<td>Medical Device</td>
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<td>2/04/2019</td>
<td>Atellica CH 930 Analyser. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
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<tr>
<td>2/04/2019</td>
<td>Dräger Disposable VentStar Helix Dual Heated Breathing Circuit</td>
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<tr>
<td>2/04/2019</td>
<td>Femoral Head Allograft</td>
<td>Biological</td>
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<td>Hospital</td>
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<tr>
<td>2/04/2019</td>
<td>FilmArray - Blood Culture Identification (BCID) Panel used with bioMérieux BACT/ALERT Blood Culture Bottles. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
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<tr>
<td>2/04/2019</td>
<td>Intraluminal Staplers (ILS)</td>
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<td>2/04/2019</td>
<td>MAJ-209 Suction Valve</td>
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<td>Aisys Anaesthesia Devices</td>
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<td>Hamilton C6 Ventilators</td>
<td>Medical Device</td>
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<tr>
<td>29/03/2019</td>
<td>Heater-Cooler 3T, 230V</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
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<td>29/03/2019</td>
<td>Mylanta Antacid Double Strength 500 mL oral liquid bottle</td>
<td>Medicine</td>
<td>Product Defect Correction</td>
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<td>Consumer</td>
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<tr>
<td>29/03/2019</td>
<td>RT Elements Radiation Treatment Planning Software</td>
<td>Medical Device</td>
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<td>Hospital</td>
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<td>29/03/2019</td>
<td>VITROS XT 7600 Integrated System. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
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<td>27/03/2019</td>
<td>cobas p 701 post-analytical units. An in vitro diagnostic medical device (IVD)</td>
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<td>Product Defect Correction</td>
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<td>27/03/2019</td>
<td>TM55 Stress Testing Treadmills</td>
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<td>26/03/2019</td>
<td>Freedom EVOlyzer 2 150/8. An in vitro diagnostic medical device (IVD)</td>
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<td>26/03/2019</td>
<td>Miller and Fogarty Abrioseptostomy Catheters</td>
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<td>25/03/2019</td>
<td>Dang Gui Yin Zi (Tangkuei &amp; Tribulus combination)</td>
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<td>22/03/2019</td>
<td>Cios Alpha VA20 Systems</td>
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<td>22/03/2019</td>
<td>Connection Lead SP (12V) for Infusomat Space, Infusomat Space P and Perfusor Space</td>
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<td>Femoral Head, living donor - bone, morselised, frozen, irradiated</td>
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<td>21/03/2019</td>
<td>ProCell II M for use on cobas e 801 analytical unit. An in vitro diagnostic medical device (IVD)</td>
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<td>20/03/2019</td>
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<td>20/03/2019</td>
<td>Shui An and Yang Xue Sheng Fa Capsules</td>
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<td>19/03/2019</td>
<td>Arthrem capsules</td>
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<td>19/03/2019</td>
<td>F-18 FDG Injection (Fludeoxyglucose F18)</td>
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<td>19/03/2019</td>
<td>IMAGEt6 6 Ophthalmic Data System</td>
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<td>Glyceryl Trinitrate 300mcg Tablets 100, Martindale UK</td>
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<td>Complementary Medicines Containing Fallopia Multiflora - Herbal International</td>
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<td>Mobility Plus Wheelchairs - Malte, Malte-Outdoor and Marcy</td>
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<td>ALBAClone Anti-Leb. An in vitro diagnostic medical device (IVD)</td>
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<td>14/03/2019</td>
<td>Alinity ci-series Software version 2.5.1. An in vitro diagnostic medical device (IVD)</td>
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<td>Canon XR System DRAD-3000E/W8, Radrex with Wireless FPD</td>
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<td>Infinity Acute Care System (IACS) and Infinity M540 Stand Alone Monitor</td>
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<td>Alinity hq Analyser and Alinity hs Slide Maker Stainer Module. An in vitro diagnostic medical device (IVD)</td>
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<td>Arjo SARA 3000, Tenor and Minstrel Patient Lifts</td>
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<td>6/03/2019</td>
<td>ChromID CPS/Horse Blood Agar. An in vitro diagnostic medical device (IVD)</td>
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<td>5/03/2019</td>
<td>MultiDiagnost-Eleva with Flat Detector and Allura Xper</td>
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<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<td>4/03/2019</td>
<td>ImmunoCAP ISAC sIgE 112. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>4/03/2019</td>
<td>Pulmonary Vein Ablation Catheter GOLD (PVC GOLD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<td>4/03/2019</td>
<td>StentBoost Release 4.0, 4.1 and 4.2</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/03/2019</td>
<td>3.4mm Certain BellaTek Abutment, ILDAT3</td>
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<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>1/03/2019</td>
<td>BD Phoenix AST Indicator and BD Phoenix AP AST-S Indicator Bag. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<td>1/03/2019</td>
<td>Femoral Head Allograft</td>
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<td>Hospital</td>
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<tr>
<td>1/03/2019</td>
<td>StealthStation Cranial and Synergy Cranial Software</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>28/02/2019</td>
<td>ARIA Radiation Therapy Management</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>28/02/2019</td>
<td>Dialysis start/stop set - FMC Dialysis Fistula Pack #61</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>28/02/2019</td>
<td>Edge Radiosurgery System or TrueBeam and VitalBeam Radiotherapy Systems</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class III</td>
<td>Hospital</td>
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<td>28/02/2019</td>
<td>neoBLUE blanket LED Phototherapy Systems</td>
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<td>Hospital</td>
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<td>28/02/2019</td>
<td>Spine &amp; Trauma 3D Navigation System 1.0</td>
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<td>Hospital</td>
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<td>28/02/2019</td>
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<td>28/02/2019</td>
<td>Velocity Advanced Imaging [AI], Velocity Advanced Imaging Solutions [AIS] or VelocityGRID</td>
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<td>Product Defect Correction</td>
<td>Class II</td>
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<td>28/02/2019</td>
<td>Velocity Advanced Imaging [AI], Velocity Advanced Imaging Solutions [AIS] or VelocityGRID</td>
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<td>27/02/2019</td>
<td>Arjo Sara Plus Lift</td>
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<td>Product Defect Correction</td>
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<tr>
<td>27/02/2019</td>
<td>Bivona Inner Cannula Tracheostomy Tube</td>
<td>Medical Device</td>
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<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>27/02/2019</td>
<td>THERA-Trainer balo / THERA-Trainer verto</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>26/02/2019</td>
<td>CELL-DYN Emerald Analyser. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>26/02/2019</td>
<td>GENTECH Molybdenum(99Mo)/Technetium(99mTc) sterile Generator for production of Sodium pertechnetate (99mTc) injection multidose vial</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
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<td>Recall Action Classification</td>
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<td>26/02/2019</td>
<td>Inferior Vena Cava (IVC) Filter Sets</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
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<td>Hospital</td>
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<tr>
<td>26/02/2019</td>
<td>Medtronic Model 37751 Recharger, in Charging Systems used with implantable neurostimulators</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>22/02/2019</td>
<td>18Gx1-1/2IN TW Precision Glide Needles</td>
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<td>Hospital</td>
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<td>21/02/2019</td>
<td>Ardo Sterile Tulips Nipple Shields, Medium and Large</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>21/02/2019</td>
<td>Maquet Cardiopulmonary Pre-Bypass Filters used for Customised Tubing Packs</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>20/02/2019</td>
<td>Dräger BabyLeo TN500 Incuwarmer</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class III</td>
<td>Hospital</td>
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<tr>
<td>20/02/2019</td>
<td>Exactamix Empty EVA Bags</td>
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<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
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<td>19/02/2019</td>
<td>Citracal Plus D</td>
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<td>Retail</td>
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<td>19/02/2019</td>
<td>Duodenovideoscope TJF-160VR</td>
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<td>Product Defect Correction</td>
<td>Class II</td>
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<td>19/02/2019</td>
<td>Femoral Head Allograft</td>
<td>Biological</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
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<td>19/02/2019</td>
<td>Multiple SOMATOM CT Scanners - syngo CT VB10A with Option Dual Spiral Dual Energy</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>19/02/2019</td>
<td>Obtrurator, short cone 7&quot; and long cone 10&quot;</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>19/02/2019</td>
<td>Terumo Needles</td>
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<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>15/02/2019</td>
<td>Access Thyrogblobulin Antibody II (TgAbII) Reagent. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<td>15/02/2019</td>
<td>Femoral Head Allograft</td>
<td>Biological</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>14/02/2019</td>
<td>Bard Lifestream Balloon Expandable Vascular Covered Stent</td>
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<td>Product Defect Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<td>14/02/2019</td>
<td>Laryseal Flexi Laryngeal Mask sizes 2 and 4</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>14/02/2019</td>
<td>Mobile X-Ray System MobileDaRt Evolution Handle (MX8 Version)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>13/02/2019</td>
<td>Alinity hq Analyser. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>13/02/2019</td>
<td>BonAlive Putty MIS 5cc</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class III</td>
<td>Hospital</td>
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<tr>
<td>13/02/2019</td>
<td>Volcano Philips s5i/CORE/Core Mobile systems with software v2.5 FFR/IFR</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/02/2019</td>
<td>Xia 3 Degen Tray and French Bender instrument</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>12/02/2019</td>
<td>Cordis Vista Brite Tip &amp; ADROIT Guiding Catheters</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/02/2019</td>
<td>JURNISTA hydromorphone hydrochloride 8 mg prolonged release 14 tablet blister pack</td>
<td>Medicine</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>12/02/2019</td>
<td>Uroskop Omnia / Uroskop Omnia Max</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>11/02/2019</td>
<td>CL2 Femoral Stem, Standard Offset, Collarless, Taper 12/14 - Size 8</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class III</td>
<td>Hospital</td>
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<tr>
<td>11/02/2019</td>
<td>Panda iRes Warmer with ResusView Heart Rate Feature</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>11/02/2019</td>
<td>Radimetrics CDM Software</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/02/2019</td>
<td>ARCHITECT and Alinity / Estradiol Reagent Kits, An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/02/2019</td>
<td>Certegra Workstation 1.0, software version 4.5</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/02/2019</td>
<td>LIFEPAK 15 Monitor/Defibrillator &amp; LIFEPAK 15 Monitor/Defibrillator Repair Service Kit</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class I</td>
<td>Retail</td>
</tr>
<tr>
<td>8/02/2019</td>
<td>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)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/02/2019</td>
<td>Various Immunoassay Controls used with Siemens Immulite 2000, An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>6/02/2019</td>
<td>ARIA OIS for Radiation Oncology version 15.5 MR1</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>6/02/2019</td>
<td>Eclipse Treatment Planning System</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/02/2019</td>
<td>ACUSON NX2 / NX2 Elite and ACUSON NX3 / NX3 Elite systems</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>4/02/2019</td>
<td>Coarse Milled Bone, Femoral Head</td>
<td>Biological</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>4/02/2019</td>
<td>NARDIL phenelzine 15mg (as sulfate) tablet bottle</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Wholesale</td>
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<tr>
<td>4/02/2019</td>
<td>Percuvance Percutaneous Shaft 29cm</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>1/02/2019</td>
<td>Edwards Commander Delivery System</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/02/2019</td>
<td>SISS BABYCONTROL Respiration monitors</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>1/02/2019</td>
<td>TrueBeam RadioTherapy Delivery System</td>
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<td>Product Defect Correction</td>
<td>Class III</td>
<td>Hospital</td>
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<tr>
<td>1/02/2019</td>
<td>VariSource HDR and GammaMed</td>
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<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>31/01/2019</td>
<td>Medical Grade Carbon Dioxide Cylinders, C Size</td>
<td>Medicine</td>
<td>Product Defect Correction</td>
<td>Class III</td>
<td>Hospital</td>
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<tr>
<td>31/01/2019</td>
<td>NutriVital Premium Magnesium Complete 100 Tablets</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
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<tr>
<td>31/01/2019</td>
<td>OVC3 (One Visit Crown) 24/25 L A2</td>
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<td>Class III</td>
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<td>31/01/2019</td>
<td>OVC3 Hybrid Molar refill A3 - 36.37 L</td>
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<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
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<tr>
<td>30/01/2019</td>
<td>AXIUS Blower / Mister</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>30/01/2019</td>
<td>BioPlex 2200 ANA Screen Control Set. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/01/2019</td>
<td>OVC (One Visit Crown) Starter Kit Package containing OVC3 16/17s A3 refills</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
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<td>30/01/2019</td>
<td>Perfix Catheter Connector</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>30/01/2019</td>
<td>STA – VWF:RCo reagent. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>30/01/2019</td>
<td>UltraTemp Regular Kit and UltraTemp Rez Fast Set Kit</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
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<tr>
<td>29/01/2019</td>
<td>5x75mm Kii Fios Advanced Fixation Access System</td>
<td>Medical Device</td>
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<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>29/01/2019</td>
<td>MYXAZOLE clotrimazole 10 mg/g and hydrocortisone acetate 11.2 mg/g cream tube</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
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<tr>
<td>29/01/2019</td>
<td>Sonosite L25 Needle Guide Bracket</td>
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<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<td>24/01/2019</td>
<td>EMPOVIR cidofovir 375 mg/5 mL concentrated injection for infusion vial</td>
<td>Medicine</td>
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<td>Class II</td>
<td>Wholesale</td>
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<td>24/01/2019</td>
<td>Ingenuity CT Core 128</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class III</td>
<td>Hospital</td>
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<td>24/01/2019</td>
<td>Philips PageWriter TC Cardiographs (TC20/30/50/70)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
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<tr>
<td>22/01/2019</td>
<td>OA/RA</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
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<tr>
<td>22/01/2019</td>
<td>Philips Efficia CM Monitors</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Retail</td>
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<tr>
<td>21/01/2019</td>
<td>Burr Oval 12 Flute 5.5mm x 13cm</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/01/2019</td>
<td>Da Vinci S/SI Harmonic Ace Curved Shear Insert</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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</tbody>
</table>

The TGA publishes Australian recall actions in a searchable database to ensure the public has access to information about therapeutic products that have been recalled from the Australian market. If you are concerned about your health or if you have experienced an adverse event please seek advice from a health professional as soon as possible. Please read all the important information at the beginning of this report.
### Recall Action Commencement Date

<table>
<thead>
<tr>
<th>Date</th>
<th>Product Name/Description</th>
<th>Type of Product</th>
<th>Recall Action</th>
<th>Recall Action Classification</th>
<th>Recall Action Level</th>
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<tr>
<td>21/01/2019</td>
<td>Otto Bock PUSH VALVE/MAG VALVE</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<td>21/01/2019</td>
<td>Swan-Ganz Thermodilution Catheter</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>18/01/2019</td>
<td>Edwards Lifesciences IntraClude Intra-aortic Occlusion Device</td>
<td>Medical Device</td>
<td>Product Defect Alert</td>
<td>Class II</td>
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<td>18/01/2019</td>
<td>Electronic Thermometer supplied in Tiny Tots First Aid Kits</td>
<td>Medical Device</td>
<td>Recall</td>
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<td>18/01/2019</td>
<td>NutriVital Premium Glucosamine 1500 Plus</td>
<td>Medicine</td>
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<tr>
<td>18/01/2019</td>
<td>VITEK 2 - Card Pouch Integrity. An in vitro diagnostic medical device (IVD)</td>
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<td>Product Defect Correction</td>
<td>Class II</td>
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<tr>
<td>16/01/2019</td>
<td>Adapta Dual Chamber Pacemakers</td>
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<td>15/01/2019</td>
<td>ARIA Oncology Information System for Radiation Oncology, versions 15.1, 15.5 &amp; 15.6</td>
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<td>Product Defect Correction</td>
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<td>15/01/2019</td>
<td>Baha Tamper-proof Battery Door, 3pcs</td>
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<td>Disposable Cranial Perforator and Disposable Scalp Clips</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
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<td>14/01/2019</td>
<td>Programmer Software Update Supporting the Micra Transcatheter Pacing System</td>
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<td>XN-10 automated haematology analysers. An in vitro diagnostic medical device (IVD).</td>
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<td>Hospital</td>
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<tr>
<td>11/01/2019</td>
<td>Acusnare Polypectomy (Duck Bill Shaped) Snare</td>
<td>Medical Device</td>
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<td>11/01/2019</td>
<td>Tritanium PL cages</td>
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<td>Xper Flex Cardio Patient Monitoring System</td>
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<tr>
<td>10/01/2019</td>
<td>RX Misano Analyser. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
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<td>10/01/2019</td>
<td>Various Suction Catheters, Gastro-enteral Tubes, Intermittent Urology Catheters, Drainage Kits and sterile Urine Drainage Bags</td>
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<td>Hospital</td>
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<tr>
<td>8/01/2019</td>
<td>Max VPC Tray Base &amp; Max VPC Screw Caddy Brackets</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
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### System for Australian Recall Actions

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<th>Recall Action Commencement Date</th>
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<tr>
<td>7/01/2019</td>
<td>Fabian HFO, Fabian +nCPAP evolution and Fabian Therapy evolution</td>
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<td>Product Defect Correction</td>
<td>Class II</td>
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<td>Fabian Therapy and Fabian +nCPAP evolution</td>
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<td>Hospital</td>
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<tr>
<td>7/01/2019</td>
<td>Ingenuity TF PET/CT running software version 4.0.2 (4.0.0.26845)</td>
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<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>7/01/2019</td>
<td>Sandoz Irbesartan 150mg film-coated tablets Blister pack 30’s</td>
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<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
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<td>4/01/2019</td>
<td>FDGEN fluodeoxyglucose [18F] 200MBq/mL to 6000 MBq/mL injection vial</td>
<td>Medicine</td>
<td>Product Defect Correction</td>
<td>Class III</td>
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<td>4/01/2019</td>
<td>FDGEN fluodeoxyglucose [18F] 200MBq/mL to 6000 MBq/mL injection vial</td>
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<td>Product Defect Correction</td>
<td>Class II</td>
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<tr>
<td>3/01/2019</td>
<td>Various Philips MR Systems</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>2/01/2019</td>
<td>Alinity i Processing Module. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
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<tr>
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<td>Dräger Disposable Breathing Circuit</td>
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<td>Product Defect Correction</td>
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<td>2/01/2019</td>
<td>EliA ANA Positive Control 250 and EliA ANA Positive Control 2500/5000. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class III</td>
<td>Hospital</td>
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<tr>
<td>2/01/2019</td>
<td>Leica M525 F20 Microscope System</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>2/01/2019</td>
<td>Panocell-16 Kit. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
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<td>Class II</td>
<td>Hospital</td>
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<td>2/01/2019</td>
<td>Revision femoral neck H60mm lateralised + Screw</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>31/12/2018</td>
<td>Integra MAYFIELD Skull Clamps</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
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<td>24/12/2018</td>
<td>Various Swan-Ganz Catheters</td>
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<tr>
<td>21/12/2018</td>
<td>BILT3, IGM-2, and LACT2 Assays. An in vitro diagnostic medical device (IVD)</td>
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<td>Product Defect Correction</td>
<td>Class III</td>
<td>Hospital</td>
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<td>21/12/2018</td>
<td>Bronchi-cough pill (Qiguanyan Kousu Tanchuanwan)</td>
<td>Medicine</td>
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<td>Class II</td>
<td>Consumer</td>
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<td>21/12/2018</td>
<td>COBAS INTEGRA 400 plus analyser. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
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<td>21/12/2018</td>
<td>Interactive Precision IO Scan Adapters (3.00mmD and 3.40mmD Platforms)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
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<tr>
<td>20/12/2018</td>
<td>ARCHITECT B12 Reagent Kit. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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</table>
## System for Australian Recall Actions

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<tr>
<th>Recall Action Commencement Date</th>
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<th>Recall Action Classification</th>
<th>Recall Action Level</th>
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<tr>
<td>20/12/2018</td>
<td>ARCHITECT Rubella IgM Reagent Kit. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
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<td>Class II</td>
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<td>20/12/2018</td>
<td>Autostainer Slide Racks. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>20/12/2018</td>
<td>GETINGE XS32 Flat Screen Holder</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>20/12/2018</td>
<td>IV Pole Collar for Spectra Optia Apheresis System</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class III</td>
<td>Hospital</td>
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<td>20/12/2018</td>
<td>Trima Accel Automated Blood Collection System</td>
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<td>Product Defect Correction</td>
<td>Class III</td>
<td>Hospital</td>
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<td>20/12/2018</td>
<td>Xyrem (sodium oxybate) 500 mg/mL oral solution</td>
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<td>Product Defect Alert</td>
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<td>18/12/2018</td>
<td>Femoral Head Allograft</td>
<td>Biological</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
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<td>18/12/2018</td>
<td>GE CareScape One Monitor with an ECG USB Patient Cable or SPO2 Masimo USB Patient Cable</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>18/12/2018</td>
<td>Mako Onlay Insert Extractor</td>
<td>Medical Device</td>
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<tr>
<td>18/12/2018</td>
<td>StealthAir Percutaneous Pin Adapter</td>
<td>Medical Device</td>
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<td>Class II</td>
<td>Hospital</td>
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<td>17/12/2018</td>
<td>Amica Generator, dual ablation system (hybrid microwave and radio frequency)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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<td>17/12/2018</td>
<td>APO-Valsartan 40/80/160/320mg products</td>
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<td>17/12/2018</td>
<td>Bayer Overhead Counterpoise mounting system</td>
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<td>Product Defect Correction</td>
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<td>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)</td>
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<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>17/12/2018</td>
<td>Fructosamine Calibrator, Fructosamine Control 1 and Control 3. An in vitro diagnostic medical device (IVD).</td>
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<td>Product Defect Correction</td>
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<td>17/12/2018</td>
<td>MOSAIQ Radiation Oncology version</td>
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<td>Class II</td>
<td>Hospital</td>
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<td>Sandoz IRBESARTAN/HCT batches</td>
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<td>ADVIA Centaur aTG. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
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<td>14/12/2018</td>
<td>Atellica IM Anti-Thyroglobulin. An in vitro diagnostic medical device (IVD).</td>
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<td>Hazard Alert</td>
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<td>Hazard Alert</td>
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<td>Power-LOAD (Cot Fastener)</td>
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<td>Various Olympus Grasping Forceps and Biopsy Forceps</td>
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<td>Platinum ICDs and CRT-Ds Devices</td>
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<td>Stryker Visum II LED Surgical Lighting system - EDS (Equipment Delivery System) Light Suspensions, Central Axis</td>
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<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>12/12/2018</td>
<td>Anatomic Tibial Base Plate for fixed bearing insert cemented, Size 4</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
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<td>12/12/2018</td>
<td>Mako Vizadiscs and Vizadisc Hip Tracking Kit</td>
<td>Medical Device</td>
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<td>Class II</td>
<td>Hospital</td>
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<td>MILRINONE-CLARIS milrinone (as lactate) 10 mg/10 mL concentrated injection ampoule</td>
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<td>PP2001 HBA Agar Plates. An in vitro diagnostic medical device (IVD).</td>
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<td>Tropisetion MYX 2mg/mL solution for injection or infusion ampoules</td>
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<td>UniCel Dxl 600 &amp; 800 Access Immunoassay Systems &amp; UniCel DxC 660i, 860i, 860i, 880i Synchron Access Clinical Systems. An in vitro diagnostic medical device (IVD).</td>
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<td>Biograph Horizon</td>
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<td>11/12/2018</td>
<td>PROXIMATE Haemorrhoidal Circular Stapler</td>
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<td>Various Signa OpenSpeed, Infinity, Profile Ovation, Brivo, Optima, Creator and Explorer MIR System software</td>
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<td>Celsite Safety SST601F 6.5F SI - Access Ports</td>
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<td>RayOne Trifocal RAO603F + 10.5 D ADD 3.5 Intraocular Lens</td>
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<td>7/12/2018</td>
<td>CORAIL Female Broaches (Size 9-20)</td>
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<td>Class II</td>
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<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
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<td>7/12/2018</td>
<td>Discovery NM 530c and Ventri Nuclear Medicine system using Premium (automatic) table and with MS Windows Operating System</td>
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<td>7/12/2018</td>
<td>SHOEBOX Audiometry Standard and Pro V5.1.</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
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<td>Retail</td>
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<td>MOSAIOQ Radiation Oncology version 2.64 SP9 and higher using Varian True BEAM or Varian 4D or Siemens RTT</td>
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<td>Class II</td>
<td>Hospital</td>
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<td>5/12/2018</td>
<td>Billed Maxi+ Phototherapy Unit</td>
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<td>Product Defect Correction</td>
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<td>4/12/2018</td>
<td>CARESCAPE B850 Monitors; Version MBC303</td>
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<td>Hospital</td>
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<td>4/12/2018</td>
<td>HeartMate 3 Left Ventricular Assist System and Outflow Graft Clip</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I</td>
<td>Hospital</td>
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<td>4/12/2018</td>
<td>MAS Alcohol/Ammonia Control. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
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<td>Cisbio - Chromogranin A (CGA-ELISA). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
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<td>Hospital</td>
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<td>Digital Angiography System Trinias</td>
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<td>Product Defect Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>3/12/2018</td>
<td>Forceps, Coupler – GEM4183C</td>
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The TGA publishes Australian recall actions in a searchable database to ensure the public has access to information about therapeutic products that have been recalled from the Australian market. If you are concerned about your health or if you have experienced an adverse event please seek advice from a health professional as soon as possible. Please read all the important information at the beginning of this report.
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The TGA publishes Australian recall actions in a searchable database to ensure the public has access to information about therapeutic products that have been recalled from the Australian market. If you are concerned about your health or if you have experienced an adverse event please seek advice from a health professional as soon as possible. Please read all the important information at the beginning of this report.
## System for Australian Recall Actions

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The TGA publishes Australian recall actions in a searchable database to ensure the public has access to information about therapeutic products that have been recalled from the Australian market. If you are concerned about your health or if you have experienced an adverse event please seek advice from a health professional as soon as possible. Please read all the important information at the beginning of this report.
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<td>13/04/2018</td>
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<td>13/04/2018</td>
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<td>Radiometer TCM5 FLEX/ BASIC Transcutaneous Monitor</td>
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<td>IntraClude Intra-aortic Occlusion Device</td>
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<td>Philips Ingenuity Core (728321)</td>
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<td>11/04/2018</td>
<td>EliA Intrinsic Factor Well. An in vitro diagnostic medical device (IVD)</td>
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<td>Pulmonary Conduit, Cryopreserved</td>
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<tr>
<td>10/04/2018</td>
<td>Hudson RCI One-Way Valve with Capped Monitoring Port</td>
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<td>6/04/2018</td>
<td>ADVIA Chemistry Systems - Urea Nitrogen (UN). An in vitro diagnostic medical device (IVD)</td>
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<td>5/04/2018</td>
<td>5mm ENDOPATH XCEL Trocars with Optiview Technology</td>
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<td>4/04/2018</td>
<td>Cobas e 801 Analytical Unit. An in vitro diagnostic medical device (IVD)</td>
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### System for Australian Recall Actions

The TGA publishes Australian recall actions in a searchable database to ensure the public has access to information about therapeutic products that have been recalled from the Australian market. If you are concerned about your health or if you have experienced an adverse event please seek advice from a health professional as soon as possible. Please read all the important information at the beginning of this report.

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<tr>
<th>Recall Action Commencement Date</th>
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<th>Recall Action Level</th>
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<tr>
<td>4/04/2018</td>
<td>Immucor MATCH IT! DNA Software version 3.29.0 (released 30 Jan 2018) for use with LIFECODES HLA-B SSO Typing Kits. In vitro diagnostic medical devices.</td>
<td>Medical Device</td>
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<td>Mako Onlay Insert Extractor (part of the Restoris MCK (Multi Compartmental Knee) Unicondylar System)</td>
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<td>3/04/2018</td>
<td>OXOID AST DISC CT1412B – Cefpirome CPO30ug 5x 50 discs. An in vitro diagnostic medical device.</td>
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<td>F &amp; P SleepStyle CPAP Device</td>
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<td>Randox Lipase Reagents for use on RX instruments. An in vitro diagnostic medical device (IVD)</td>
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<td>RPK-01 Luer Connector</td>
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<td>28/03/2018</td>
<td>Spot Vision Screener 100 with software version up to and including 3.0.01.07</td>
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<td>StoneBreaker Pneumatic Lithotripter and associated accessories</td>
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<td>Dimension Vista CTNI Sample Diluent and Multi 2 Sample Diluent. An in vitro diagnostic medical device (IVD)</td>
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<td>27/03/2018</td>
<td>Getinge VOLISTA StandOP and TRIPOD surgical lights</td>
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<td>Product Defect Correction</td>
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<td>27/03/2018</td>
<td>PTS Panels CHOL+GLU test strips. An in vitro diagnostic medical device (IVD)</td>
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<tr>
<td>27/03/2018</td>
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<td>27/03/2018</td>
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<tr>
<td>27/03/2018</td>
<td>Ultrafilter U9000 for use with AK96 and AK98 v1 dialysis machines</td>
<td>Medical Device</td>
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<td>26/03/2018</td>
<td>ACUSON SC2000 ultrasound with 5.0 software (VB20A, VB20B, or VB20C) and the ECG (physio) hardware and Auxiliary (AUX IN/OUT) cable</td>
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<td>Product Defect Correction</td>
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<td>Cornea (left and right)</td>
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<td>Entroy Pool Lifter</td>
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<tr>
<td>26/03/2018</td>
<td>Infinity MCable Mainstream Sensor, Revision 16 only (used with Acute Care System (IACS) Monitoring Solution; and the Infinity M540 Stand-Alone Patient Monitor)</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
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<td>NAT Testing for ocular, musculoskeletal and skin grafts</td>
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<td>22/03/2018</td>
<td>iQ200 Series Urine Microscopy Analysers</td>
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<td>IH-1000 with software version 04.07.02. An in vitro diagnostic medical device (IVD)</td>
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<td>IMRIS ORT100 and ORT300 Operating Room Tables</td>
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<td>Covidiens LigaSure Exact Dissector Nano-Coated 20.6mm-21cm</td>
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<td>20/03/2018</td>
<td>Thermo Scientific Remel Neisseria meningitidis Poly A-D 2mL and Neisseria meningitidis Group D 2mL. An in vitro diagnostic medical device (IVD)</td>
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<td>19/03/2018</td>
<td>HemoCue WBC Diff analysers and WBC Diff Microcuvettes. An in vitro diagnostic medical device (IVD)</td>
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<td>Ingenuity TF PET/CT System with Addonics Mass Storage Device (MSD)</td>
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<td>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</td>
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<td>Capio Suture Capturing Devices (SLIM, Standard, Open Access, RP)</td>
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<td>da Vinci X Patient Side Cart Arm Controller Joint Circuit Boards</td>
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<td>Drager Infinity Acute Care System (IACS) Monitoring Solution with s/w VG2.2 to VG6.0 &amp; the Infinity M540 Stand-Alone Patient Monitor s/w from VG2.2 to VG6.0</td>
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<td>RayStation and RayPlan</td>
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<td>U-100 Insulin Syringe 0.5mL 27G and 29G</td>
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<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>23/02/2018</td>
<td>Use of Tristel Trio Wipes System with GE TEE probe</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
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<tr>
<td>22/02/2018</td>
<td>Femoral Head</td>
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<td>Hazard Alert</td>
<td>Class II</td>
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<tr>
<td>21/02/2018</td>
<td>Enterprise 8000 Electrical Bed</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
<td>Class III</td>
<td>Consumer</td>
</tr>
<tr>
<td>21/02/2018</td>
<td>Invivo DynaCAD Breast and Prostate with software versions 3.4 and 3.5</td>
<td>Medical Device</td>
<td>Product Defect Correction</td>
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<tr>
<td>21/02/2018</td>
<td>LUCAS 2 Chest Compression System</td>
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<td>Product Defect Correction</td>
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<tr>
<td>20/02/2018</td>
<td>ACM W/FEM NOZZLE/PRESS (PK6) and INRPLS HP W/HIGH FLOW TIP</td>
<td>Medical Device</td>
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<tr>
<td>20/02/2018</td>
<td>ARGENE Adenovirus R-gene and Parechovirus R- Gene Control Kits. An in vitro diagnostic medical device (IVD)</td>
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<td>Product Defect Alert</td>
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<tr>
<td>20/02/2018</td>
<td>Faulding Vitamin B12</td>
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<tr>
<td>19/02/2018</td>
<td>AQUIOS CL Flow Cytometry System. An in vitro medical device.</td>
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<td>Medical Device</td>
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<td>19/02/2018</td>
<td>Single Use Instruments including Scissors, Forceps, and Suckers</td>
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<td>Hospital</td>
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<tr>
<td>14/02/2018</td>
<td>balanSys UNI convex PE inlay x/6, x/7, x/9</td>
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<td>Hazard Alert</td>
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<tr>
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<td>14/02/2018</td>
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<tr>
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<td>VIDAS and mini VIDAS systems. An in vitro diagnostic medical device (IVD)</td>
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<td>Enterprise and Citadel Range Beds</td>
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<td>Hypothermia Caps, Mittens and Slippers</td>
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<td>Indigo carmine - Oral Solution - 20mg/5ml</td>
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<td>12/02/2018</td>
<td>TRUST FENMOL paracetamol 500mg ibuprofen 200mg tablet blister pack</td>
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<td>8/02/2018</td>
<td>Biograph Horizon with VJ20A Software</td>
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<td>Cortisol Saliva ELISA. An in vitro diagnostic medical device (IVD)</td>
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<td>Foetal Haemoglobin Monoclonal Antibody (HBF-1), FITC. An in vitro diagnostic medical device (IVD)</td>
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<td>Maquet PowerLED, HLED 700 SF and Volista 600SF Surgical Lighting Systems</td>
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<td>Small Pedicle Probe ELL-IN 02 23-N</td>
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<td>Zenith Branch Iliac Endovascular Graft (ZBIS) - Patient Card</td>
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<td>Recall Action Commencement Date</td>
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<td>Type of Product</td>
<td>Recall Action</td>
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<td>6/02/2018</td>
<td>3M Bair Hugger Full Access Underbody Blanket</td>
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<td>6/02/2018</td>
<td>ACUSON SC2000 ultrasound systems with software versions VB10A, VB10B, VB10D, VB10E that have PRIME and eSie PISA software licenses</td>
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<td>Automate 2550 and 1250 Aliquotter Tip Present Sensor. An in vitro diagnostic medical device (IVD)</td>
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<td>Dimension Vista Calcium (CA) Flex reagent cartridge. An in vitro diagnostic medical device (IVD)</td>
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<td>Mako RIO System Ethernet to Fiber Optic Converter</td>
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<td>5/02/2018</td>
<td>Radiometer TCM5 FLEX / BASIC Transcutaneous Monitor</td>
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<td>5/02/2018</td>
<td>Signature Ceramic Femoral Head</td>
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<td>Class II</td>
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<td>Unomedical ConvaTec Frazier Suction Handle (included in Foot Pack Health and Lower Extremity Procedure Packs)</td>
<td>Medical Device</td>
<td>Product Defect Alert</td>
<td>Class II</td>
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<td>Phadia AB Product EliA anti-TSH-R Well. An in vitro diagnostic medical device (IVD)</td>
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<td>Hospital</td>
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<tr>
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<td>Valleylab FT10 energy platform</td>
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<td>Wholesale</td>
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<tr>
<td>31/01/2018</td>
<td>Femoral Head</td>
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<td>Hazard Alert</td>
<td>Class III</td>
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<td>31/01/2018</td>
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<td>Hazard Alert</td>
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<td>31/01/2018</td>
<td>O-Arm 1000 Imaging System (3rd Edition)</td>
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<td>Brilliance Big Bore Oncology CT, Brilliance Big Bore Radiology CT with software version 4.2.0</td>
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<td>Hospital</td>
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<td>30/01/2018</td>
<td>Custom Made Implant Systems with Minimally Invasive Grower (MIG) component</td>
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<td>30/01/2018</td>
<td>ETEST Polymyxin B (PO1024) blister packaging. An in vitro diagnostic medical device (IVD)</td>
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<td>29/01/2018</td>
<td>Double Row Footplates, TL-HEX Sterile</td>
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<td>Recall Action Commencement Date</td>
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<td>29/01/2018</td>
<td>Swish Tapered Implant 4.1mmD x12mmL SBM Dual Blast; 4.8mmD Platform</td>
<td>Medical Device</td>
<td>Recall</td>
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<td>25/01/2018</td>
<td>BD Phoenix Gram Negative Panels containing colistin.</td>
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<tr>
<td>25/01/2018</td>
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<td>24/01/2018</td>
<td>Frazier suction handle</td>
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<td>24/01/2018</td>
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<tr>
<td>22/01/2018</td>
<td>ADVIA Centaur Cyclosporine, DHEA-SO4, Folate and HBc IgM Assays. An in vitro diagnostic medical device (IVD)</td>
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<tr>
<td>22/01/2018</td>
<td>Calmurid Cream tube 100g</td>
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<tr>
<td>22/01/2018</td>
<td>therascreen PyroMark Gold Q24 Reagents and Pyro Buffers. An in vitro diagnostic medical device (IVD)</td>
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<td>19/01/2018</td>
<td>Allura Xper Systems with an attached 7th or 8th monitor</td>
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<td>Class II</td>
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<td>19/01/2018</td>
<td>APO-METFORMIN XR 1000 metformin hydrochloride 1000mg modified release tablet blister pack 60 tablets</td>
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<td>19/01/2018</td>
<td>Artis One in conjunction with table</td>
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<td>18/01/2018</td>
<td>ADVIA Centaur CP, XP, and XPT Systems with use of BNP and TSH3-Ultra</td>
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<td>18/01/2018</td>
<td>Panther and Panther Fusion Systems with 19-in monitor</td>
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<td>17/01/2018</td>
<td>Moog Infusion System Administration Sets</td>
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<td>16/01/2018</td>
<td>AFFINITY NT Cardiotomy Venous Reservoirs stand-alone uncoated and coated models.</td>
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<td>BVM (Bag-Valve-Mask) Manual Resuscitation Systems</td>
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<tr>
<td>16/01/2018</td>
<td>FC 500 Series Flow Cytometers (new, reconditioned or refurbished). An in vitro diagnostic medical device (IVD)</td>
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<td>16/01/2018</td>
<td>LiNA Gold Loop</td>
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<td>16/01/2018</td>
<td>MAQUET VOLISTA central handle on StanOP, TRIPOD and ACCESS Cupolas</td>
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</table>

The TGA publishes Australian recall actions in a searchable database to ensure the public has access to information about therapeutic products that have been recalled from the Australian market. If you are concerned about your health or if you have experienced an adverse event please seek advice from a health professional as soon as possible. Please read all the important information at the beginning of this report.
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<td>16/01/2018</td>
<td>Vacuette Minicollect Complete 1ml Sodium Citrate 3.2%. An in vitro diagnostic medical device.</td>
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<td>16/01/2018</td>
<td>VIRAZOLE (Ribavirin Solution for Injection 0.1g/mL), 5 x 12 mL vials</td>
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<td>Retail</td>
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<td>BrightView, BrightView X, BrightView XCT, Precedence 6, Precedence 16</td>
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<td>15/01/2018</td>
<td>Vadi Heater</td>
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<td>12/01/2018</td>
<td>CARESCAPE Central Station (CSCS) software version 2.0.2</td>
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<td>Recall for Product Correction</td>
<td>Class I</td>
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<td>Hematoxylin II and Horseradish Peroxidase Reagents - An in vitro medical diagnostic device (IVD)</td>
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<td>Class II</td>
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<td>12/01/2018</td>
<td>Radiolucent Spine Surgery Frame</td>
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<td>12/01/2018</td>
<td>Runyes Autoclave</td>
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<td>Class II</td>
<td>Retail</td>
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<tr>
<td>12/01/2018</td>
<td>Xpert HIV-I Viral Load. An in vitro diagnostic medical device (IVD)</td>
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<td>Nellix EndoVascular Aneurysm Sealing System</td>
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<td>NAJA Spinal Ligament Systems for Spinal Stabilisation</td>
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<tr>
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<td>Phadia ImmunoCAP Allergen c5, Ampicilloyl and ImmunoCAP Allergen c6, Amoxicilloyl</td>
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<tr>
<td>9/01/2018</td>
<td>SIGMA HP PFJ Cemented Trochlear Implants</td>
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<td>DBL METRONIDAZOLE INTRAVENOUS INFUSION metronidazole 500mg/100mL solution for injection bag</td>
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<td>Class II</td>
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<td>5/01/2018</td>
<td>Philips IntelliVue Information Center (PIIC) IX</td>
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<td>Recall for Product Correction</td>
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<td>4/01/2018</td>
<td>Salter Labs Oxygen Cannulas</td>
<td>Medical Device</td>
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<tr>
<td>4/01/2018</td>
<td>da Vinci Xi Surgical System P6b Software</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
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</table>
# System for Australian Recall Actions

The TGA publishes Australian recall actions in a searchable database to ensure the public has access to information about therapeutic products that have been recalled from the Australian market. If you are concerned about your health or if you have experienced an adverse event please seek advice from a health professional as soon as possible. Please read all the important information at the beginning of this report.

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<tr>
<th>Recall Action Commencement Date</th>
<th>Product Name/Description</th>
<th>Type of Product</th>
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<tr>
<td>4/01/2018</td>
<td>Synchron Enzyme Validator. An in vitro diagnostic medical device (IVD).</td>
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<td>ClearSight Heart Reference Sensor</td>
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<td>DuraClone B27 Reagent Kit - an in vitro diagnostic medical device (IVD)</td>
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<td>Haemoglobin A1c (HbA1c) Reagent. An in vitro medical device.</td>
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<td>SynchroMed II Implantable Drug Infusion Pump</td>
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<tr>
<td>21/12/2017</td>
<td>Ingenuity TF PET/CT running software version 4.0.2 (4.0.0.26645)</td>
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<tr>
<td>21/12/2017</td>
<td>Restorelle DirectFix Anterior, Restorelle DirectFix Posterior and Altis Single Incision Sling</td>
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<tr>
<td>20/12/2017</td>
<td>DePuy Synthes Confidence Kit Spinal Cement System</td>
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<td>Hospital</td>
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<td>20/12/2017</td>
<td>Ready-Prep %CDT by HPLC using the CDM software version MVC133091. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
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<td>20/12/2017</td>
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<td>19/12/2017</td>
<td>CARBAGLU carglumic acid 200 mg dispersible tablets tube</td>
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<td>19/12/2017</td>
<td>CARESCAPE R860 ventilators with software version 10SP05</td>
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<td>19/12/2017</td>
<td>CELL-DYN Emerald 22 Analyser with software version v3.0.0. An in vitro diagnostic medical device (IVD)</td>
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<td>ETEST Teicoplanin 256 (TP) SPB and Foam packaging. An in vitro diagnostic medical device (IVD)</td>
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<td>Recall Action Commencement Date</td>
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<td>19/12/2017</td>
<td>Flexible Uretero-Reno Videoscope &amp; Flexible Uretero-Reno Fiberscope</td>
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<td>19/12/2017</td>
<td>Medtronic Clip Gun Scalp Clip System</td>
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<tr>
<td>19/12/2017</td>
<td>PEDEA ibuprofen 10 mg/2 mL solution for intravenous infusion 2 mL glass ampoule</td>
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<td>19/12/2017</td>
<td>Philips Intellivue Patient Monitor X3</td>
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<td>19/12/2017</td>
<td>Signia Power Handle</td>
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<td>19/12/2017</td>
<td>SynCardia Freedom Driver System (a component of the SynCardia temporary Total Artificial Heart System)</td>
<td>Medical Device</td>
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<tr>
<td>18/12/2017</td>
<td>Architect c4000, c8000, c16000 Cuvette Segment. An in vitro diagnostic medical device (IVD)</td>
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<td>18/12/2017</td>
<td>ARCHITECT DHEA-S Reagents. An in vitro diagnostic medical device (IVD)</td>
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<td>18/12/2017</td>
<td>Equinox Advantage</td>
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<tr>
<td>18/12/2017</td>
<td>IMMULITE/IMMULITE 1000 IMMULITE 2000/IMMULITE 2000 XPI Assays. An in vitro diagnostic medical device (IVD)</td>
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<td>Recall for Product Correction</td>
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<td>18/12/2017</td>
<td>Nv Guider Catheter 90cm</td>
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<td>18/12/2017</td>
<td>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.</td>
<td>Medical Device</td>
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<td>Uphold LITE with Capio SLIM and Solyx Single Incision Sling System</td>
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<td>14/12/2017</td>
<td>Artis systems with Artis tables</td>
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<td>14/12/2017</td>
<td>Vacuette Minicollect Complete 1mL Sodium Citrate 3.2%</td>
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<td>13/12/2017</td>
<td>C- Series lifts</td>
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<td>Consumer</td>
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<td>13/12/2017</td>
<td>Transseptal Needle</td>
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<td>Recall Action Commencement Date</td>
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<td>12/12/2017</td>
<td>MCK Tibial Baseplate-RM/LL-SZ 2 and MCK Tibial Baseplate-RM/LL-SZ 7</td>
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<tr>
<td>12/12/2017</td>
<td>Spaplus Weekly wash Protocol and Bottles. An in vitro diagnostic medical device (IVD)</td>
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<td>12/12/2017</td>
<td>Volcano Imaging Systems and Core Mobile Imaging Systems</td>
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<tr>
<td>12/12/2017</td>
<td>Volcano sSi, CORE, CORE Mobile Systems with software version V3.5</td>
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<td>C-Series Lifts</td>
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<td>11/12/2017</td>
<td>Malecot Nephrostomy Catheter Set</td>
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<td>11/12/2017</td>
<td>TomoTherapy High Performance Patient Couch</td>
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<td>8/12/2017</td>
<td>Hercules Patient Lifter</td>
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<td>8/12/2017</td>
<td>Pipet Tips used with AutoDG System. An in vitro diagnostic medical device</td>
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<td>6/12/2017</td>
<td>AQUIOS CL Flow Cytometry System. software versions 2.0, 2.0.1, 2.1. An in vitro diagnostic medical device (IVD)</td>
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<td>6/12/2017</td>
<td>MIA FORA NGS HLA FLEX 11 KIT (24 tests). An in vitro diagnostic medical device (IVD)</td>
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<td>Airsep Impulse Elite Oxygen Conserving Device</td>
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<td>Balt Cristal Balloons</td>
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<td>4/12/2017</td>
<td>Brilliance iCT (Model 728306), Brilliance iCT SP (Model 728311) and IQon Spectral CT (Model 728332) Scanner systems</td>
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<td>Digital Accelerators with iViewGT or XVI</td>
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<td>Phadia Prime with software up to and including version 2.1.4. An in vitro diagnostic device (IVD)</td>
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<td>PRICELINE PHARMACY PERIOD PAIN RELIEF naproxen sodium 275mg tablet blister pack</td>
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<td>Cordis S.M.A.R.T. Flex Vascular Stent System</td>
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<td>CADD Legacy 1, Model 6400 Ambulatory Infusion Pump</td>
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<td>IntelePACS with software versions 4-3-1 and up</td>
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<td>27/11/2017</td>
<td>Thermo Scientific Remel Shigella sonnei (Phases 1 &amp; 2) Agglutinating Serum. An in vitro diagnostic medical device (IVD)</td>
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<td>RayStation and RayPlan</td>
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<td>SURGICAL GOWN UL HP L</td>
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<td>Global Cup Poly Liner, Neutral prostheses</td>
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<td>Integrity R1.2 and Integrity R3.2 systems with a Precise Treatment Table for ATM license option</td>
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<td>Rechargeable Li-Ion Batteries with incorrect firmware used in Puritan Bennett 980 Ventilators</td>
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<td>LIPITOR atorvastatin 80mg (as calcium) tablet blister pack</td>
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<td>20/11/2017</td>
<td>Fujifilm Synapse PACS software version 4.0, 4.1, 4.2, 4.3 (a picture archiving and communication system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>Recall Action Commencement Date</td>
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<td>20/11/2017</td>
<td>Pentacam AXL, with software versions 1.21r01, 1.21r03, 1.21r11 and 1.21r13</td>
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<td>20/11/2017</td>
<td>Spectra System/Legacy Guided Surgery Handle Kit Inserts</td>
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<td>20/11/2017</td>
<td>Tango Reflex - Lasers, Ophthalmic Model LTS106-T</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>Hospital</td>
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<td>17/11/2017</td>
<td>Bard ArcticSun ArticGel Pads</td>
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<td>17/11/2017</td>
<td>Epiclone Anti-M Blood Grouping Reagent. An in vitro diagnostic medical device (IVD)</td>
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<td>Recall for Product Correction</td>
<td>Class II</td>
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<tr>
<td>16/11/2017</td>
<td>iChemVELOCITY Urine Chemistry Strips. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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<tr>
<td>16/11/2017</td>
<td>iQ200 Series Urine Microscopy Analyzer with Barcode Reader Model NFT-2100</td>
<td>Medical Device</td>
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<td>16/11/2017</td>
<td>Remisol Advance Software Versions 1.6-1.9, Architect Driver</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>15/11/2017</td>
<td>Foetal Haemoglobin Monoclonal Antibody (HBF-1). An in vitro diagnostic medical device (IVD)</td>
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<td>15/11/2017</td>
<td>ProTrack Microcatheter</td>
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<td>15/11/2017</td>
<td>Signature Orthopaedics Logival 20 degree Hooded XLPE Liner</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
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<td>Hospital</td>
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<td>15/11/2017</td>
<td>TunneLoc Tibial Fixation Devices (used during anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) reconstruction)</td>
<td>Medical Device</td>
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<td>Hospital</td>
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<td>14/11/2017</td>
<td>MAQUET HLX 2004-5 DF, HLX 3004-5 DF and XTEN DF cupolas Surgical Lighting System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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<tr>
<td>13/11/2017</td>
<td>CP5 control panels and HLM bubble sensors and EP packs manufactured prior to 10 February, 2017</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/11/2017</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
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<tr>
<td>13/11/2017</td>
<td>METS Principal Shaft</td>
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<td>13/11/2017</td>
<td>Percuvance Percutaneous Surgical System</td>
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<td>13/11/2017</td>
<td>Thermolisher Remel Bactipstaph Latex Kits</td>
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<td>Recall</td>
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<tr>
<td>10/11/2017</td>
<td>Accent / Anthem, Accent MRI / Accent ST, Assurity / Allure and Assurity MRI devices</td>
<td>Medical Device</td>
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<td>Class II</td>
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<tr>
<td>10/11/2017</td>
<td>APO-Perindropril Arginine 2.5mg, AUST R: 184808</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
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<tr>
<td>8/11/2017</td>
<td>Disposable Reuter Tip-Deflecting Wire Guide</td>
<td>Medical Device</td>
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<td>Class II</td>
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<tr>
<td>8/11/2017</td>
<td>DxH 500 Open-Vial Haematology System, with software version 1.0.2 and 1.1. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
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<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>8/11/2017</td>
<td>LIFEPAK EXPRESS AED, LIFEPAK CR Plus AED, LIFEPAK 1000 defibrillator, or LIFEPAK 500 Biphasic AED with a pink connector</td>
<td>Medical Device</td>
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<tr>
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<tr>
<td>8/11/2017</td>
<td>Philips Brilliance 64, Ingenuity Core128 and Ingenuity CT with software version 4.1.6</td>
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<td>SOMATOM Definition AS, Definition, Definition Edge, Definition Flash and SOMATOM Force</td>
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<td>Eluvia 150mm and Innova 200mm Stent Systems</td>
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<td>Preloaded hydrophobic intraocular lenses</td>
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<td>7/11/2017</td>
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<tr>
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<td>V-PRO 60 Low Temperature Sterilisation System with VAPROX HC Sterilant</td>
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<tr>
<td>6/11/2017</td>
<td>Compella Air Surfaces Bed System (220 - 240 V, 50 Hz), used in conjunction with International 220 - 240 V, 50 Hz Controllers</td>
<td>Medical Device</td>
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<tr>
<td>6/11/2017</td>
<td>Compounded Medications within CADD Medication Non-flow stop Cassette Reservoirs</td>
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</table>
### System for Australian Recall Actions

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<tr>
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<tr>
<td>6/11/2017</td>
<td>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)</td>
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<tr>
<td>6/11/2017</td>
<td>SENSATION PLUS 8Fr. 50cc Intra-Aortic Balloon Catheter with Insertion Kit &amp; STATLOCK</td>
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<td>3/11/2017</td>
<td>Acetabular Cup Introducer (32mm)</td>
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<td>3/11/2017</td>
<td>Alaris System Pump module (LVP), Mechanism Sub-assembly and Kit Assembly</td>
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<td>Doro Sterile Disposable Skull Pins</td>
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<td>2/11/2017</td>
<td>Midazolam APOTEX midazolam 5mg/1 mL solution for injection ampoule</td>
<td>Medicine</td>
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<tr>
<td>1/11/2017</td>
<td>RHD2.5 Hex Driver, 2.5mm with GemLock Retention, contained within TSVKIT Surgical Kit</td>
<td>Medical Device</td>
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<tr>
<td>1/11/2017</td>
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<td>31/10/2017</td>
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<td>31/10/2017</td>
<td>FLEX Monoclonal Rabbit Anti-Human Estrogen Receptor Clone EP1, Ready-to-use. An in vitro diagnostic medical device (IVD).</td>
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<tr>
<td>30/10/2017</td>
<td>Drystar DT 2 C Hardcopy Film 14” x 17”</td>
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<td>30/10/2017</td>
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<tr>
<td>30/10/2017</td>
<td>Veletri Consumables Kit with non Flow-Stop CADD Medication Cassette Reservoirs</td>
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<td>27/10/2017</td>
<td>Sorin Group perfusion system – Heater Cooler 1T devices</td>
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<tr>
<td>27/10/2017</td>
<td>Sorin Group perfusion system – Heater Cooler 3T devices</td>
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System for Australian Recall Actions

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<tbody>
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<td>Medical Device</td>
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<tr>
<td>17/10/2017</td>
<td>Beater-Positioner-Aligner</td>
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<tr>
<td>17/10/2017</td>
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<tr>
<td>17/10/2017</td>
<td>Ingenuity TF PET/CT System with software version 4.0.3.26129</td>
<td>Medical Device</td>
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<tr>
<td>17/10/2017</td>
<td>Non-Flow-Stop CADD Medication Cassette Reservoirs 50 and 100mL</td>
<td>Medical Device</td>
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<tr>
<td>16/10/2017</td>
<td>AQUIOS CL Flow Cytometry System. An in vitro diagnostic medical device (IVD)</td>
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<tr>
<td>16/10/2017</td>
<td>CareLink iPro Therapy Management Software MMT-7340</td>
<td>Medical Device</td>
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<tr>
<td>16/10/2017</td>
<td>Pentax ED-3490TK Video Duodenoscope</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>16/10/2017</td>
<td>Radiometer ABL800 series with FLEXQ module. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
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<td>13/10/2017</td>
<td>Ceiling Unit CU5001/3 and CU 3-21/23</td>
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<td>Recall for Product Correction</td>
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<tr>
<td>13/10/2017</td>
<td>ERGO version 1.7.3 and higher and using a Multileaf Collimator (MLC) device for planning</td>
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<td>Recall for Product Correction</td>
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<tr>
<td>12/10/2017</td>
<td>Gentamicin / Gentamicin &amp; Citrate, Syrings, Bags and Eye Drops</td>
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<tr>
<td>11/10/2017</td>
<td>All Carestation 620, 650 and 650c Anaesthesia systems</td>
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<td>Corpus Powered Wheelchairs</td>
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<td>Recall for Product Correction</td>
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<tr>
<td>11/10/2017</td>
<td>DIMETAPP COUGH COLD &amp; FLU DAYTIME/NIGHTTIME LIQUID CAPS capsule blister pack</td>
<td>Medicine</td>
<td>Recall</td>
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<td>11/10/2017</td>
<td>Integra CUSA Clarity Footswitch packaged with CUSA Clarity Console C7000</td>
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<tr>
<td>9/10/2017</td>
<td>Abut Gold Friction-Fit</td>
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<td>Retail</td>
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<td>9/10/2017</td>
<td>Conformable GORE TAG Thoracic Endoprosthesi</td>
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<td>Recall for Product Correction</td>
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<td>Prick-Test Diagnostic Rye Flour B16</td>
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<tr>
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<td>Xpert EV Assay. An in vitro diagnostic medical device (IVD)</td>
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<tr>
<td>6/10/2017</td>
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<td>Fluorocell PLT reagent. An in vitro diagnostic medical device (IVD)</td>
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<td>Bard Max-Core Disposable Core Biopsy Instrument</td>
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<td>3/10/2017</td>
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<td>Artis systems with wireless footswitch</td>
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<td>Mobile Detector Holder Trolley (9890-010-88152)</td>
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<tr>
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<td>Lucrin Depot Paediatric acetate 30mg for injection, prefilled dual chamber syringe</td>
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<td>Recall for Product Correction</td>
<td>Class II</td>
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<tr>
<td>26/07/2017</td>
<td>Various Trauma and Extremity Instruments (drill bits, screw taps and saw blades)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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<tr>
<td>25/07/2017</td>
<td>Fujifilm Digital Mammography System</td>
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<td>Class II</td>
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<tr>
<td>25/07/2017</td>
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<td>24/07/2017</td>
<td>Maquet Heater-Cooler Unit HCU 40</td>
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<td>21/07/2017</td>
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<tr>
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<td>20/07/2017</td>
<td>CareScape Patient Data Module (PDM) with software v2.6</td>
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<tr>
<td>20/07/2017</td>
<td>Various Microgenics Applications Sheets. An in vitro diagnostic medical device (IVD)</td>
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<td>Thin and Radial Osteotome Blades</td>
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<tr>
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<td>Multiple AxiEM ENT Suction Instruments</td>
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<td>Alere HIV Combo. An in vitro diagnostic medical device (IVD)</td>
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<td>ADVIA Chemistry Products - Ammonia, Salicylate and Alanine Aminotransferase Assays. An in vitro diagnostic medical device (IVD)</td>
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<td>Dimension Clinical Chemistry System and Dimension Vista System. An in vitro diagnostic medical device (IVD)</td>
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<tr>
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<td>Emblem and SQ-RX Subcutaneous-Implantable Cardiac Defibrillators (S-ICDs)</td>
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<td>4/07/2017</td>
<td>Maquet/Datascop Intra-Aortic Balloon Pump (IABP)</td>
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<td>4/07/2017</td>
<td>MOSAIQ and Treating on linear accelerators with the RATM license</td>
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<tr>
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<td>Haemophilus Test medium (HTM). An in vitro diagnostic medical device (IVD)</td>
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<tr>
<td>29/06/2017</td>
<td>Sysmex XN-450, XN-550 &amp; other XN-L series Automated Haematology Analysers. An in vitro diagnostic medical device (IVD)</td>
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<td>28/06/2017</td>
<td>Zenith Alpha Thoracic Endovascular Graft</td>
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<td>27/06/2017</td>
<td>Bard ArcticSun ArticGel Pads</td>
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<tr>
<td>27/06/2017</td>
<td>Codan Extension Set with T Connector</td>
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<tr>
<td>27/06/2017</td>
<td>Comprehensive Nano Humeral Component PPS</td>
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<tr>
<td>27/06/2017</td>
<td>Coulter LH and HmX Analysers. An in vitro diagnostic medical device (IVD)</td>
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<tr>
<td>27/06/2017</td>
<td>Recapper for the AutoMate 2500 Family. An in vitro diagnostic medical device (IVD).</td>
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<tr>
<td>27/06/2017</td>
<td>Sealing Caps (A0282 and A0313) used with compatible endoscopy instruments</td>
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<tr>
<td>27/06/2017</td>
<td>Trauma Guide Wires, 70cm</td>
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<td>26/06/2017</td>
<td>ArjoHuntleigh Flowtron ACS900 Active Compression System</td>
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<tr>
<td>26/06/2017</td>
<td>Pivot, Pivot Hygiene, Pivot Hammock and Tony Pringle clip style sling with the keyhole clip fastening</td>
<td>Medical Device</td>
<td>Recall</td>
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</tr>
</tbody>
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<td>Pre-Transfusion Blood Testing System PK7300 Automated Microplate System. An in vitro diagnostic medical device (IVD)</td>
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<td>Promed High Concentration Oxygen Masks, Elongated (under chin). Adult Med Concentration</td>
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<tr>
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<td>Unomedical High Concentration Oxygen Masks</td>
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<td>Artis Systems in conjunction with Artis Table</td>
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<td>BacT/ALERT BPN Culture Bottles. An in vitro diagnostic medical device (IVD)</td>
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<td>BK Virus R-gene Real-time Detection and Quantification Kit. An in vitro diagnostic medical device (IVD)</td>
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<td>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).</td>
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<td>Philips IntelliVue MX40 Wearable Patient Monitors manufactured prior to the 6th of July 2015</td>
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<tr>
<td>5/06/2017</td>
<td>MULTIGENT Creatinine (Enzymatic) assay. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
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<td>Hospital</td>
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<tr>
<td>5/06/2017</td>
<td>Organ Care System (OCS) Heart system - OCS Heart Console</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>Hospital</td>
</tr>
<tr>
<td>5/06/2017</td>
<td>Phenocell B 0.8% and 3% and Abtectcell III 0.8%RhD. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>Hospital</td>
</tr>
<tr>
<td>2/06/2017</td>
<td>Alcon LuxOR LX3 Microscope Floor Stand</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>2/06/2017</td>
<td>MiniMed 640G Insulin Infusion Pump</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>Consumer</td>
</tr>
<tr>
<td>1/06/2017</td>
<td>Access Total T3, Access Thyroglobulin, Access Free T4, Access GI Monitor Immunoassays. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>1/06/2017</td>
<td>DRX Revolution Mobile X-Ray System</td>
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<tr>
<td>1/06/2017</td>
<td>DuraDiagnost Release 1.0, 2.0, 3.0 X-Ray systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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</tr>
<tr>
<td>1/06/2017</td>
<td>OptiLite Multi-Use Holmium Laser Fibers</td>
<td>Medical Device</td>
<td>Recall</td>
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<tr>
<td>1/06/2017</td>
<td>PrepPlus &amp; PrepPlus 2. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
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<tr>
<td>31/05/2017</td>
<td>Stemetil 5mg Tablets</td>
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<td>30/05/2017</td>
<td>Cook Multi-Use Holmium Laser Fibers</td>
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<tr>
<td>30/05/2017</td>
<td>DxH 500 Haematology Analyser, with software version 1.0.2. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
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<tr>
<td>30/05/2017</td>
<td>F-18 FDG Injection</td>
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<tr>
<td>30/05/2017</td>
<td>Laser Guide, Endotherapy, single use - TXMF600BFS Fibres, when using pullback device</td>
<td>Medical Device</td>
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<tr>
<td>30/05/2017</td>
<td>VueOptic Visualisation Source &amp; Flexor Vue Deflecting Endoscopic System</td>
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<tr>
<td>29/05/2017</td>
<td>Randox Liquid Cardiac Controls when used with CKMB and Myoglobin assays. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
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<tr>
<td>29/05/2017</td>
<td>Various Terumo Introducer Kits</td>
<td>Medical Device</td>
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<tr>
<td>26/05/2017</td>
<td>Blooms The Chemist (BTC) Paracetamol Codeine tablets, BTC Rosuvastatin 10mg tablets and APOTEX-Pantoprazole 20mg and 40mg tablets</td>
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<tr>
<td>26/05/2017</td>
<td>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)</td>
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<tr>
<td>26/05/2017</td>
<td>PROT 1 CAL and PROT 1 CON when used with Dimension Vista CER Flex Reagent Cartridge. An in vitro diagnostic medical device (IVD)</td>
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<tr>
<td>26/05/2017</td>
<td>ROSA Brain and ROSA One Surgical Robots</td>
<td>Medical Device</td>
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<td>26/05/2017</td>
<td>Valium 5mg tablets</td>
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<tr>
<td>25/05/2017</td>
<td>ALBAclone Advanced Partial RhD Typing Kit. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
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<tr>
<td>24/05/2017</td>
<td>V-Lyte Dilution Check &amp; V-Lyte Integrated Multisensor Technology (IMT). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
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<td>23/05/2017</td>
<td>Endo Peanut 5mm Device</td>
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<td>23/05/2017</td>
<td>Philips V60 non-invasive ventilator</td>
<td>Medical Device</td>
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<tr>
<td>22/05/2017</td>
<td>Dynabeads HLA Class II and Dynabeads HLA Cell Prep II. An in vitro diagnostic medical device (IVD)</td>
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<tr>
<td>19/05/2017</td>
<td>1322 3M Comply Lead Free Steam Indicator Tapes &amp; 1355 3M Comply Lead Free Steam Indicator Tapes for Disposable Wraps</td>
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<td>19/05/2017</td>
<td>Kii abdominal trocars</td>
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<td>19/05/2017</td>
<td>OEC Elite systems</td>
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<tr>
<td>19/05/2017</td>
<td>Philips IntelliVue Neuromuscular Transmission (NMT) Patient Cables</td>
<td>Medical Device</td>
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<tr>
<td>18/05/2017</td>
<td>Carestation 620, 650 and 650c A1 Anaesthesia devices</td>
<td>Medical Device</td>
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<td>18/05/2017</td>
<td>DigitalDiagnost Release 3.1.x</td>
<td>Medical Device</td>
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<td>18/05/2017</td>
<td>Sysmex XN-10 and XN-20 Automated Haematology Analysers. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
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<td>17/05/2017</td>
<td>AbbVie Percutaneous Endoscopic Gastronomy and Jejunal tubing kits (AbbVie PEG and AbbVie J)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>17/05/2017</td>
<td>LABType DNA Typing Tests (for transplant compatibility analysis). An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
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<tr>
<td>16/05/2017</td>
<td>Miele washer-disinfectors when connected to an in-house network</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>16/05/2017</td>
<td>Spectra Optia Apheresis Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>16/05/2017</td>
<td>Trauma Implants - intramedullary nails</td>
<td>Medical Device</td>
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<tr>
<td>16/05/2017</td>
<td>UniCel DxH 800 Coulter Cellular Analysis System and UniCel DxH 600 Coulter Cellular Analysis System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>15/05/2017</td>
<td>cobas 4800 HPV Amplification/Detection Kit. An in vitro diagnostic medical device (IVD)</td>
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<td>Hospital</td>
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<td>15/05/2017</td>
<td>Synchron Systems Microalbumin (MA) Reagent</td>
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<td>12/05/2017</td>
<td>Carina Mobile Lifts</td>
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<td>Microcatheter SONIC 1.5F</td>
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<td>12/05/2017</td>
<td>Ultrasound Probe Cover (Telescopic folded with gel); and</td>
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<td>10/05/2017</td>
<td>Asserachrom Von Willebrand Factor (VWF):Collagen (CB). An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
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<tr>
<td>10/05/2017</td>
<td>Ovatio, Paradym, Paradym RF and Intensia Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronisation Therapy Defibrillators (CRT-Ds)</td>
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<td>9/05/2017</td>
<td>Acor and Integrale primary femoral stem with modular neck</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>9/05/2017</td>
<td>Endoscopic Curved Needle Driver, LapSac Introducer and LapSac Introducer Set</td>
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<td>9/05/2017</td>
<td>Polysorb Braided Absorbable Suture and EndoStitch Loading Unit with Polysorb Suture</td>
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<td>9/05/2017</td>
<td>Wingman35 Crossing Catheters</td>
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<td>Cook Pereyra-Raz Ligature Carrier, Stamey Needle and Clarke-Reich Laparoscopic Knot Pusher</td>
<td>Medical Device</td>
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<tr>
<td>8/05/2017</td>
<td>ETEST ETP32 (Ertapenem) WW B30, An in vitro diagnostic medical device (IVD) for Antimicrobial susceptibility testing.</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>8/05/2017</td>
<td>Medtronic SynchroMed II Pumps</td>
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<td>8/05/2017</td>
<td>Prosigna Breast Cancer Prognostic Gene Signature Assay, An in vitro diagnostic medical device (IVD)</td>
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<tr>
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<td>Sysmex XN-550 Automated Haematology Analyser, An in vitro diagnostic medical device (IVD)</td>
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<td>3/05/2017</td>
<td>Jackson-Pratt Perforated and Hemaduct Wound Drainage Systems</td>
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<td>2/05/2017</td>
<td>Abilify Maintena aripiprazole (as monohydrate) 400 mg powder and solvent for prolonged release suspension for injection</td>
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<td>ARCHITECT Free T4 Reagent, An in vitro diagnostic medical device (IVD)</td>
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<td>Meducore Easy Automatic External Defibrillator (AED) - Battery Pack</td>
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<td>Brennen Skin Graft Mesher - 4.5 and 6.5 inch</td>
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<td>Omega+ Lag Screw</td>
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<td>Alaris Syringe Pumps (GH, CC, TIVA, PK and Enteral) - All Variants</td>
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<td>Artis Dialysis Systems - 230V, 230V Physio &amp; 230 V Physio I</td>
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<td>27/04/2017</td>
<td>Safety Clip - Hoffmann Limb Reconstruction Frame (LRF) Bone Transport</td>
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<td>Architect Sex Hormone Binding Globulin (SHBG) reagents. An in vitro diagnostic medical device (IVD)</td>
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<td>Healon Ophthalmic Viscosurgical Devices (OVD) 0.55mL</td>
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<td>neoBLUE LED Phototherapy Lights (2nd Generation)</td>
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<tr>
<td>26/04/2017</td>
<td>Prismaflex Control Unit (with software versions prior to 8.10)</td>
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<td>26/04/2017</td>
<td>RAPIDPoint 500 Blood Gas Analyser with V2.4 Software</td>
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<td>26/04/2017</td>
<td>Vitrectomy Cutter</td>
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<td>21/04/2017</td>
<td>Absorb Bioresorbable Vascular Scaffold (BVS) System</td>
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<td>21/04/2017</td>
<td>Access BR Monitor. An in vitro diagnostic medical device (IVD)</td>
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<td>ACQUITY UPLC Sample Organisers. An in vitro diagnostic medical device (IVD)</td>
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<td>AQUIOS CL Flow Cytometer utilising software versions 2.0 and 2.0.1. An in vitro diagnostic medical device (IVD)</td>
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<td>20/04/2017</td>
<td>iChemVELOCITY Automated Urine Chemistry Systems equipped with Colour/Clarity/Specific Gravity Module. An in vitro diagnostic medical device (IVD)</td>
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<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>2/03/2017</td>
<td>Screwdriver Shaft, hexagonal, large, diameter 3.5mm, length 165mm, for Quick Coupling</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/03/2017</td>
<td>Reflection Deadblow Mallet</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>28/02/2017</td>
<td>Artiste, Oncor and Primus Digital Linear Accelerators running Control Console software version 13.0.302</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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</tr>
<tr>
<td>28/02/2017</td>
<td>ConMed Hyfrecator 2000 Electrosurgical Unit and Accessory Packages containing Handpiece Sheaths</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>28/02/2017</td>
<td>Getinge HS33 Sterilisers</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>28/02/2017</td>
<td>MobiCath Bi-Directional Guiding Sheath, Small Curve</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>28/02/2017</td>
<td>Turon Impaction Fixture and RSP Monoblock Impaction Fixture (found in instrument trays - FA RSP Glenoid, FA RSP Monoblock Ltd Release and FA Turon Humeral Head 2010)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>28/02/2017</td>
<td>Various ID-Diacell Products. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>27/02/2017</td>
<td>Aerowound Combine Dressing ACD2040S, size 20cm x 40cm</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>27/02/2017</td>
<td>Liquichek Diabetes Control</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>27/02/2017</td>
<td>Magnetic Silica MagSIL. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>27/02/2017</td>
<td>V60 Respiratory Ventilator with software version 2.20</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/02/2017</td>
<td>Cordis S.M.A.R.T. Flex Vascular Stent System</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/02/2017</td>
<td>Lotus Valve System</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/02/2017</td>
<td>Philips BrightView / BrightView X / BrightView XCT and BrightView X upgrade to XCT</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/02/2017</td>
<td>Philips Ingenuity CT system</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/02/2017</td>
<td>Various Polyethylene Implants</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/02/2017</td>
<td>Ellex Prager scleral shell for Biometry and 10MHZ Biometric A Scan Probe Kit</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/02/2017</td>
<td>ADVIA Chemistry Lactate Dehydrogenase (LDLP and LDPL). An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>21/02/2017</td>
<td>Atrium Thoracic Catheters, Sizes 8Fr &amp; 10Fr</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/02/2017</td>
<td>First Response Digital Pregnancy Test and First Response Test &amp; Reassure. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>21/02/2017</td>
<td>ImmunoCAP Allergen fx20, Food. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/02/2017</td>
<td>Biolox Forte 36mm Alumina Ceramic Head</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/02/2017</td>
<td>Medtronic Strata II/Strata NSC Valves (including Burr Hole and Lumbar Peritoneal [LP]) used in the management of hydrocephalus</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/02/2017</td>
<td>Radpharm PYP kit for the production of Technetium (99mTc) tin pyrophosphate powder for injection multidose vial</td>
<td>Medicine</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/02/2017</td>
<td>i-STATI Analyser when used with i-STAT Celite Activated Clotting Time (ACT) &amp; Kaolin ACT Cartridges. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/02/2017</td>
<td>Steelco DS1000 Washer Disinfectors with an auto load/unload module attached</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/02/2017</td>
<td>Artis Systems with software versions VC14, VC21,VD10, VD11 and VE10</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/02/2017</td>
<td>Difflam Sore Throat Ready to Use Iodine Gargle (povidone-iodine 10mg/mL), 200mL Bottle</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>14/02/2017</td>
<td>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).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/02/2017</td>
<td>HYDRO LeMaitre Valvulotome Devices</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/02/2017</td>
<td>Inhalo Medical Oxygen with Integrated Pressure Regulator/Flowmeter</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>13/02/2017</td>
<td>MiniMed 640G Insulin Infusion Pump (with software version 2.6)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Consumer</td>
</tr>
<tr>
<td>9/02/2017</td>
<td>ENDOEYE HD II Rigid Videoscope</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>9/02/2017</td>
<td>METS Modular Tumour System</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/02/2017</td>
<td>Philips BrightView XCT and Philips BrightView X to XCT Upgrade Kit</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/02/2017</td>
<td>ABC1 HLA Typing Tray included in ABC1 / ABC2 Kits. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/02/2017</td>
<td>Advanxt Legacy/Legacy-D Radiographic and Fluoroscopic System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/02/2017</td>
<td>ADVIA Centaur XPT System with software versions V1.0 to V1.2. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/02/2017</td>
<td>AngioJet Ultra 5000A Console - Foot Switch</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/02/2017</td>
<td>Duloxetine 30mg and 60mg capsules, RBX and Sandoz</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>8/02/2017</td>
<td>Immulite 2000 / Immulite 2000 XPI Sex Hormone Binding Globulin (SHBG). An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/02/2017</td>
<td>StarClose SE Vascular Closure System (VCS), International Green Sheath</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/02/2017</td>
<td>Brainlab Offset Cup Impactor Universal (blue handle)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/02/2017</td>
<td>Drager V Series Ventilator with the Optional PSS00 External Power Supply Unit installed</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/02/2017</td>
<td>E.T.O.I.L.E sytem extension table (leg holder)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/02/2017</td>
<td>AnastoClip AC Closure System</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/02/2017</td>
<td>ARTISTE, ONCOR and PRIMUS Digital Linear Accelerators</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/02/2017</td>
<td>Figulla Flex II ASD, Figulla Flex II PFO and Occlutech PDA Occluder Cardiac Occluders</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/02/2017</td>
<td>iChemVELOCITY Automated Urine Chemistry Systems. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/02/2017</td>
<td>Uronav, Transperineal option - Stepper with Stand</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>2/02/2017</td>
<td>Meropenem Kabi 500mg and 1g (Powder for injection) vials</td>
<td>Medicine</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/02/2017</td>
<td>ETEST XM256 (Cefuroxime) Foam and SPB. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/02/2017</td>
<td>Lysercell WDF 2 x 4L used on Sysmex XN-Series Automated Haematology Analysers. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/02/2017</td>
<td>Valleylab Laparoscopic Handset, Four-Function</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>31/01/2017</td>
<td>Diego Elite Tubeset, Standard and Declog</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>31/01/2017</td>
<td>Glucose-6-Phosphate Dehydrogenase. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>31/01/2017</td>
<td>LIFEPAK 1000 Defibrillators</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Retail</td>
</tr>
<tr>
<td>30/01/2017</td>
<td>Alaris System Pump module (LVP) 8100 and Air-In-Line (AIL) Sensor Kits</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/01/2017</td>
<td>Boostrix, Havrix, Twinrix, Typherix, Varilrix Vaccines</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>30/01/2017</td>
<td>OER-AW Endoscope Reprocessor</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>27/01/2017</td>
<td>Aecide Test Strips</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>27/01/2017</td>
<td>Alaris Syringe Module Model 8110</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>27/01/2017</td>
<td>NX workstation with NX 3.0.8950 image processing software</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/01/2017</td>
<td>BK Virus R-gene kit when used on SmartCycler 2.0 platform. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/01/2017</td>
<td>Magnetic Silica MagSIL. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/01/2017</td>
<td>Radiometer ABL800 Series Analysers (used with software version 3.1 MR5). An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/01/2017</td>
<td>RaySearch RayStation 4.5, 4.7, 5, and 6</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>25/01/2017</td>
<td>SynchroMed II Infusion System and Model 8870 Software Application Card used in the 8840 N'Vision Clinician Programmer</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/01/2017</td>
<td>Sysmex XN-9000 Automated Haematology System. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/01/2017</td>
<td>Clements Suction Regulators</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/01/2017</td>
<td>DRX Revolution Mobile X-Ray System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/01/2017</td>
<td>IRT Screening Assay used for screening newborns for cystic fibrosis. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/01/2017</td>
<td>Radiometer ABL90 Series Analysers (used with software version 3.1 MRS). An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/01/2017</td>
<td>Innovance D-Dimer assay run on Sysmex CS Systems. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/01/2017</td>
<td>LIFEPAK 15 Monitor/Defibrillator</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/01/2017</td>
<td>Li-Ion Battery used with the Cardiosave Hybrid/Rescue Intra-aortic Balloon Pump (IABP)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/01/2017</td>
<td>Xpert BCR-ABL Monitor assay (used for monitoring patients being treated for chronic myelogenous leukaemia). An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/01/2017</td>
<td>Model 3200 programmer for Emblem, Emblem MRI and SQ-Rx Subcutaneous-Implantable Cardiac Defibrillators (S-ICDs)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/01/2017</td>
<td>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).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/01/2017</td>
<td>ISOmed Arterial Embolectomy Catheters – Single Lumen (2F &amp; 3F)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>18/01/2017</td>
<td>Vanguard Open Box Femoral Components</td>
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<td>17/01/2017</td>
<td>Mammomat Inspiration System with software version VB30 and Biopsy functionality</td>
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<tr>
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<td>Cryptococcal Antigen Lateral Flow Assay (CrAg LFA). An in vitro diagnostic medical device (IVD).</td>
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<tr>
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<tr>
<td>11/01/2017</td>
<td>MEDPOR Facial and Oculoplastic Sizer Sets and TLS Drain System</td>
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<td>ADVIA Centaur, Dimension Vista &amp; Immulite Systems</td>
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<td>Monaco (with the use of Elekta Motorised Wedges)</td>
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<td>ARROW OnControl Bone Marrow Biopsy System Tray</td>
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<td>Plum 360 Infusion Pump, software version 15.02</td>
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<td>BioFlo PICC with ENDEXO and PASV Valve Technology with Nitinol Guidewire - Catheterisation kit, central venous</td>
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<td>Biograph mCT and Biograph mCT Flow</td>
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### System for Australian Recall Actions

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<td>Chinese Sports Injuries Pill (Zhong Guo Die Da Wan)</td>
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<td>Glucose GLUC-PAP. An in-vitro diagnostic medical device (IVD).</td>
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<td>Nellcor RS10 SpO2 Forehead Sensor</td>
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<td>Trauma RIA (Reamer/Irrigator/Aspirator) System</td>
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<td>23/12/2016</td>
<td>UniCel DxH 600 &amp; 800 Coulter Cellular Analysis Systems. An in-vitro diagnostic medical device (IVD).</td>
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<td>Arsenal Set-Screw, a sub-component of the Arsenal Spinal Fixation System</td>
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<td>Imager II Angiographic Catheter</td>
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<td>22/12/2016</td>
<td>Oncentra External Beam (formerly known as Oncentra MasterPlan during release of v3.x)</td>
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<td>SMF and MDF Modular Neck Hip Prosthesis</td>
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<td>21/12/2016</td>
<td>Dimension Vista V-LYTE Integrated Multisensor (used for measuring Na+/K+/Cl). An in-vitro diagnostic medical device (IVD).</td>
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<td>Artis zee, Artis Q and Artis Q zen systems with software version VD11B</td>
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<td>Greatbatch Medical Offset Reamer Handle</td>
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<td>20/12/2016</td>
<td>sleep.safe Set, sleep.safe Set Plus and sleep.safe Set Paed</td>
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<tr>
<td>16/12/2016</td>
<td>Smart Site Add-on Bag Access Device</td>
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<td>16/12/2016</td>
<td>Vinyl examination/treatment glove, non-powdered</td>
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<tr>
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<td>15/12/2016</td>
<td>DePuy Synthes Impactor for PFNA Blade</td>
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<td>15/12/2016</td>
<td>PreciControl Varia when used with Elecsys Parathyroid Hormone (PTH) assay on the cobas e 411 analyser. An in vitro diagnostic medical device (IVD).</td>
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<tr>
<td>14/12/2016</td>
<td>Artiset HD SN HC Bloodlines (blood tubing system used for haemodialysis with Artis system)</td>
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<td>14/12/2016</td>
<td>Dräger Oxylog Transport Ventilators - Oxylog 3000 and Oxylog 3000plus</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>14/12/2016</td>
<td>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</td>
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<td>14/12/2016</td>
<td>VITROS Chemistry Products UPRO Slides for measurement of protein in urine (using VITROS 250/350/5,1 FS/4600 and 5000 Systems). An in vitro diagnostic medical device (IVD).</td>
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<td>13/12/2016</td>
<td>Ampla MRI CRT-D SureScan and Claria MRI CRT-D SureScan</td>
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<td>Bard StatLock Catheter Stabilisation Device</td>
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<td>13/12/2016</td>
<td>Cancellous Bone Screws 16mm, 20mm, 25mm, 30mm, 35mm, 45mm, 50mm</td>
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<td>Conmed GS2000 - 50L Abdominal Insufflator</td>
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<td>13/12/2016</td>
<td>HICO - Variotherm 550 Hypothermia/Hyperthermia Unit</td>
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<td>LOT6283LB In-line leukoreduction system for red cell concentrates with LCRD2 Leucoflex soft filter</td>
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<td>13/12/2016</td>
<td>Reagent Red Blood Cells 0.8% Resolve Panel C. An in vitro diagnostic medical device (IVD).</td>
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<td>13/12/2016</td>
<td>UniCel DxC Synchron Wash Concentrate II when used with Thermo-Fisher Lithium reagent (Ref A19611). An in vitro diagnostic medical device (IVD).</td>
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The TGA publishes Australian recall actions in a searchable database to ensure the public has access to information about therapeutic products that have been recalled from the Australian market. If you are concerned about your health or if you have experienced an adverse event please seek advice from a health professional as soon as possible. Please read all the important information at the beginning of this report.
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<td>Philips Ingenia 1.5T and Ingenia 3.0T MR systems with Ingenia MR-OR solution</td>
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<td>F-18 FDG Injection (Fludeoxyglucose 18F)</td>
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<td>Radiometer ABL700 and ABL800 series blood gas analysers. An in vitro diagnostic medical device (IVD).</td>
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<td>CONSERVE Shell, DYNASTY Metal Liner, RIM-LOCK Metal Liner, LINEAGE Metal Liner</td>
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<td>28/11/2016</td>
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</tr>
<tr>
<td>24/11/2016</td>
<td>Nanostim Leadless Cardiac Pacemaker (LCP)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/11/2016</td>
<td>SynchroMed II Implantable Drug Infusion Pump</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/11/2016</td>
<td>Optipac Bone Cement</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/11/2016</td>
<td>Philips Brilliance 64 and Ingenuity CT/Core/Core128 with software versions 4.1.6.XX030 or 4.1.6.XX032</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/11/2016</td>
<td>Quantum Blue Calprotectin Assay and Quantum Blue Calprotectin High Range</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>23/11/2016</td>
<td>ROTAIO Cervical Disc Prosthesis</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/11/2016</td>
<td>3R62 Pheon Modular Knee Joint (External leg prosthesis)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/11/2016</td>
<td>Artis zee with sw versions VC21C, VD11 and Megalix Cat+ X-Ray tubes</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/11/2016</td>
<td>ImmunoCAP Specific IgG/IgG4 and IgE Control H when used with ImmunoCAP Allergen i1, Honey bee venom. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>Hospital</td>
</tr>
<tr>
<td>21/11/2016</td>
<td>SynReam Flexible Shaft (re-usable surgical instrument supplied as part of the SynReam medullary reaming system)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/11/2016</td>
<td>BIOLOX delta ceramic components</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>18/11/2016</td>
<td>Kasios TCP and Kages</td>
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<tr>
<td>17/11/2016</td>
<td>MAQUET HLS and PLS Sets with BIOLINE Coating (extracorporeal support sets)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/11/2016</td>
<td>ADVANCE HA Coated TitaniumTibial Bases, all sizes</td>
<td>Medical Device</td>
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<tr>
<td>16/11/2016</td>
<td>EasySept HYDRO+ (3% hydrogen peroxide) Cleaning &amp; Disinfecting Solution (Contact lens care Kit)</td>
<td>Medical Device</td>
<td>Recall</td>
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<tr>
<td>16/11/2016</td>
<td>Neuro Flap Fix Kit (used for fixation of cranial bone flaps and fractures)</td>
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<tr>
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<td>Pico 70 Arterial blood sampler (used with Radiometer Blood Gas Analysers)</td>
<td>Medical Device</td>
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<td>Source Administration Sets (SAS) used with the Medrad Intego PET Infusion System</td>
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<td>16/11/2016</td>
<td>Supergloves Vinyl Examination Gloves, powdered &amp; powder free</td>
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<tr>
<td>16/11/2016</td>
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<td>14/11/2016</td>
<td>ARROW OnControl System Trays</td>
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<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>14/11/2016</td>
<td>Du Huo Ji Sheng Tang (Tuhuo &amp; Loranthus Combination), Chuan Xiong Cha Tiao San (Ligusticum &amp; Tea Formula) and Dang Gui Si Ni Tang (Tangkuei &amp; Jujube Combination)</td>
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<td>F-18 FDG Injection (Fludeoxyglucose F 18)</td>
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<td>10/11/2016</td>
<td>K-Wires for T2 and Gamma Systems (Internal fixation wire)</td>
<td>Medical Device</td>
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<tr>
<td>9/11/2016</td>
<td>Freelite Human Lambda Free kit for use on SPAPLUS</td>
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<tr>
<td>9/11/2016</td>
<td>Offset Cup Reamer Handle</td>
<td>Medical Device</td>
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<tr>
<td>9/11/2016</td>
<td>SOMATOM Force with software version VA50_SP2 (Computed tomography x-ray system)</td>
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<td>iMR Cabinet label of Brilliance iCT, Ingenuity CT, Ingenuity Core 128</td>
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<tr>
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<td>Lumenis FemTouch Delivery System (used with AcuPulse laser system and AcuScan120 microscanner for gynecological treatments)</td>
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<tr>
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<tr>
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<td>ARRIVE Braided Transseptal Sheath</td>
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</tr>
<tr>
<td>4/11/2016</td>
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<td>Medical Device</td>
<td>Recall for Product Correction</td>
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</tr>
<tr>
<td>4/11/2016</td>
<td>Wallis Posterior Dynamic Stabilisation System instruments and containers</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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</tr>
<tr>
<td>3/11/2016</td>
<td>AU680 chemistry analysers with software version 4.05. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
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<tr>
<td>3/11/2016</td>
<td>LMA MAD Nasal Intranasal Mucosal Atomisation Device (used for intranasal drug delivery)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/11/2016</td>
<td>Medtronic Model 37751 Recharger, in Charging Systems used with implantable neurostimulators (INS)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/11/2016</td>
<td>Monaco V 5.11 and V 5.20 (used for radiation treatment planning)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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</tr>
<tr>
<td>3/11/2016</td>
<td>SOMATOM Definition AS and SOMATOM Definition Flash (Computed tomography x-ray diagnostic system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>Hospital</td>
</tr>
<tr>
<td>3/11/2016</td>
<td>SOMATOM Definition AS and SOMATOM Definition Flash (Computed tomography x-ray diagnostic system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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</tr>
<tr>
<td>2/11/2016</td>
<td>Atrium Trocar Catheters, Sizes 8Fr to 32Fr</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>2/11/2016</td>
<td>Nellix EndoVascular Aneurysm Sealing System</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I</td>
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<tr>
<td>2/11/2016</td>
<td>Radiometer TCM5 transcutaneous blood gas monitor</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/11/2016</td>
<td>AK 98 Self-Care Haemodialysis machine with software versions 1.1.0 and earlier</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/11/2016</td>
<td>Infinity Acute Care Monitoring System (IACS) with software version VG5.0 and Microstream (Patient monitoring system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/11/2016</td>
<td>Spot-light Tissue Pre-treatment Kit (Antigen retrieval reagent used in cellular imaging). An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall</td>
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</tr>
<tr>
<td>31/10/2016</td>
<td>Intuitive Surgical Endoscope Instrument Control System - da Vinci Xi Surgical System with P5 software</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>31/10/2016</td>
<td>Pressure Care Medical Mattresses and Mattress Covers</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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</tr>
<tr>
<td>27/10/2016</td>
<td>Avance CS2, Avance, and Amino anaesthesia devices with the optional large tray insert accessory installed</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>27/10/2016</td>
<td>Brainlab Knee Navigation System: Femoral and Tibial Cutting Block Adapter Base</td>
<td>Medical Device</td>
<td>Recall</td>
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<tr>
<td>26/10/2016</td>
<td>Atropine Injection BP atropine sulfate monohydrate 600 mcg in 1mL (sterile) Steriluer ampoules, 10 pack</td>
<td>Medicine</td>
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<tr>
<td>Recall Action Commencement Date¹</td>
<td>Product Name/Descriptionii</td>
<td>Type of Product³</td>
<td>Recall Actioniv</td>
<td>Recall Action Classificationv</td>
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<tr>
<td>24/10/2016</td>
<td>Achieva 3.0T and Ingenia 3.0T MR Systems with passive shielding in the rear wall</td>
<td>Medical Device</td>
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<tr>
<td>24/10/2016</td>
<td>ARCHITECT Lactic Acid. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
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<tr>
<td>21/10/2016</td>
<td>Active Knee Total Knee Replacement System</td>
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<tr>
<td>21/10/2016</td>
<td>TBS iNsight v. 3.0.1 (software installed on bone densitometers for estimating fracture risk)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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</tr>
<tr>
<td>20/10/2016</td>
<td>Hallu-Fix Drill, Diameter 1.9mm, supplied in Hallu-Fix system instrumentation set (used for orthopaedic foot surgery)</td>
<td>Medical Device</td>
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<tr>
<td>20/10/2016</td>
<td>Human sTfR Quantikine IVD ELISA Kit (used as indicator of iron status). An in vitro diagnostic medical device (IVD).</td>
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<td>20/10/2016</td>
<td>SynReam Reaming Rod 2.5mm, L 650mm, sterile</td>
<td>Medical Device</td>
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<tr>
<td>19/10/2016</td>
<td>Blood Pressure Monitoring Kits with Transpac IV Transducers</td>
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<tr>
<td>19/10/2016</td>
<td>VITROS Immunodiagnostic Products Intact iPTH Reagent Packs &amp; Calibrators (used on VITROS ECi/ECiQ/3600 Immunodiagnostic Systems, &amp;</td>
<td>Medical Device</td>
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<td>18/10/2016</td>
<td>Bard Inlay Optima Ureteral Stents</td>
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<tr>
<td>18/10/2016</td>
<td>Chemistry Calibrator used with ADVIA Chemistry Systems Direct Bilirubin Assay (DBIL_2). An in vitro diagnostic medical device (IVD).</td>
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</tr>
</tbody>
</table>

The TGA publishes Australian recall actions in a searchable database to ensure the public has access to information about therapeutic products that have been recalled from the Australian market. If you are concerned about your health or if you have experienced an adverse event please seek advice from a health professional as soon as possible. Please read all the important information at the beginning of this report.
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<tr>
<td>7/10/2016</td>
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<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/10/2016</td>
<td>Philips IntelliVue MX40 Patient Wearable Monitor s/w versions B.05.28, B.05.29 and B.05.32</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/10/2016</td>
<td>Xpert HIV-1 Viral Load Assay. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/10/2016</td>
<td>Devon Light Glove (Used as a cover with a compatible surgical light handle)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/10/2016</td>
<td>Freelite Human Kappa Free Kit (use on the Beckman AU (400, 480, 640, 680, 2700, 5400) Series). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>6/10/2016</td>
<td>Invacare Birdie Lifters (Patient lifters)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Consumer</td>
<td></td>
</tr>
<tr>
<td>6/10/2016</td>
<td>SenoMark UltraCor MRI 14 Gauge Breast Tissue Markers (used for radiographic marking of breast biopsy sites)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>5/10/2016</td>
<td>Clearify Visualization System (Laparoscopic Care Kit)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>5/10/2016</td>
<td>Rack Trays used with cobas, Modular Analytics and Ursys instruments/systems. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>4/10/2016</td>
<td>EZ-Strip 145ìm (Assisted reproduction microtool)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>30/09/2016</td>
<td>AlignRT patient positioning/tracking video camera system (when used with TrueBeam Radiotherapy Delivery System)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I Hospital</td>
<td></td>
</tr>
<tr>
<td>30/09/2016</td>
<td>Arctic Sun Temperature Management System (used for regulating the temperature and circulation of water to a vest worn by the patient)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>30/09/2016</td>
<td>Feather Touch Vinyl Examination Gloves</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II Retail</td>
<td></td>
</tr>
<tr>
<td>29/09/2016</td>
<td>AVOXimeter 1000E Cuvettes (used for oximetery assessment during heart catheterisation procedures). An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>29/09/2016</td>
<td>Zero-Gravity Radiation Protection System (overhead suspended radiation protection shield)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
<td></td>
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<tr>
<td>28/09/2016</td>
<td>Monaco V5.10 and V5.20 (used for radiation treatment planning)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>28/09/2016</td>
<td>STAR Instruments Kit, sterile packaged (used to implant Scandinavian Total Ankle Replacement System)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II Hospital</td>
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</tr>
<tr>
<td>28/09/2016</td>
<td>Sterile Single Use Minor Surgery Bipolar Cable, IEC-BC (Used for connecting the bipolar handpieces to the RF generator for electrosurgical procedures)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II Retail</td>
<td></td>
</tr>
<tr>
<td>23/09/2016</td>
<td>Radiometer TCM5 Flex Monitor (non-invasive blood gas monitor)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>23/09/2016</td>
<td>VITROS Automation Solutions configured with a Thermo Scientific Centrifuge Module. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I Hospital</td>
<td></td>
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<tr>
<td>Recall Action Commencement Date</td>
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<tr>
<td>22/09/2016</td>
<td>Automatic QC Cartridge THb Level 1 (used with RAPIDPoint 400/405/500 instruments). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/09/2016</td>
<td>Chemistry 1 Calibrator (used with the Dimension Vista System). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/09/2016</td>
<td>Fludarabine Ebewe 50mg/2ml concentrated injection solution (5 vials)</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/09/2016</td>
<td>Metagenics Nasoclear Nasal Spray 30mL</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>21/09/2016</td>
<td>Spinocath G22 / G27 (Spinal anaesthesia kit)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/09/2016</td>
<td>Twin-Pass dual access catheters</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/09/2016</td>
<td>FerriScan (software for determining liver iron concentration from MRI images)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/09/2016</td>
<td>Ingenuity CT system with software version 4.1.5</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/09/2016</td>
<td>LFIT Anatomic CoCr V40 Femoral Heads (Modular components used in total hip replacement procedures)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/09/2016</td>
<td>MAGIC (MAGnetic resonance image Compilation) on Signa Pioneer MRI systems running application software version DV25.1</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/09/2016</td>
<td>Macopharma blood bags</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/09/2016</td>
<td>NIO-A device (Automatic intraosseous infusion device that provides rapid, safe and easy intravascular access through the bone marrow)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/09/2016</td>
<td>F-18 FDG Injection (Fludeoxyglucose F 18)</td>
<td>Medicine</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/09/2016</td>
<td>Getinge ED-FLOW AER, ED-FLOW SD AER (Automated washer-disinfector for endoscopes)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/09/2016</td>
<td>MAQUET operating table accessories with Accessory Adaptor 600525A0</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/09/2016</td>
<td>AQUIOS CL Flow Cytometer System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
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<tr>
<td>14/09/2016</td>
<td>C-series carry bars (used with C300, C450 Manual, C625 ceiling lifts/hoists)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>14/09/2016</td>
<td>Debriflo Ultrasonic Wound Irrigation Hand-piece</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/09/2016</td>
<td>SIGNA Creator and SIGNA Explorer (MRI System)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/09/2016</td>
<td>Combir-Test and ChoiceLine 10 test kits (urine test strips). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/09/2016</td>
<td>Infant Warmer System (IWS)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/09/2016</td>
<td>Philips BV25, BV300, BV Libra, BV Endura, BV Pulsera (Fluoroscopic x-ray systems)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/09/2016</td>
<td>Radiometer ABL90FLEX and ABL90FLEX PLUS Blood Gas Analyser with software version below 3.2. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/09/2016</td>
<td>Arthrex ITD Articulating Arm 300 + 350MM</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/09/2016</td>
<td>Pennine Healthcare Ryles Tubes (used for enteral feeding)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/09/2016</td>
<td>Philips Brilliance 64 and Ingenuity CT, Core, Core128 with software version 4.1.6.XX030</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/09/2016</td>
<td>Plum 360 Infusion Pump, with software version 15.02</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/09/2016</td>
<td>RAPIDPoint 400/405 Systems Measurement Cartridge (blood gas analysers). An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/09/2016</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/09/2016</td>
<td>Coxiella burnetii IFA IgG Kit</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/09/2016</td>
<td>FIDS dsDNA Kit</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/09/2016</td>
<td>Iron Assay performed with the Dimension &amp; Dimension Vista Systems. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
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</tr>
<tr>
<td>7/09/2016</td>
<td>Accu-Chek Connect Diabetes Management App for iPhone (iOS) v1.2.0(.5)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I Consumer</td>
<td></td>
</tr>
<tr>
<td>7/09/2016</td>
<td>GlucaGen HypoKit (glucagon (rys) as HCl 1 mg (1 IU) powder vial with 1 mL, pre-filled solvent syringe)</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class I Consumer</td>
<td></td>
</tr>
<tr>
<td>7/09/2016</td>
<td>HF Cable used with ESG-400 Electrosurgical Generator (bipolar)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III Hospital</td>
<td></td>
</tr>
<tr>
<td>7/09/2016</td>
<td>Pulmonary Patch</td>
<td>Biological</td>
<td>Hazard Alert</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>7/09/2016</td>
<td>Resus-EZY Air Cushion Mask</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III Hospital</td>
<td></td>
</tr>
<tr>
<td>6/09/2016</td>
<td>Panthera S3 Wheelchair</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>6/09/2016</td>
<td>Tandem Bipolar Hip System (hemiarthroplasty hip prosthesis)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>5/09/2016</td>
<td>Sage Comfort impregnated cloth topical skin products</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II Consumer</td>
<td></td>
</tr>
<tr>
<td>2/09/2016</td>
<td>Alaris GP Infusion set with Back Check Valve</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I Hospital</td>
<td></td>
</tr>
<tr>
<td>2/09/2016</td>
<td>Sensitest Agar</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>2/09/2016</td>
<td>TECNIS 1-Piece Intraocular Lens (IOL) with TECNIS iTEC Preloaded Delivery System PCB00</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>1/09/2016</td>
<td>Lescol 20mg Tablets</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III Retail</td>
<td></td>
</tr>
<tr>
<td>30/08/2016</td>
<td>APO-Cabergoline 500mcg Tablets</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II Consumer</td>
<td></td>
</tr>
<tr>
<td>30/08/2016</td>
<td>HeartWare Ventricular Assist Device (HVAD) System</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I Hospital</td>
<td></td>
</tr>
<tr>
<td>29/08/2016</td>
<td>Hamilton Medical C3 Ventilator</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
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<tr>
<td>29/08/2016</td>
<td>Hamilton Medical MR1 Ventilator</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>29/08/2016</td>
<td>Ventricular Catheter Accessory Kit (used for external cerebrospinal fluid (CSF) drainage)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II Hospital</td>
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<tr>
<td>Recall Action Commencement Date</td>
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<tr>
<td>26/08/2016</td>
<td>CONMED Concept Heatwave Electrode, 130mm x 2.3mm diameter (5 per box) (electrosurgical electrode used for ablation of soft tissue and coagulation of vessels)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/08/2016</td>
<td>Universal Impactor/Positioner (used to introduce and extract compatible universal window trials and acetabular cups into the prepared acetabulum during total hip arthroplasty)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/08/2016</td>
<td>iGUIDE with software version 2.2.0 (used with HexPOD evo RT System, used for accurate patient positioning during radiation therapy treatment)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/08/2016</td>
<td>Molift Air 205 and 300 ceiling hoist (a powered lifting device)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>25/08/2016</td>
<td>VITROS Chemistry Products Slide Assays - GLU, LAC, TRIG, URIC. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/08/2016</td>
<td>Dimension &amp; Dimension Vista Urine Opiates Screen assays. In vitro diagnostic medical devices (IVDs).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/08/2016</td>
<td>Medela breastpumps detachable wall plug component of AC Power Adaptor</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>24/08/2016</td>
<td>Oxoid Antimicrobial Susceptibility Testing Disc - Ceftazidime CAZ10. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/08/2016</td>
<td>Viva Cardiac Resynchronisation Therapy Defibrillators (CRT-Ds) and Evera Implantable Cardioverter Defibrillator (ICDs)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/08/2016</td>
<td>Bard EnCor Needle Guide Insert (part of the EnCor Breast Biopsy Probe)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/08/2016</td>
<td>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</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/08/2016</td>
<td>ADVIA Chemistry Triglyceride Concentrated (TRIG_c) Reagent. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/08/2016</td>
<td>da Vinci Xi EndoWrist Stapler 45 Instrument</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
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<td>Recall Action Level</td>
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<tr>
<td>22/08/2016</td>
<td>RAPIDPoint 400/405/500 Systems and RAPIDLab 1240/1245/1260/1265 Systems (blood gas analysers). An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>22/08/2016</td>
<td>Red top histology jars containing 10% Neutral Buffered Formalin Solution. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III Hospital</td>
<td></td>
</tr>
<tr>
<td>22/08/2016</td>
<td>Stryker Instruments Heavy Duty Sagittal Blade 18x0.97x90mm (used to cut bone and bone related tissue in orthopaedic procedures)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>22/08/2016</td>
<td>Sysmex CS-2000i and CS-2100i systems (Automated blood coagulation analysers). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>19/08/2016</td>
<td>Monaco with software versions 3.1 and higher (Radiation therapy treatment planning system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>19/08/2016</td>
<td>QMS Everolimus Immunoassay (used for the therapeutic monitoring of immunosuppressant drugs). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>19/08/2016</td>
<td>UniCel DxH 600 and DxH800 Coulter Cellular Analysis System. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>18/08/2016</td>
<td>Flocare Infinity Pump and Infinity Plus Pump (enteral feeding pumps)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Consumer</td>
<td></td>
</tr>
<tr>
<td>18/08/2016</td>
<td>LifePak CR Plus and LifePak Express Automatic External Defibrillators</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I Retail</td>
<td></td>
</tr>
<tr>
<td>18/08/2016</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>17/08/2016</td>
<td>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</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I Hospital</td>
<td></td>
</tr>
<tr>
<td>16/08/2016</td>
<td>Astral 100 and Astral150 Ventilators - Degraded Battery Pack</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I Consumer</td>
<td></td>
</tr>
<tr>
<td>15/08/2016</td>
<td>Ceiling Bracket, Arch 71 White (used for installing Liko patient lifts to wooden and concrete ceilings)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II Wholesale</td>
<td></td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>15/08/2016</td>
<td>Cemented resurfacing patellar implant, Ø 33mm and 36mm</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/08/2016</td>
<td>BARD Toomey Irrigation Syringe 70cc with Resectoscope Tip, Catheter Tip, Luer Adapter and Cap</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/08/2016</td>
<td>Certegra Workstation used in conjunction with Medrad Stellant CT Injection System</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/08/2016</td>
<td>IntelePACS InteleViewer software 4-10-1 and earlier versions (Picture archiving and communication system for radiology)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/08/2016</td>
<td>Medtronic EnVevo R Delivery Catheter System (DCS)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/08/2016</td>
<td>ADVIA Centaur Systems Calibrator U (Myoglobin). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/08/2016</td>
<td>Allen Wrench 5mm in SMR supplied in instrument set (surgical instrument used during implantation of SMR anatomic and Reverse shoulder prosthesis)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/08/2016</td>
<td>e.cam and Symbia E systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/08/2016</td>
<td>Renasys Transparent Film and Renasys Gauze Dressing Kits (used to dress, protect and seal wounds undergoing Negative Pressure Wound Therapy (NPWT))</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/08/2016</td>
<td>Scorpio Patella Clamp (used to hold the patella in place during the cementing process)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/08/2016</td>
<td>da Vinci Xi EndoWrist Stapler</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/08/2016</td>
<td>Leongatha Delivery Pack containing umbilical clamps</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/08/2016</td>
<td>UniCel DxH Slidemaker Stainer Coulter Cellular Analysis System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/08/2016</td>
<td>1.5 mm HYDRO LeMaitre Valvulotome, 40 cm</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/08/2016</td>
<td>Whipknot Soft Tissue Cinch #5 Sutures (used in assisting in the harvest, preparation, and placement of soft tissue grafts during ligament reconstructive surgery)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
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<tr>
<td>5/08/2016</td>
<td>ATEC Canister (used with ATEC vacuum-assisted breast biopsy systems)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/08/2016</td>
<td>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).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/08/2016</td>
<td>Ethicon Mersilene Tape (intended for use in circular suture of the cervix)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/08/2016</td>
<td>COLESTID colestipol HCl 5 g granules for oral suspension, 120 sachets</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>4/08/2016</td>
<td>Lotus Valve System (transcatheter aortic valve implantation (TAVI) system)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/08/2016</td>
<td>Philips IntelliVue Patient Monitors</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>2/08/2016</td>
<td>Cell Marque Rabbit Monoclonal Antibody. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/08/2016</td>
<td>Prostate-specific antigen (PSA) Assay performed on ADVIA Centaur, Centaur XP, Centaur XPT, and Centaur CP Analysers. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/08/2016</td>
<td>Various Kits containing Anticoagulant Citrate Dextrose Solution, Solution A (ACDA) 30mL Vials (Supplied in apheresis and surgical procedure kits)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/07/2016</td>
<td>Absorb Bioreabsorbable Vascular Scaffold (BVS) System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/07/2016</td>
<td>Etest COLISTIN CO 256 WW. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/07/2016</td>
<td>Multiple Laerdal Suction Units (LSU) with NiMH Battery</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>28/07/2016</td>
<td>AXIOM Artis, Artis zee and Artis Q/Q.zen system (fluoroscopic angiographic x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>27/07/2016</td>
<td>Multiple Polishing Products containing Optrapol (a dental polishing system)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>27/07/2016</td>
<td>VITROS Immunodiagnostic Products Estradiol Reagent Pack (used for the determination of estradiol in human serum). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/07/2016</td>
<td>Bisolvon Chesty Natural Kids Oral Liquid, 200mL</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Wholesale</td>
</tr>
<tr>
<td>26/07/2016</td>
<td>Sterrad 100NX system (Sterilisation system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/07/2016</td>
<td>ADVIA Chemistry XPT System Software Test Definition (TDef) Version 1.0 disks. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/07/2016</td>
<td>ImmunoCAP Specific IgE Control H (used to aid the diagnosis of allergy or asthma). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/07/2016</td>
<td>NIM Standard Reinforced EMG Endotracheal Tube</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/07/2016</td>
<td>Zimmer Air Dermatome II Handpiece (used during skin grafting surgeries)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/07/2016</td>
<td>Locking Screws Stardrive Ø 2.4 mm, Self-Tapping, Length 12 mm, Titanium-Alloy-Niobium Alloy (Orthopaedic bone screw)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/07/2016</td>
<td>Maquet Operating Table with Fixture 1002.65AO</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/07/2016</td>
<td>Progressa Bed System with European (OIML) Version Scale</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/07/2016</td>
<td>Steelco Washer Disinfectors (Instrument cleaner and disinfectors)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/07/2016</td>
<td>Trigen Internal Hex Captured Recon Screw Blue 6.4mm x 65mm (Internal fixation screw supplied as part of the Intramedullary Nail System)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/07/2016</td>
<td>G-scan Brio Magnetic Resonance System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/07/2016</td>
<td>Medline Procedure Packs containing ConvaTec Unomedical Brand Frazier Suction Handle</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/07/2016</td>
<td>Adapter for Colibri, Electric Pen Drive and Light Adapter for Colibri and Colibri II hand piece</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>20/07/2016</td>
<td>Medtronic O-Arm O2 Surgical Imaging System (a portable, diagnostic, fluoroscopic x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Hospital</td>
<td></td>
</tr>
<tr>
<td>20/07/2016</td>
<td>MOSAIQ Medical Oncology version 2.50.05 and higher (oncology information system used to manage workflows for treatment planning and delivery)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Hospital</td>
<td></td>
</tr>
<tr>
<td>20/07/2016</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Hospital</td>
<td></td>
</tr>
<tr>
<td>20/07/2016</td>
<td>O-Arm 1000 Surgical Imaging System (Portable, diagnostic, fluoroscopic x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Hospital</td>
<td></td>
</tr>
<tr>
<td>20/07/2016</td>
<td>Tecotherm Neo (a heating/cooling system for use with infants)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Hospital</td>
<td></td>
</tr>
<tr>
<td>19/07/2016</td>
<td>LIAISON Estradiol II Gen Assay (used for the determination of estradiol in human serum). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Hospital</td>
<td></td>
</tr>
<tr>
<td>18/07/2016</td>
<td>SOMATOM Definition AS, Definition Edge and Definition Flash CT scanners with coupled contrast agent injectors in software version VA48A-SP2</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Hospital</td>
<td></td>
</tr>
<tr>
<td>15/07/2016</td>
<td>MultiDiagnost Eleva and MultiDiagnost Eleva with Flat Detector (diagnostic fluoroscopic x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Hospital</td>
<td></td>
</tr>
<tr>
<td>14/07/2016</td>
<td>Exeter Non V40 Rasp with plastic handle</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Hospital</td>
<td></td>
</tr>
<tr>
<td>14/07/2016</td>
<td>Twinfix Quick-T Knot Pusher Suture Cutters</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Hospital</td>
<td></td>
</tr>
<tr>
<td>13/07/2016</td>
<td>Medtronic DBS Pocket Adaptor for use with Activa PC (Model 37601) and Activa RC (Model 37612) brain neuro-stimulators</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Hospital</td>
<td></td>
</tr>
<tr>
<td>13/07/2016</td>
<td>Synthesis, Avant &amp; Primo2x Families Adult Oxygenator Mounting Brackets (used with Sorin 3T Heater-Cooler devices)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Hospital</td>
<td></td>
</tr>
<tr>
<td>12/07/2016</td>
<td>Avenir Müller Stem 6 Lateral uncemented and Avenir Müller Stem 4 Standard uncemented</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Hospital</td>
<td></td>
</tr>
<tr>
<td>12/07/2016</td>
<td>DuraDiagnost X-ray systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Hospital</td>
<td></td>
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<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>12/07/2016</td>
<td>Frazier Suction instrument (used for precision suction in spinal or neurological surgeries)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/07/2016</td>
<td>RayStation 3.0, 3.5, 4.0, 4.5, 4.7, and 5</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/07/2016</td>
<td>Savion ED Trolley (mobile stretcher)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/07/2016</td>
<td>SerenoCem Granules BCG050 (Orthopaedic bone cement)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/07/2016</td>
<td>Artis Systems with 19&quot; Live Display</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/07/2016</td>
<td>Covidien Valleylab Laparoscopic Wire Retractable Electrode (used in laparoscopic and thoracic surgeries for electrosurgical cutting and coagulation)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/07/2016</td>
<td>Sara Combilizer</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/07/2016</td>
<td>Triathlon Modular Handle</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/07/2016</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/07/2016</td>
<td>Quickie Q7 Manual Wheelchair</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>7/07/2016</td>
<td>Sorenson’s Buffer. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/07/2016</td>
<td>UniCel DxC Synchron Systems No Foam Reagent (used with the UniCel DxC Synchron Clinical System). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/07/2016</td>
<td>Merge CADstream. All versions (used for breast cancer or general MRI studies)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/07/2016</td>
<td>PHIL (Precipitating Hydrophobic Injectable Liquid) Non-Adhesive Liquid Embolic System</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/07/2016</td>
<td>Guide Sleeve, yellow for Trochanteric Fixation Nail Advanced (TFNA) Proximal Femoral Nailing System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/07/2016</td>
<td>VITROS Immunodiagnostic Products HBsAg Controls. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>4/07/2016</td>
<td>Zenostar MT Color and Zenostar MT Color Impulse products</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>1/07/2016</td>
<td>Allura Xper R8.2 and UNIQ R1.0 X-Ray Systems (diagnostic, fluoroscopic x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/07/2016</td>
<td>Chloroifflofrr Gel 30mL and 250mL bottles and 100mL pump pack</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>1/07/2016</td>
<td>General Laparoscopy Procedure Pack and Gynaecological Laparoscopy Procedure Pack containing CORE Suction Irrigation Handpiece (sterile)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/07/2016</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/07/2016</td>
<td>Safil Quick (synthetic absorbable sterile surgical suture)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/07/2016</td>
<td>VASCU-GUARD Peripheral Vascular Patch, 0.8 x 8cm</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/06/2016</td>
<td>Merge CADstream with software versions earlier than 5.2.6.</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/06/2016</td>
<td>Merge iConnect Enterprise Archive (iCEA) with software versions 8.30.7 through 9.4.3, with tier 2 storage enabled</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/06/2016</td>
<td>Merge iConnect Enterprise Archive (iCEA) with software versions 8.80 through 9.4.4 (a picture archiving and communications system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/06/2016</td>
<td>Merge iConnect Enterprise Archive (iCEA) with software versions: 5.30.0 and greater up to and including 9.4.3</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/06/2016</td>
<td>Merge OrthoCase with software versions 3.7.3 and earlier (a picture archiving and communications system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/06/2016</td>
<td>Merge PACS with software versions 6.0MR2 and greater up to and including 6.6.2. Merge PACS versions 7.0 and greater up to and including 7.0.2</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/06/2016</td>
<td>Merge PACS with software versions V6.0.2.0 MR2 and earlier (a picture archiving and communications system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/06/2016</td>
<td>Volker LTC bed (with lateral release button for the side rails)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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</tr>
<tr>
<td>29/06/2016</td>
<td>Access AMH QC Kits for use with Access Family of Immunoassay Systems. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/06/2016</td>
<td>James Leckey Design Mygo Stander</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>29/06/2016</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/06/2016</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/06/2016</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/06/2016</td>
<td>Stratus CS Acute Care Diagnostics System. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>27/06/2016</td>
<td>ADVIA Chemistry Theophylline_2 Reagent</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>27/06/2016</td>
<td>cobas 6800 system - cobas MPX, 96 tests and cobas MPX, 480 tests. An in-vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>27/06/2016</td>
<td>Torque Limiting Adapter for use in orthopaedic and trauma surgical procedures (Re-useable surgical instrument)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/06/2016</td>
<td>ADVIA Centaur XPT System. An in-vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/06/2016</td>
<td>Aquasil Easy Mix Putty (used for taking impressions of teeth)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>24/06/2016</td>
<td>CONMED CORE Suction Irrigation Handpieces (used to perform suction and irrigation during endoscopic procedures)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/06/2016</td>
<td>Prodisc-C Vivo Cervical Disc Prosthesis (part of the Prodisc-C Vivo Cervical Disc Prosthesis System)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/06/2016</td>
<td>Temporary Transvenous Pacing Lead System Model 6416</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/06/2016</td>
<td>da Vinci Xi 5mm-8mm Universal Cannula Seal and da Vinci Xi 12mm &amp; Stapler Universal Cannula Seal</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date¹</td>
<td>Product Name/Description²</td>
<td>Type of Product³</td>
<td>Recall Action⁴</td>
<td>Recall Action Classification⁵</td>
<td>Recall Action Level⁶</td>
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<tr>
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</tr>
<tr>
<td>22/06/2016</td>
<td>Shipping cartons labelled as Frusemide-Claris, frusemide 20 mg/2 mL, Solution for Injection contains incorrect product (Ondansetron 4mg/2mL ,UK product)</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/06/2016</td>
<td>Medrad MRXperion MR Injection System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/06/2016</td>
<td>QIAsymphony DSP DNA Mini Kits. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/06/2016</td>
<td>ACHILLON Minimally Invasive Achilles Tendon Suture System</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/06/2016</td>
<td>Sirona Dac Universal Combination Steriliser</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>20/06/2016</td>
<td>V-PRO 1, V-PRO 1 Plus, V-PRO maX Low Temperature Sterilisation Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/06/2016</td>
<td>Access Free T3 Reagent Kit (used in the diagnosis and monitoring of patients with thyroid disorders). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/06/2016</td>
<td>Softpac C299 (used in preparing dialysate for haemodialysis therapies)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/06/2016</td>
<td>Xenform Soft Tissue Repair Matrix 8cm x 12cm</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/06/2016</td>
<td>Dimension Creatinine (CRE2) Flex reagent cartridge (Used with Dimension clinical chemistry system). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/06/2016</td>
<td>Dimension Vista Creatinine (CRE2) Flex reagent cartridge (Used with Dimension Vista system). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/06/2016</td>
<td>GENTECH molybdenum (99Mo) / technetium (99mTc) sterile generator for production of sodium pertechnetate (99mTc) injection multidose vial</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/06/2016</td>
<td>Alaris System Infusion PC Unit</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/06/2016</td>
<td>Alphadent Ceka-Preciline Dental Devices - Ceka, Revax, Preci-Ball, Preci-Horix, Preci-bar and Preci-Clip</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>15/06/2016</td>
<td>Dräger Babytherm Infant Warmer</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
</tbody>
</table>

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

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</tr>
</thead>
<tbody>
<tr>
<td>8/06/2016</td>
<td>Herculite Ultra, Herculite XRV, Point 4, and Premise Dental Composite (used in dental restoration)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>8/06/2016</td>
<td>RaySearch RayStation 5</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/06/2016</td>
<td>STATLOCK IAB Stabilisation Device</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/06/2016</td>
<td>Medtronic Reveal LINQ Insertable Cardiac Monitor (ICM)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/06/2016</td>
<td>PowerPro Ambulance Cots</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/06/2016</td>
<td>Medtronic deep brain stimulation (DBS) devices</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/06/2016</td>
<td>Medtronic Deep Brain Stimulation (DBS) Extension Models 7483 and 37086</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/06/2016</td>
<td>LumaDent Light Battery Charger</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>2/06/2016</td>
<td>Neonate Resuscitator with Coded Airway &amp; Filter Resuscitator Kit</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/06/2016</td>
<td>Sorbsan Calcium Alignate Dressings (Flat, Ribbon, Packing, Plus and Border) and Sorbsan Silver Calcium Alignate Dressing (Flat)</td>
<td>Medical Device</td>
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<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>30/05/2016</td>
<td>ADVIA Centaur XPT System</td>
<td>Medical Device</td>
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<td>30/05/2016</td>
<td>Ethicon Physiomesh Flexible Composite Mesh</td>
<td>Medical Device</td>
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<td>27/05/2016</td>
<td>Drager Ventstar Paediatric Circuit, used in conjunction with the Dräger Oxylog 3000plus Transport Ventilator</td>
<td>Medical Device</td>
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<td>Class I</td>
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<tr>
<td>27/05/2016</td>
<td>EliA IgG Conjugate. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/05/2016</td>
<td>ONLINE TDM Gentamicin assay and Preciest TDM I Calibrator. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/05/2016</td>
<td>Philips Brilliance iCT/iCT SP with software version 4.1.3, 4.1.5</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/05/2016</td>
<td>2016 Fluvax, 10 x 0.5ml packs</td>
<td>Medicine</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>25/05/2016</td>
<td>Monaco software versions 5.10.00 and higher</td>
<td>Medical Device</td>
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<tr>
<td>25/05/2016</td>
<td>Philips Brilliance 64 and Ingenuity CT/Core/Core128 with software version 4.1.3, 4.1.4 and 4.1.5</td>
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<td>Class II</td>
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<tr>
<td>25/05/2016</td>
<td>Self Tapping Bone Screws, 6.5 x 20 and 6.5 x 25</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
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<tr>
<td>23/05/2016</td>
<td>DuraDiagnost X-ray systems with software version 3.0.3</td>
<td>Medical Device</td>
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<tr>
<td>23/05/2016</td>
<td>DuraDiagnost X-ray systems with software version 4.0.2, 4.0.3 and 4.0.4</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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<tr>
<td>23/05/2016</td>
<td>Hettich Centrifuge Bucket Model 4464-R, An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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<tr>
<td>23/05/2016</td>
<td>Zoledasta (Zoledronic Acid 5mg/100mL) injection solution</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
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</tr>
<tr>
<td>19/05/2016</td>
<td>Dimension Enzyme II Calibrator (used with Dimension clinical chemistry system). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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</tr>
<tr>
<td>19/05/2016</td>
<td>Dimension Vista Enzyme 2 Calibrator (used on the Dimension Vista System). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>19/05/2016</td>
<td>Hexapod iGUIDE 2.1, iGUIDE 2.2</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>19/05/2016</td>
<td>Specialty Size 33mm Reduced Diameter Reaming Cutter</td>
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<tr>
<td>19/05/2016</td>
<td>Sterile-Packaged Knee Implants</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
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<tr>
<td>18/05/2016</td>
<td>Children's Panadol 5-12 Years Colourfree Suspension 48mg/mL</td>
<td>Medicine</td>
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<tr>
<td>18/05/2016</td>
<td>ConMed ThermoGuard Plus ABC Paediatric Dual Dispersive Electrodes</td>
<td>Medical Device</td>
<td>Recall</td>
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<tr>
<td>18/05/2016</td>
<td>RestoreSensor Implantable Neurostimulators</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
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<tr>
<td>18/05/2016</td>
<td>TRUEresult Blood Glucose Test Strip (10 counts) (used with the TRUEresult Blood Glucose Monitoring System). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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</tr>
<tr>
<td>17/05/2016</td>
<td>Laryngeal Tube Set – size 4 (LTS-D S4 Adult)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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</tr>
</tbody>
</table>
## System for Australian Recall Actions

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<tr>
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<tbody>
<tr>
<td>16/05/2016</td>
<td>VITROS Immunodiagnostic Products AFP Reagent Packs and Calibrators. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/05/2016</td>
<td>Brilliance CT and Ingenuity CT systems with software version v4.1.3 and v4.1.4</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>13/05/2016</td>
<td>DigitalDiagnost</td>
<td>Medical Device</td>
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<tr>
<td>13/05/2016</td>
<td>MSK 1.5T Extreme and Optima MR430s (MRI Systems)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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<tr>
<td>13/05/2016</td>
<td>Surgical Clipper Charger</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/05/2016</td>
<td>AVOXimeter System (a whole blood oximeter used during heart catheterisation procedures)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/05/2016</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/05/2016</td>
<td>Brilliance iCT and iCT SP, with software versions v4.1.3 and v4.1.5</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/05/2016</td>
<td>LIFECODES HLA-C eRES SSO Typing Kit. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/05/2016</td>
<td>MX 16-slice CT x-ray systems with software version v1.1.4.21426.</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/05/2016</td>
<td>Resus-EZY Manual Resuscitator (single-use pulmonary resuscitator)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/05/2016</td>
<td>Revolution CT (diagnostic x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>12/05/2016</td>
<td>TnI-Ultra (Troponin) Assay, 100 and 500 tests (used in the determination of cardiac troponin). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>11/05/2016</td>
<td>Cordis PRECISE PRO RX Nitinol Stent System (Carotid)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
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<td>11/05/2016</td>
<td>HeartWare HVAD system</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/05/2016</td>
<td>Multiple Assay for Enzymatic Creatinine, Cholesterol, Triglyceride, Uric Acid, Lactate, Lipase. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
</tbody>
</table>

The TGA publishes Australian recall actions in a searchable database to ensure the public has access to information about therapeutic products that have been recalled from the Australian market. If you are concerned about your health or if you have experienced an adverse event please seek advice from a health professional as soon as possible. Please read all the important information at the beginning of this report.
<table>
<thead>
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<th>Recall Action Commencement Date</th>
<th>Product Name/Description</th>
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<tbody>
<tr>
<td>10/05/2016</td>
<td>RAPID Hp STAR Kit (used in the detection of H. pylori). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/05/2016</td>
<td>Volcano S5, S5ï, 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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>9/05/2016</td>
<td>Centurion FMS (Fluidics Management System) Pack (used to control irrigation and aspiration in the eye during cataract surgery)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>9/05/2016</td>
<td>Rifadin IV 600mg (Rifampicin B.P. 600mg powder for I.V. infusion and diluent)</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/05/2016</td>
<td>Threader Monorail and Threader Over the Wire Micro-Dilatation Catheters (used during angioplasty procedures)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
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<tr>
<td>6/05/2016</td>
<td>Engenuity Core128 CT System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>6/05/2016</td>
<td>MobileDiagnost wDR 2, all software versions affected (diagnostic x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>Hospital</td>
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<td>6/05/2016</td>
<td>SMR Glenosphere Impactor</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>5/05/2016</td>
<td>D-Vapor and D-Vapor 3000 Vaporisers (used in connection with Baxter Desflurane Agent and Bottles)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>4/05/2016</td>
<td>Hydralyte Sports Lemon Lime 600mL Bottle</td>
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<tr>
<td>3/05/2016</td>
<td>ADVIA Centaur XPT Systems. An in vitro diagnostic medical device (IVD)</td>
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<td>Recall for Product Correction</td>
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<td>ADVIA Chemistry XPT System with software versions 1.0.3 and 1.1. An in vitro diagnostic medical device (IVD)</td>
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<td>Birmingham Hip Product Range</td>
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<td>3/05/2016</td>
<td>Cortex Screw Ø 4.5mm, self-tapping, length 20mm, Pure Titanium</td>
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<td>Class II</td>
<td>Hospital</td>
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<td>3/05/2016</td>
<td>Xhibit Central Station (patient monitoring system)</td>
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<td>Recall for Product Correction</td>
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<tr>
<td>29/04/2016</td>
<td>ARCHITECT STAT High Sensitive Troponin-I Reagent Kit. An in vitro diagnostic medical device (IVD)</td>
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<td>Recall</td>
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<td>Hospital</td>
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<td>29/04/2016</td>
<td>Hamilton-G5 and Hamilton -S1 Ventilators with software versions v2.41, v2.42 and v2.50</td>
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<td>ID-Papain Assay. An in vitro diagnostic medical device (IVD)</td>
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<td>Maxi Air Blower Unit - Model 230V</td>
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<td>29/04/2016</td>
<td>Novoceastra Liquid Mouse Monoclonal Antibody Calretinin. An in vitro diagnostic medical device (IVD)</td>
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<tr>
<td>28/04/2016</td>
<td>ALUTEK and ALUXOID Immunotherapy Products</td>
<td>Medicine</td>
<td>Product Defect Alert</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>28/04/2016</td>
<td>Concerto &amp; Basic Shower Trolleys (used for assisted hygiene care)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>28/04/2016</td>
<td>DX-D 600 Digital Radiography System (general purpose x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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<tr>
<td>28/04/2016</td>
<td>Essure Permanent Birth Control</td>
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<td>Recall for Product Correction</td>
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<tr>
<td>28/04/2016</td>
<td>Groshong NXT PICC Connector (used to repair the damaged external segment of a catheter)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
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<tr>
<td>28/04/2016</td>
<td>Image Suite Software Versions 3.0 and 4.0</td>
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<tr>
<td>28/04/2016</td>
<td>Terumo CDI Blood Parameter Monitoring System 500</td>
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<td>27/04/2016</td>
<td>GE Revolution CT Computed Tomography X-ray systems</td>
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<td>Hospital</td>
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<tr>
<td>27/04/2016</td>
<td>LenSx Laser System with Corneal Flap Capability (used to perform corneal flaps in LASIK surgery or other treatment involving the incision of the cornea)</td>
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<td>27/04/2016</td>
<td>Philips EPIQ Ultrasound System</td>
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<td>G-scan Brio Magnetic Resonance System</td>
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<td>26/04/2016</td>
<td>ThinPrep 5000 Processor with Autoloader</td>
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<tr>
<td>22/04/2016</td>
<td>Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pumps (IABP)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>Recall Action Commencement Date</td>
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<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<td>22/04/2016</td>
<td>Catheters with Beacon Tip Technology</td>
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<td>22/04/2016</td>
<td>CinchLock SS Knotless Anchor with Inserter (intended for the fixation of soft tissue to bone)</td>
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<td>22/04/2016</td>
<td>Dexamethasone Oral Solution 1mg/mL (used in the treatment of mild to moderate croup in paediatric patients)</td>
<td>Medicine</td>
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<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>22/04/2016</td>
<td>EnCor Probes (used for breast biopsies)</td>
<td>Medical Device</td>
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<tr>
<td>22/04/2016</td>
<td>iLED 3/5, TruLight 3000/5000, Hellon, TruVidia SD, TruVidia HD, VidaPort Surgical Lighting, Camera and Monitoring Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/04/2016</td>
<td>Capnostream 20p Patient Monitors - battery pack (used for combined capnograph/pulse oximeter monitor)</td>
<td>Medical Device</td>
<td>Recall</td>
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<td>Hospital</td>
</tr>
<tr>
<td>21/04/2016</td>
<td>Elecsys Estradiol Assay with Fulvestrant. An in-vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>21/04/2016</td>
<td>Given Imaging Bravo pH monitoring systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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</tr>
<tr>
<td>21/04/2016</td>
<td>Insulin-Like Growth Factor I (IGF-I) Assay (Used on Immulite and Immulite 1000 Systems). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/04/2016</td>
<td>PF6 Tube Assembly (a component of the Peripheral Vascular Infusion/Ashpiration Catheter or “PAD” catheter)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/04/2016</td>
<td>Biosense Webster PENTARAY NAV and PENTARAY NAV eco Catheters (used for electrophysiological mapping of the heart)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/04/2016</td>
<td>DBL Vancomycin Hydrochloride for Intravenous injection infusion 500mg, 500,000 I.U./vial</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/04/2016</td>
<td>Ingenuity Core using software version 3.5.4</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/04/2016</td>
<td>Lotus Valve System (a transcatheter aortic valve implantation (TAVI) system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/04/2016</td>
<td>RAPIDQC Complete Solution Level 3. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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</tr>
<tr>
<td>18/04/2016</td>
<td>Aperio eSlide Manager with ImageScope, software versions 12.2.1, 12.2.2 and 12.3. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/04/2016</td>
<td>Lightspeed CT, Discovery PET/CT (Computed tomography x-ray and nuclear medicine gamma camera diagnostic systems)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/04/2016</td>
<td>American Surgical Company (ASC ) Neuro Sponges</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/04/2016</td>
<td>D-Vapor and D-Vapor 3000 Vapourisers (used in connection with Baxter Desflurane Agent and Bottles)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/04/2016</td>
<td>IRISpec CA/CC and IRISpec CA/CC Control Kits (quality control for the detection of Bilirubin). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/04/2016</td>
<td>Military Trauma &amp; Haemorrhage Wound Dressing, size 10 x 17cm</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>12/04/2016</td>
<td>Aquasil Easy Mix Putty (used for taking impressions of teeth)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>12/04/2016</td>
<td>CareLink Monitor and CareLink Express Monitor</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/04/2016</td>
<td>VITROS 3600 Immunodiagnostics System and VITROS 5600 Integrated System, software version 3.2.2 and below. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/04/2016</td>
<td>Cuff Controller with Clamp (monitors the cuff pressure of tracheal tubes for intubated patients)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/04/2016</td>
<td>e.cam and all Symbia systems with foresight detectors (Nuclear medicine gamma camera systems)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/04/2016</td>
<td>Fujifilm ED-530XT Duodenoscope</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/04/2016</td>
<td>Mizuho General Purpose Operating Table</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/04/2016</td>
<td>Aisys and Aisys CS2 Anaesthesia machines with the optional Vacuum Suction Function</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/04/2016</td>
<td>LifeCycle for Prenatal Screening, Version 4.0 Revisions 2, 3 and 4. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
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<tr>
<td>8/04/2016</td>
<td>Papoose Infant Spine Immobilisers</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/04/2016</td>
<td>UniCel (DxH 800/DxH 600/ DxH Slidemaker Stainer) Coulter Cellular Analysis Systems. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/04/2016</td>
<td>Vaxcel and Xcela PICC with PASV Valve Technology/Kits, BioFlo PICC Triple Lumen with Endexo and PASV Valve Technology/Kits</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/04/2016</td>
<td>Hickman and Leonard Central Venous Catheter Kits</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/04/2016</td>
<td>ID Anti-N and ID Anti-M/N. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/04/2016</td>
<td>ME DPHC 0001 deltastream HC, 230V</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/04/2016</td>
<td>Pentax ED-3490TK Video Duodenoscope</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/04/2016</td>
<td>AutoSPECT Pro Reconstruction application on Extended Brilliance Workplace NM software version 2.0</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/04/2016</td>
<td>Burinex Bumetanide 1mg tablet</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>6/04/2016</td>
<td>Leksell Gammaknife Perfexion and Leksell Gammaknife Icon</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/04/2016</td>
<td>10mm Direct Drive Clip Applier (Used for ligation of tubular structures or vessels in laparoscopic and general surgical procedures)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/04/2016</td>
<td>ARCHITECT Estradiol Reagent. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/04/2016</td>
<td>CELL-DYN Emerald Cleaner. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/04/2016</td>
<td>EZee-Nest Insert Cups used with ADVIA Centaur CP. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/04/2016</td>
<td>Gene Amplification Reagent – Lynoamp BC. An in vitro diagnostic medical device.</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
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<tr>
<td>5/04/2016</td>
<td>Somatom Force with software versions, VA50A and VA50A_SP2 with paediatric kernel Hp38 (Computed Tomography (CT) system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/04/2016</td>
<td>PneumoSure XL High Flow Insufflator (Used to create a cavity by insufflating CO2 during diagnostics and/or therapeutic laparoscopy)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/04/2016</td>
<td>AutoSPECT Pro Reconstruction application on Intellispace Portal software versions 5.0, 6.0 and 7.0</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/04/2016</td>
<td>INTELEPACS Versions 4.5.1 to 4.12.1</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>31/03/2016</td>
<td>Artis zee Systems with generator A100Plus or Artis zeego Systems with software version VC21B. (fluoroscopic angiographic x-ray systems)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/03/2016</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/03/2016</td>
<td>T34L and NIKI T34 Ambulatory syringe pumps</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/03/2016</td>
<td>Acuson 2000 ultrasound system (with structural foam core).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/03/2016</td>
<td>Acuson SC200 ultrasound systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/03/2016</td>
<td>ADVIA Chemistry Systems (using Trinder and Trinder-like assays). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/03/2016</td>
<td>Dimension and Dimension Vista Clinical Chemistry Systems. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/03/2016</td>
<td>Fetch 2 Aspiration Catheter</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/03/2016</td>
<td>MobileDiagnost wDR Rel1 and 2 (general purpose mobile digital x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/03/2016</td>
<td>TCAutomation System with Thermo Scientific Recapper (used with VITROS Automation Solutions). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
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<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>23/03/2016</td>
<td>Aisys CS2 and upgraded Aisys anaesthesia devices (with software version 10.X)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/03/2016</td>
<td>Brilliance CT and Ingenuity CT with software versions v4.13 and v4.1.4 (Computed tomography full-body x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/03/2016</td>
<td>Betamin 100mg tablets (Thiamine Hydrochloride), Bottle of 100 Tablets</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>22/03/2016</td>
<td>da Vinci Si and Xi Surgical System - Touchpad Compact Flashcards</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/03/2016</td>
<td>Integre S Surgical frequency doubled Nd YAG laser system and Retinal Rejuvenation Therapy System (2RT)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/03/2016</td>
<td>Omrix Pressure Regulators</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/03/2016</td>
<td>Methotrexate Assay performed on Syva Emit Methotrexate Application (DVMTX.1) for the Dimension Vista System. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/03/2016</td>
<td>Symbia E and e.cam collimator</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/03/2016</td>
<td>Versant kPCR Molecular System Sample Preparation. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/03/2016</td>
<td>Allura Xper with software release FD R8.1.16</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/03/2016</td>
<td>Oxoid Nitrocefin (+ Reconstitution Fluid)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/03/2016</td>
<td>Neuroform Atlas Stent System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/03/2016</td>
<td>CARDIOSAVE Hybrid and Rescue Intra-aortic Balloon Pumps (IABP)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/03/2016</td>
<td>Hamilton Medical G5 / S1 Ventilator with software version V2.42</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/03/2016</td>
<td>ORTHO VISION Analyser, software version 2.12.6 &amp; below and ORTHO VISION Max Analyser, software version 2.12.10 (for ORTHO BioVue Cassette). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
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<td>Recall Action Level</td>
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<tr>
<td>15/03/2016</td>
<td>Renasys GO External Power Supply Units supplied with Renasys GO NPWT Pumps (Negative Pressure Wound Therapy System)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/03/2016</td>
<td>ClaveGuard Diathermy Pencil</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/03/2016</td>
<td>Dymista 125/50 Nasal Spray 17ml</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>11/03/2016</td>
<td>TOPAZ MicroDebrider Wand (used for ablation and microdebridment in the tendons of the ankles, knees and shoulders)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/03/2016</td>
<td>Virage Occipital-Cervical-Thoracic (OCT) Spinal Fixation System - Closure Caps (used to stabilise support or correct alignment of spinal vertebrae)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/03/2016</td>
<td>Cios Alpha</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/03/2016</td>
<td>e.cam system</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/03/2016</td>
<td>Drill Sleeve 9.0/2.8, L 191 mm, f/AFN</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/03/2016</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/03/2016</td>
<td>Hydralyte Sports Berry, Oral Liquid 600mL</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>9/03/2016</td>
<td>Syngo X-Workplace with software version VD10E (image processing workstation used with x-ray based diagnostic imaging system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/03/2016</td>
<td>AvantGuard 1600 Li160A0</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/03/2016</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/03/2016</td>
<td>NIM-ECLIPSE Notebook Computer, NCCPU-E4</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/03/2016</td>
<td>Universal Clamp System and UniWallis System (used during spinal cord surgery)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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</tr>
<tr>
<td>8/03/2016</td>
<td>VERION Reference Unit (Vision Planner) - used with the Alcon LenSx Laser System (Surgery planning system for ophthalmic surgery)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/03/2016</td>
<td>AXIOM Artis, Artis zee and Artis Q/Q.zen (fluoroscopic angiographic x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/03/2016</td>
<td>Dexcom G4 PLATINUM and Dexcom G5 Mobile receiver (Continuous Glucose Monitoring Device)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>4/03/2016</td>
<td>Freelite Human Kappa Integra Kit. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/03/2016</td>
<td>Mums The One One Step hCG Urine Pregnancy Test</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>4/03/2016</td>
<td>STERIS Quick Connects (used with the Steris System 1 Express and System 1 Plus sterilisers)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/03/2016</td>
<td>WIZARD2 Gamma Counters. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/03/2016</td>
<td>ARCTICGEL Pads (used with the Arctic Sun Temperature Management System)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/03/2016</td>
<td>Dimension Vista Chemistry 3 Calibrator. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/03/2016</td>
<td>Locking Screw Stardrive 1.5 mm and Cortex Screw Stardrive 1.5mm</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/03/2016</td>
<td>SIGNA Pioneer MRI System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/03/2016</td>
<td>B.R.A.H.M.S Free BhCG Kryptor Kit. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/03/2016</td>
<td>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</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/03/2016</td>
<td>i-STAT troponin I Assay Cartridges (cTnl). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/03/2016</td>
<td>ORTHO VISION Analyzer for ORTHO BioVue Cassettes, software version 2.12.6 and below. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/03/2016</td>
<td>Safe-T-Vue 6 and Safe-T-Vue 10 Temperature Indicators (used to monitor the temperature of blood bags during transit)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
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<td>Recall Action</td>
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<tr>
<td>1/03/2016</td>
<td>USB Communication Data Loss – Handheld Base Unit and Accuchek Inform II Base Unit</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/02/2016</td>
<td>VITROS 5600 Integrated System: An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/02/2016</td>
<td>VITROS Immunodiagnostic Products Total B-hCG II Reagent Packs &amp; Calibrators (used with EC/ECiQ, 3600 Immunodiagnostic Systems and 5600 Integrated Systems). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/02/2016</td>
<td>Blood Urea Nitrogen (BUN) Flex Reagent Cartridge (used with Dimension Vista System). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/02/2016</td>
<td>Covidien Emprint Percutaneous Antenna (short, standard &amp; long) with Thermosphere Technology (used with microwave generator for coagulation of soft tissue)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/02/2016</td>
<td>GENTECH Generator (99Mo/99mTc Sterile Generator)</td>
<td>Medicine</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/02/2016</td>
<td>Medtronic Reveal LINQ Insertable Cardiac Monitor (ICM)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/02/2016</td>
<td>QuikRead go wrCRP and QuikRead go wrCRP+Hb</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/02/2016</td>
<td>IntelePACS InteleViewer software version 4.11.1 P144 (Radiology picture archiving and communication system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/02/2016</td>
<td>ARROW Intra-Aortic Balloon Catheter and Percutaneous Insertion Kits</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/02/2016</td>
<td>Coban 2 Compression Layer (active support bandage)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/02/2016</td>
<td>Coban 2 Lite Compression Layer (active support bandage)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>24/02/2016</td>
<td>Renitec Plus (enalapril maleate/hydrochlorothiazide) 20/6mg tablets</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>24/02/2016</td>
<td>Verso Shoulder Forked Retractor (Comprehensive Instrumentation (2 Prong Retractor))</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/02/2016</td>
<td>175 cartons of GONAL-F follitropin alfa (rch) and 10 cartons of CETROTIDE cetrotelix</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>23/02/2016</td>
<td>Conceiveplease One Step HCG Urine Pregnancy test</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
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<tr>
<td>23/02/2016</td>
<td>ITD VESA 75/100 Adaptation with Rotation (Articulating Arm on Endoscope Trolley)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/02/2016</td>
<td>Maxagra 300 mg Capsules</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>22/02/2016</td>
<td>ADVIA Centaur Systems Calibrator E (Used with Advia Centaur, Centaur XP, Centaur XPT Systems), An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/02/2016</td>
<td>iMDsoft MetaVision ICU (MV-ICU), Version 5.47.4622</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/02/2016</td>
<td>Paracetamol Osteo-Tab, paracetamol 665 mg modified release tablet bottle (no other paracetamol brands are impacted)</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>19/02/2016</td>
<td>Boston Scientific Urogynaecological Surgical Meshes</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/02/2016</td>
<td>Sangofix set with hand pump (Blood/Solution Transfusion Set)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/02/2016</td>
<td>Spiggle &amp; Theis ENT sinus single-use suction tubes (used for paranasal sinus suction)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/02/2016</td>
<td>cobas p 512 pre-analytical system. An in vitro diagnostic device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/02/2016</td>
<td>Nuelin SR 250 (theophylline 250mg) tablets, Bottle 100s</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>17/02/2016</td>
<td>Cardiopulmonary Bypass Packs containing Terumo CDI H/S Cuvettes used with the CDI Blood Parameter Monitoring System 500</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/02/2016</td>
<td>FGD (Fludeoxyglucose [18F]) Injection</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/02/2016</td>
<td>Helioseal Clear, 1.25g syringes</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>17/02/2016</td>
<td>Powerheart G3 Defibrillation Electrodes (used in Powerheart G3 9300A, 9300E, 9300P, 9390A, and 9390E Automatic External Defibrillator (AEDs))</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>16/02/2016</td>
<td>MitraClip System (Product Number # MSK02ST) containing the Clip Delivery System (Part number # CDS02ST) and the Steerable Guide Catheter (Part number # SGC01ST)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/02/2016</td>
<td>RayStation 3.0, 3.5, 4.0, 4.5 and 4.7 (Radiation therapy treatment planning system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>16/02/2016</td>
<td>Syntometrine Injection 1 mL Ampoule</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Wholesale</td>
</tr>
<tr>
<td>15/02/2016</td>
<td>3.0T GEMflex Coil used with GE Healthcare 3.0T Scanners (used to transmit and receive RF pulses for diagnostic MRI procedures)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/02/2016</td>
<td>Berichrom Antithrombin III Kits. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/02/2016</td>
<td>Sureclip and Sureclip Plus Haemostasis Clips (Gastrointestinal endotherapy clip applier)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/02/2016</td>
<td>Depuy Synthes Universal Battery Charger II (UBC II)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/02/2016</td>
<td>Klikfit CT Syringe with QFT and 75cm Extension tube</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/02/2016</td>
<td>Leica M525 OH4 and M720 OH5 Surgical Microscope Stands with 400W Illumination</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/02/2016</td>
<td>Merifluor EBV VCA IgM IFA (an Immunofluorescence Test for the Detection of Antibodies). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/02/2016</td>
<td>Rotor Yokes (used in Allegra X-5 Centrifuge). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/02/2016</td>
<td>Drager V Series Ventilator with the Optional PSS00 Installed</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/02/2016</td>
<td>Ondansetron Tablets - Ondansetron-DRLA and Ondansetron-SZ 4mg and 8mg</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>10/02/2016</td>
<td>Terumo CDI H/S Cuvette</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/02/2016</td>
<td>Trinity Acetabular Shell</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/02/2016</td>
<td>VIDAS TOXO IgM Assay (used for the detection of toxoplasmosis antibodies). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/02/2016</td>
<td>Colleague P1.7 CXE Single Channel Pump and Colleague P1.7 CXE Triple Channel Pump (Infusion Pump)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/02/2016</td>
<td>Veletri Consumables Kit - Infusion administration set containing B. Braun Water for Injections</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
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<td>Recall Action Level</td>
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<tr>
<td>8/02/2016</td>
<td>COULTER ReticPrep Reagent Kit (used for reticulocyte counting). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/02/2016</td>
<td>DVR ePAKs</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/02/2016</td>
<td>Liquichek Specialty Immunoassay Controls. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/02/2016</td>
<td>PRN 50-M+ Digital Writer</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/02/2016</td>
<td>Carestation 620 A1, 650 A1, and 650c A1 Anaesthesia devices and service kits</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/02/2016</td>
<td>Glidescope Titanium Single-Use Video Laryngoscope Blades</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/02/2016</td>
<td>Surgical Clipper Charger</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/02/2016</td>
<td>3M ESPE Adper Single Bond 2</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>3/02/2016</td>
<td>Clobex clobetasol propionate 500 microgram/mL Shampoo Application Bottle 125mL</td>
<td>Medicine</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>3/02/2016</td>
<td>D-10 Rack Loader. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/02/2016</td>
<td>Kangaroo Polyurethane Feeding Tube, Radiopaque Line, Safe Enteral Connections 6.5 Fr/Ch (2.2 mm) x 36&quot; (91 cm)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/02/2016</td>
<td>Puritan Bennett 980 Series Ventilator System PB980</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/02/2016</td>
<td>Terumo CVS CDI H/S Cuvette provided within the Medtronic Perfusion Tubing Pack</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>2/02/2016</td>
<td>Anti-Jk (Jk1).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>2/02/2016</td>
<td>HomeChoice Pro Automated PD System devices</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Consumer</td>
</tr>
<tr>
<td>2/02/2016</td>
<td>Water for Injections 100 mL bottle (for parenteral use)</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/02/2016</td>
<td>Panocell 16 and Panocell 20. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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</tr>
<tr>
<td>28/01/2016</td>
<td>Acetaminophen (Paracetamol) Reagent (used with L3K Assay in conjunction with the Architect cSystem Analyser). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>28/01/2016</td>
<td>Endobon Xenograft Granules</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>28/01/2016</td>
<td>PyroTitan Humeral Resurfacing Arthroplasty Shapers</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>28/01/2016</td>
<td>Super Arrow-Flex Percutaneous Sheath Introducer Set</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>28/01/2016</td>
<td>Trilogy dual prescription ventilators with software versions 13.2.04, 13.2.05, 14.0.00, and 14.1.01</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Consumer</td>
</tr>
<tr>
<td>27/01/2016</td>
<td>TJF-Q180V Duodenoscope</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/01/2016</td>
<td>DIAMOX (acetazolamide) 250mg tablet bottle</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>25/01/2016</td>
<td>LCP Distal Tibial Plates 3.5 anterolateral, left, 9 holes, length 132mm Stainless Steel Sterile</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/01/2016</td>
<td>Beaver 4.0mm Banana Blade</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/01/2016</td>
<td>Liko Universal SlingBar 350, SlingBar 450 and SlingBar 600 (used with Golvo, Uno, LikoLight, Likorall, Multirall and Viking XS/S/M/L mobile patient lifts)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>20/01/2016</td>
<td>Hexad 12-Lead ECG Monitoring derivation with Philips IntelliVue Patient Monitors, software versions K.21.54 or L.00.96</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/01/2016</td>
<td>Astral Ventilators - ResMed Astral 100 &amp; Astral 150 with SR1.1 software (SX544-0301)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>18/01/2016</td>
<td>Bond Ready-to-Use Primary Antibody and Probe kits used with Bond Polymer Refine Detection Kit. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/01/2016</td>
<td>BrightView X/XCT/XCT Upgrade</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/01/2016</td>
<td>Curlin 6000 and Painsmart IOD Ambulatory Infusion Pumps</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/01/2016</td>
<td>PS900 Power Module supplied with 12 Lead ECG Interp. 210mm Basic Monitors</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
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<tr>
<td>15/01/2016</td>
<td>ADVIA Centaur Systems, Dimension Vista Systems &amp; IMMULITE Systems Estradiol Assays</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/01/2016</td>
<td>Brain Metastases v1.0.0 and Adaptive Hybrid Surgery Analysis (AHSA) v1.0.0</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/01/2016</td>
<td>Eclipse Treatment Planning System v 11, 13.0, 13.5 and 13.6 using Pencil Beam Convolution (PBC) Algorithm 11.0.31</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/01/2016</td>
<td>Flocare Transition Giving Sets (Enteral feeding tube)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>15/01/2016</td>
<td>ImmunoCAP Specific IgG/IgG4 i1 Control H. An in vitro diagnostic device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/01/2016</td>
<td>Ingenuity CT/Core/Core128/Flex, Brilliance CT Big Bore /iCT/iCT SP Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/01/2016</td>
<td>Central Venous Catheter and Pressure Monitoring Sets</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/01/2016</td>
<td>Saline 0.9% in 240ml elastomeric device</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/01/2016</td>
<td>Rayner Intraocular Lenses - Sulcoflex Aspheric 653L, Sulcoflex Torie 653T, C-flex Aspheric 970C, Superflex Aspheric 920H, Sulcoflex Aspherie 653L, T-flex Aspheric 623T</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/01/2016</td>
<td>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</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/01/2016</td>
<td>Steris Amsco Warming Cabinet</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/01/2016</td>
<td>BCS / BCS XP Automated Blood Coagulation Analyser with Dade Innovin, An in vitro diagnostic device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/01/2016</td>
<td>Integra Camino Intracranial Pressure (ICP) Monitor and the Integra Licox PO2 and Temperature Monitor</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/01/2016</td>
<td>One Step HCG Urine Pregnancy Test, An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>7/01/2016</td>
<td>Extraction Screw for PFNA Blade</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/01/2016</td>
<td>HeartWare HVAD Controller AC Adapter and HeartWare HVAD Battery</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/01/2016</td>
<td>INNOVANCE PFA P2Y. An in vitro diagnostic device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/01/2016</td>
<td>VITROS Chemistry System. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/01/2016</td>
<td>ADVIA Centaur PSA 100 test kit and 500 test kit. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/01/2016</td>
<td>AQUIRE data management system</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/01/2016</td>
<td>Cook Beacon Tip Angiography Catheters</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/01/2016</td>
<td>EliA SmDP Well</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/01/2016</td>
<td>Guide Wires and K-Wires for T2 and Gamma Nailing Systems</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/01/2016</td>
<td>Mavig Monitor suspension arms manufactured before January 2009 (used with x-ray fluoroscopic imaging systems)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/01/2016</td>
<td>Optima XR200amx, Optima XR220amx and Brivo XR285amx X-ray imaging systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/12/2015</td>
<td>API ZYM B. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/12/2015</td>
<td>da Vinci Xi instrument &amp; accessories</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/12/2015</td>
<td>PFNA Nails (used during internal fixation surgery)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/12/2015</td>
<td>Syner-Kinase Urokinase powder for solution for injection or infusion, 10,000 IU vial (used for lysis of blood clots in cannulas)</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/12/2015</td>
<td>TruLight 3000, TruLight 5000, iLED 3, iLED 5 and TruVidia Lighting and Video Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/12/2015</td>
<td>VariAx 2 3.5 mm screws</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/12/2015</td>
<td>Coulter S-CAL Calibrator Kits used on the Unicel DxH 800, DxH 600, LH 750 and LH 780 Systems.</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
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<td>Recall Action Level</td>
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<tr>
<td>23/12/2015</td>
<td>Oxylog Transport Ventilator</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/12/2015</td>
<td>2-Way Foley Catheters and 2-Way Council Tip Foley Catheters (used for urinary drainage)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/12/2015</td>
<td>96 Deep Well Plate 2mL (used on the VERSANT kPCR Sample Preparation and Tissue Preparation System)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/12/2015</td>
<td>All Magnetom MRI systems with superconductive magnets</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/12/2015</td>
<td>Ambu AuraGain Single Use Laryngeal Mask – Sterile</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/12/2015</td>
<td>Dengue NS1 Ag Strip</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/12/2015</td>
<td>Maxolon Metoclopramide 10mg Tablets, Blister pack 100s</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>22/12/2015</td>
<td>VerifyNow Aspirin Test Kit</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/12/2015</td>
<td>All Giraffe Carestation Beds shipped between 18 September 2015 and 1 November 2015</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/12/2015</td>
<td>BD Vacutainer Heparin Tube. n in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/12/2015</td>
<td>Samarys Peek Anterior Cervical Cage</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/12/2015</td>
<td>TCM CombiM module (used with Radiometer Transcutaneous Monitors)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/12/2015</td>
<td>Synream Medullary Reamer Head Size 13.5mm</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/12/2015</td>
<td>Reflotron Uric Acid (used with Reflotron Plus &amp; Reflotron Sprint Single test chemistry systems) An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/12/2015</td>
<td>IntelliVie Information Centre (PIIC) IX (centralised patient monitor)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/12/2015</td>
<td>Kirschner Wire 1.6 mm, with drill tip, length 200 mm</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/12/2015</td>
<td>miraDry System (used for the treatment of primary axillary hyperhidrosis)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/12/2015</td>
<td>Arcadophta SARL– Arcotane 5ml</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/12/2015</td>
<td>Hypochlorite 1% Solution &amp; Hypochlor 1% Solution</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>15/12/2015</td>
<td>STALORAL and PHOSTAL</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Consumer</td>
</tr>
<tr>
<td>11/12/2015</td>
<td>BladderScan BVI 9600 with AortaScan</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/12/2015</td>
<td>Genotropin 5 mg and 12 mg GoQuick Pre-filled Pens</td>
<td>Medicine</td>
<td>Product Defect Alert</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>10/12/2015</td>
<td>Gynecare Thermachoice III Thermal Balloon Ablation Silicone Catheter</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/12/2015</td>
<td>MediRedi Fistula Packs</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/12/2015</td>
<td>MOSAIQ version 2.5 and above - Medical Oncology only</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/12/2015</td>
<td>PFN/PFNA Insertion Handle (used for the insertion of Proximal Femur Nail during internal fixation surgery)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/12/2015</td>
<td>ADVIA Centaur XPT System, with software versions V1.0.1, V1.0.2 and V1.0.3</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/12/2015</td>
<td>Multiple dental abutment products and their accessories.</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>9/12/2015</td>
<td>Sysmex XN and XN-L Series - All Sysmex XN analysers versions 16 to 19</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/12/2015</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/12/2015</td>
<td>Polymer Refine Red Detection (used for testing and identification of neoplasm). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/12/2015</td>
<td>Titanium Fluted Stem Extender</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/12/2015</td>
<td>Absorb Bioresorbable Vascular Scaffold (BVS) System (Bioresorbable balloon expandable scaffold with bioresorbable polymeric drug coating mounted on a balloon dilatation catheter)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/12/2015</td>
<td>ACUITY Pro 9 Fr Guide Catheter</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/12/2015</td>
<td>Bayer Source Administration Sets (SAS) used with the Medrad Intego PET Infusion System [Catalogue Number INT CSS]</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
</tbody>
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<th>Recall Action Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>7/12/2015</td>
<td>ENA RELISA Single Well Screen (576 well) Kit. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/12/2015</td>
<td>Endo GIA Ultra Universal Stapler Handles (Short, Standard &amp; XL versions)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/12/2015</td>
<td>Shape Arm Kit Left and Shape Arm Kit Right (Mounting/positioning system for flat panel monitors)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/12/2015</td>
<td>Switch Point Infinity 3 (Operating Room Management System)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/12/2015</td>
<td>Opti-Mist Nebuliser / Nebuliser Mask Products</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/12/2015</td>
<td>Oxoid Antimicrobial Susceptibility Testing Disc QD15 Quinupristin / Dalfopristin, CT1644B</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>2/12/2015</td>
<td>300mL Canister (with Gel) for use with the ActiV.A.C. Therapy System</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>2/12/2015</td>
<td>Birmingham Hip Modular Head (BHMH) - Monoblock version</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>2/12/2015</td>
<td>Etest PIPTAZO PTC 256 (used for testing of Enterobacteria strains). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>2/12/2015</td>
<td>Fresnius Medical Care (FME) Dialysis Fistula Pack 5 and Safety AVF Needle - Fixed Wing</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>2/12/2015</td>
<td>MediRedi A.V. Fistula Pack</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>2/12/2015</td>
<td>Sapphire Multi-Therapy and Sapphire Epidural Pumps with software versions 11.00 and below</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/12/2015</td>
<td>syngo X-Workplace with software VD10E and tabcard “4D”</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/11/2015</td>
<td>A.L.P.S. 4.0mm Cancellous Locking Screws (non-sterile)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/11/2015</td>
<td>ADVIA Chemistry Halogen Lamp</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>27/11/2015</td>
<td>Brainlab Brain Metastases v1.0.0 and Adaptive Hybrid Surgery Analysis v1.0.0</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>27/11/2015</td>
<td>Careline Colostrum 820mg chewable tablets 200's and 400's with expiry dates of 10/2016, 04/2017 and 09/2017</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
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<tbody>
<tr>
<td>27/11/2015</td>
<td>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</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
</tr>
<tr>
<td>27/11/2015</td>
<td>Nebulisers / Nebuliser Mask Products</td>
<td>Medical Device</td>
<td>Recall</td>
</tr>
<tr>
<td>26/11/2015</td>
<td>IntellaTip MiFi XP Asymmetric (N4) Curve Temperature Ablation Catheters</td>
<td>Medical Device</td>
<td>Recall</td>
</tr>
<tr>
<td>25/11/2015</td>
<td>Drager V Series Ventilator with the Optional PSS00 battery Installed</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
</tr>
<tr>
<td>25/11/2015</td>
<td>Karma Wheelchairs</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
</tr>
<tr>
<td>24/11/2015</td>
<td>Abtectcell III 0.8% and Abtectcell III 0.8% Bulk Pack. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
</tr>
<tr>
<td>24/11/2015</td>
<td>AHG Control Cells 3%. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
</tr>
<tr>
<td>23/11/2015</td>
<td>Artis systems with large display module</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
</tr>
<tr>
<td>23/11/2015</td>
<td>ENDOEYE Video Telescope</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
</tr>
<tr>
<td>20/11/2015</td>
<td>A.V. Fistula sets for Haemodialysis - Safety AVF Needle fixed wing</td>
<td>Medical Device</td>
<td>Recall</td>
</tr>
<tr>
<td>20/11/2015</td>
<td>VITROS 4600 Chemistry System and VITROS 5,1 FS Chemistry System. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
</tr>
<tr>
<td>20/11/2015</td>
<td>Xper Flex Cardio Patient Monitoring System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
</tr>
<tr>
<td>19/11/2015</td>
<td>Non Buffered Formalin. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
</tr>
<tr>
<td>18/11/2015</td>
<td>ADVIA Centaur and ADVIA Centaur XP</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
</tr>
<tr>
<td>17/11/2015</td>
<td>Allura Xper, Allura Clarity &amp; Integris</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
</tr>
<tr>
<td>17/11/2015</td>
<td>AU480, AU680, AU5800 Chemistry Analysers. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
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<tr>
<td>17/11/2015</td>
<td>Bard Arctic Sun 5000 Temperature Management System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>17/11/2015</td>
<td>Dimension Integrated Chemistry Systems.</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
</tr>
<tr>
<td>17/11/2015</td>
<td>Two and three stage I.V. Poles (used as an optional accessory to a stretcher)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
</tr>
<tr>
<td>16/11/2015</td>
<td>artus C. trachomatis Plus kits</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
</tr>
<tr>
<td>16/11/2015</td>
<td>ECG Electrode SKINTACT W-60</td>
<td>Medical Device</td>
<td>Recall</td>
</tr>
<tr>
<td>16/11/2015</td>
<td>HemoCue HbA1c 501 Test Cartridge. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
</tr>
<tr>
<td>16/11/2015</td>
<td>Provide Protection Caps and Provide Impression Copings</td>
<td>Medical Device</td>
<td>Recall</td>
</tr>
<tr>
<td>16/11/2015</td>
<td>Various surgical instruments actuated by the da Vinci Si Single Site Grip Release mechanism</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
</tr>
<tr>
<td>13/11/2015</td>
<td>Allura Xper and Allura Clarity - software releases 1.2.7, or 2.0.6, or 7.2.x where x&lt;8 or 7.6.x or 7.8.x or 8.1.x where x&lt;16 or 8.2.x where x&lt;16</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
</tr>
<tr>
<td>13/11/2015</td>
<td>BARRIER Easywarm (Active Self Warming Blanket) and BARRIER Easywarm+ (Flexible Active Self Warming Blanket)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
</tr>
<tr>
<td>13/11/2015</td>
<td>Compounded Fentanyl and/or Fentanyl Bupivicaine combinations stored in Becton-Dickinson Syringes 3ml or 10ml Plastipak Syringes</td>
<td>Medicine</td>
<td>Recall</td>
</tr>
<tr>
<td>13/11/2015</td>
<td>InSync III Cardiac Resynchronisation Therapy Pacemakers (CRT-P)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
</tr>
<tr>
<td>13/11/2015</td>
<td>VITROS 3600 and 5600 Systems using Software Version 3.2 and Below. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
</tr>
<tr>
<td>12/11/2015</td>
<td>ECG Electrode</td>
<td>Medical Device</td>
<td>Recall</td>
</tr>
<tr>
<td>12/11/2015</td>
<td>Lymph-flo Injection Composite Pack (Technetium99m-ATC (Tc99m-ATC))</td>
<td>Medicine</td>
<td>Recall</td>
</tr>
<tr>
<td>12/11/2015</td>
<td>Screw Inserter for TFN-Advanced (TFNA) Proximal Femoral Nailing System</td>
<td>Medical Device</td>
<td>Recall</td>
</tr>
<tr>
<td>11/11/2015</td>
<td>Arceole C3F8 and SF6</td>
<td>Medical Device</td>
<td>Recall</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
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</tr>
<tr>
<td>10/11/2015</td>
<td>Attachment for Acetabular and Medullary Reaming (used with the Compact Air Drive II, an air-driven power tool for use in traumatology, endoprosthetics and spinal column surgery)</td>
<td>Medical Device</td>
<td>Recall</td>
</tr>
<tr>
<td>10/11/2015</td>
<td>DGDE DirectGuideTM Drill Extender and kits containing the DGDE Drill Extender</td>
<td>Medical Device</td>
<td>Recall</td>
</tr>
<tr>
<td>9/11/2015</td>
<td>Bard 100% Latex-Free Urinary Drainage Bag with Anti-Reflux Chamber and Bard EZ-Lok</td>
<td>Medical Device</td>
<td>Recall</td>
</tr>
<tr>
<td>9/11/2015</td>
<td>ichem VELOCITY Urine Chemistry Strips. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall</td>
</tr>
<tr>
<td>9/11/2015</td>
<td>LeMaitre Single Lumen Embolectomy Catheter 3F, 80 cm</td>
<td>Medical Device</td>
<td>Recall</td>
</tr>
<tr>
<td>9/11/2015</td>
<td>MAQUET HCU 30 Base Unit</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
</tr>
<tr>
<td>9/11/2015</td>
<td>Rainbow Reusable Sensors for rainbow SET Devices with SpCO, SpO2, and SpMet. (used with pulse oximeter for the measurement of parameters such as arterial oxygen).</td>
<td>Medical Device</td>
<td>Recall</td>
</tr>
<tr>
<td>6/11/2015</td>
<td>Oxoid Anti-microbial Susceptibility Testing Disc CT0024B Gentamicin (CN 10) 5x50 discs</td>
<td>Medical Device</td>
<td>Recall</td>
</tr>
<tr>
<td>6/11/2015</td>
<td>Oxoid Anti-microbial Susceptibility Testing Disc</td>
<td>Medical Device</td>
<td>Recall</td>
</tr>
<tr>
<td>6/11/2015</td>
<td>QConnect HBVNAT Positive</td>
<td>Medical Device</td>
<td>Recall</td>
</tr>
</tbody>
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### System for Australian Recall Actions

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<tr>
<td>4/11/2015</td>
<td>Prius Elite Bed</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>Hospital</td>
</tr>
<tr>
<td>4/11/2015</td>
<td>Ultra-Fine Insulin Syringe for use with U-100 insulin</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/11/2015</td>
<td>IOLMaster 500, software version 7.5.2, 7.7.2 and 7.7.3</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/11/2015</td>
<td>Vented Paclitaxel Set (infusion set used during the administration of medication of anaesthetic drugs)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>2/11/2015</td>
<td>N Latex β2–Microglobulin</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/10/2015</td>
<td>ADVIA Centaur XPT. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/10/2015</td>
<td>SOMATOM Definition AS when used with Patient table PHS1600 and software license for &quot;Adaptive 4D Spiral&quot;</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/10/2015</td>
<td>Vital Signs LightWand Stylet</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/10/2015</td>
<td>Zarontin (ethosuximide) 250mg capsule bottle</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>28/10/2015</td>
<td>Access Free T3 Reagent Kit (For use with the Access Family of Immunoassay Systems). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>28/10/2015</td>
<td>ADVIA Chemistry XPT Systems with software version 1.0.3. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>28/10/2015</td>
<td>eVent Medical Inspiration LS &amp; i Series Ventilator Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>28/10/2015</td>
<td>Revolution CT Scanners, software version 15MW03.12</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/10/2015</td>
<td>All Welch Allyn KleenSpec Corded Illumination Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/10/2015</td>
<td>Amphirion Deep Percutaneous Transluminal Angioplasty (PTA) Balloon Dilation Catheter</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/10/2015</td>
<td>LifePack 1000 Automated External Defibrillator (AED's), software version 2.42 or earlier</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
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<tr>
<td>23/10/2015</td>
<td>Oxoid M.I.C Evaluator for Penicillin 256 microgram/ml</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/10/2015</td>
<td>Access CEA Reagent Kit (For use with the Access Family of Immunooassay Systems). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/10/2015</td>
<td>Quidel Sofia Legionella FIA. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/10/2015</td>
<td>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).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/10/2015</td>
<td>Sodium Chromate (Cr-51) 8MBq/mL Injections</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/10/2015</td>
<td>Brianlab iPlan RT Image (versions below v.4.1.2) / iPlan RT and BrainSCAN (discontinued in 2002)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/10/2015</td>
<td>Epilim EC200 sodium valproate 200mg tablet blister pack (used for the treatment of primary generalised epilepsy)</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>20/10/2015</td>
<td>LIFECODES LifeScreen Deluxe (LMX). An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/10/2015</td>
<td>MONACO, version 5.10.00 and above</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/10/2015</td>
<td>MoPyc Radial Head Prosthesis Stem (used in elbow reconstruction)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/10/2015</td>
<td>Roche Clinical Chemistry tests using NAD(H) or NADP(H) reaction. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/10/2015</td>
<td>Triathlon MIS Modular Distal Capture</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/10/2015</td>
<td>AU480 Clinical Chemistry Analyser - software version 1.81</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/10/2015</td>
<td>Multiple Children’s Suspensions, Pack size 200 ml</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class I</td>
<td>Consumer</td>
</tr>
<tr>
<td>19/10/2015</td>
<td>Synchron Systems Enzymatic Creatinine (CR-E) and Uric Acid (URIC) Reagents. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/10/2015</td>
<td>Vaios Total Shoulder Replacement System</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<td>15/10/2015</td>
<td>VariSource iX Control Software</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/10/2015</td>
<td>Cook Beacon Tip Angiography Catheters</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/10/2015</td>
<td>Enzygnost Anti-VZV/IgG</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/10/2015</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/10/2015</td>
<td>Disposable Myringotomy blade with handle (used during surgery on the ear drum to relieve pressure)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/10/2015</td>
<td>LifeCycle for Prenatal Screening software</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/10/2015</td>
<td>Plum 360 Infusion Pump, Software Version 15.01.XX.009</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/10/2015</td>
<td>Zimmer Natural Nail CM Long-Cephalomedullary Nails</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/10/2015</td>
<td>EndoBarrier Gastrointestinal Liner System</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/10/2015</td>
<td>EnVision Flex/HRP visualisation reagent, part of EnVision Flex/Flex+ Kits</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/10/2015</td>
<td>Allura Xper FD Release 8.2.16</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/10/2015</td>
<td>Neupogen (filgrastim) 480microgram 10s</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/10/2015</td>
<td>Pangea, USS II Polyaxial, Matrix Deformity, Matrix Degenerative and Pangea Degenerative Systems, Pedicle Awl 4.0mm with Canevasit and Silicone Handle (internal fixation system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/10/2015</td>
<td>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</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>8/10/2015</td>
<td>Ethicon HARMONIC ACE+ 7 Laparoscopic Shears</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/10/2015</td>
<td>Sydney IVF PVP (Used during microinjection techniques for reducing sperm motility to enable easier capture using a pipette)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>7/10/2015</td>
<td>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</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/10/2015</td>
<td>MAJ-1606 instrument adaptor (designed for use with the Olympus MAJ-1607 instrument channel water tube)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/10/2015</td>
<td>OLS-500 &amp; OLS-700 surgical lights</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>2/10/2015</td>
<td>Duracon Augments - Tibial Wedge Implants</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/10/2015</td>
<td>Apohealth &amp; Terry White Children's Paracetamol and Ibuprofen children's suspensions</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>1/10/2015</td>
<td>Exeter Small and Large Tapered Pin Reamer (used as part of the Exeter Procedure Pack)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/10/2015</td>
<td>Giraffe Shuttle Products (uninterruptable power supply for Giraffe Products)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/10/2015</td>
<td>PCA Tapers, LFIT V40 Tapers, V40 Tapers (Vitallium Femoral Heads)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/10/2015</td>
<td>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).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/09/2015</td>
<td>MiniMed 640G insulin pump</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>30/09/2015</td>
<td>Prism Medical P300 and C300 Lifts</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>30/09/2015</td>
<td>Shuttle Discovery Seat (designed for children aged between six months and four years who have a physical disability)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>29/09/2015</td>
<td>AXIOM Artis dFA, dFC, dFCM, dBA, dBC, dBCM, dMP systems with SW version VB35D</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/09/2015</td>
<td>AXIOM Artis FA, FC, dFA, dFC, dFCM, BA, BC, dBA, dBC, dBCM, MP, dMP systems with SW version VB23N/P</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/09/2015</td>
<td>Brainlab Patient Data Manager</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/09/2015</td>
<td>HeartWare Ventricular Assist System Battery</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>29/09/2015</td>
<td>MULTIGENT Ammonia Ultra Reagent. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/09/2015</td>
<td>Alkaline Phosphatase (ALPAMP, ALPDEA and ALPA_c) used on the ADVIA 1200, 1650, 1800,</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<td></td>
<td>2400, and XPT Chemistry Systems</td>
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<tr>
<td>25/09/2015</td>
<td>EPREX PROTECS 4000U 6X0.4ML SYR.</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>25/09/2015</td>
<td>Intramedullary (SP 2 IM) Rod 400mm Instrument</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/09/2015</td>
<td>PORT-A-CATH Plastic Hub Needles; 0.9mm (20G) x 19mm (3/4 in) 90 deg</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/09/2015</td>
<td>PreciControl ClinChem Multi 1Lot No. 174787 &amp; 174794</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/09/2015</td>
<td>REFRESH NIGHT TIME and Ircal Eye Ointments</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Consumer</td>
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<tr>
<td>21/09/2015</td>
<td>Neoss Guide – Drill-Hubs I to V included in Neoss</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/09/2015</td>
<td>ALBAclone Anti-Leb, (LEB2) 1 x 5mL</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/09/2015</td>
<td>Medtronic Navigated Solera Driver Tips for Spinal Surgery</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/09/2015</td>
<td>Retractor for Sciatic Nerve; and Retractor for Sciatic Nerve, long</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>18/09/2015</td>
<td>Unitek Victory Mini Tube Lower Left Buccal Tube</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/09/2015</td>
<td>True Cut Oscillating Blade, 0.9mm x 80mm x 12mm, single use device (used to cut skeletal</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
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<td></td>
<td>bone and tissue)</td>
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<td>16/09/2015</td>
<td>GE 3.0T MR Systems (Full body MRI system):</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
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<td>16/09/2015</td>
<td>Monaco 5.10.00</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/09/2015</td>
<td>Suction Adapter Type A (Gauge)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/09/2015</td>
<td>4FR Single Lumen Pressure Injectable Peripherally Inserted Central Catheter (PICC)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/09/2015</td>
<td>Application Instrument for Sternal ZIPFIX</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
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<td>Type of Product</td>
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<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<td>15/09/2015</td>
<td>Brio Charging System Model 6721 (used with Deep Brain Stimulator, Brio IPG Model 65-6788)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/09/2015</td>
<td>Bulk Loader Module for cobas p 471 centrifuge unit</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/09/2015</td>
<td>EIZO Medical Monitors</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/09/2015</td>
<td>Novoceastra Lyophilised Mouse Monoclonal Antibody CD10 Reagents. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/09/2015</td>
<td>seleXys TH+ and seleXys TPS acetabular shells</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/09/2015</td>
<td>GF-UCT180 Ultrasonic Gastrovideoscope</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>10/09/2015</td>
<td>Liko Viking mobile lifts</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/09/2015</td>
<td>SEROPHENE clomiphene citrate 50mg tablet</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>8/09/2015</td>
<td>Base array component of the MAKO RIO Robotic Arm</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/09/2015</td>
<td>Flexi-Slip endotracheal tube stylets</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>8/09/2015</td>
<td>Gram Crystal Violet stain MV1031</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
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<tr>
<td>8/09/2015</td>
<td>Maxi Air Blower Unit - Model 230V</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/09/2015</td>
<td>CA1:1L EVO 15 (Contrangle used in dentistry)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>4/09/2015</td>
<td>KIMVENT Closed Suction Systems (Tube, tracheal, general-purpose, single-use)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/09/2015</td>
<td>Medtronic CryoConsole</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/09/2015</td>
<td>RAPIDPoint 500 Measurement Cartridges used on the RAPIDPoint 500 System. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>4/09/2015</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>2/09/2015</td>
<td>Blackmores Triple Action Bone Formula</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>2/09/2015</td>
<td>Coloplast urogynaecological surgical mesh</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>2/09/2015</td>
<td>GYNEMESH PS and TVT Devices</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>2/09/2015</td>
<td>MetaVision ICU (MV-ICU)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/09/2015</td>
<td>ALIQUOT Delivery System Complete Set (orthopaedic surgical kit, used to place injectable synthetic cortical bone void filler in weakened or diminished bone stock)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/09/2015</td>
<td>BD Affirm VP III Microbial Identification Tests (used for the testing of multiple infectious organisms). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>31/08/2015</td>
<td>ACUSON SC2000 ultrasound systems with software versions VB10B and lower</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>31/08/2015</td>
<td>Medi-Trace Cadence Adult Multi-Function Defibrillation Electrodes, Pre-connect (used in conjunction with Automatic External Defibrillators)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>31/08/2015</td>
<td>syngo Lab Data Manager with software version VA12B. (Software used to supplement operational functions). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>28/08/2015</td>
<td>ADVIA Centaur, ADVIA Centaur XP, ADVIA Centaur XPT – HbsAgII Assay</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>28/08/2015</td>
<td>Allura Xper FD</td>
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<td>Hospital</td>
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<tr>
<td>28/08/2015</td>
<td>Apo-Paracetamol 500mg tablets, Bottle, 1000,</td>
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<td>Retail</td>
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<td>28/08/2015</td>
<td>Bactroban Cream (mupirocin calcium 2% w/w) 15g; and Bactroban Nasal Ointment (mupirocin calcium 2% w/w) 3g</td>
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<td>Recall</td>
<td>Class II</td>
<td>Wholesale</td>
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<tr>
<td>28/08/2015</td>
<td>Cios Alpha mobile C-arm x-ray system</td>
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<td>28/08/2015 Dimetapp Daytime/Night time Liquid Caps</td>
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<tr>
<td>28/08/2015 Philips HeartStart MRx Monitor/Defibrillator with Q-CPR</td>
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<tr>
<td>28/08/2015 ABL90Flex battery module used with Radiometer ABL90FLEX blood gas analyser (Optional battery). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>28/08/2015 CONTOUR NEXT control solutions. In vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
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<td>27/08/2015 Disposable Reflective Marker Spheres</td>
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<td>27/08/2015 Mitoxantrone Hydrochloride Injection Concentrate 20mg/10ml</td>
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<td>27/08/2015 Shen Neng Ching Fei Yi Hou Pien</td>
<td>Medicine</td>
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<td>27/08/2015 WATCHMAN Left Atrial Appendage Closure Device with Delivery System</td>
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<td>27/08/2015 chromID S.aureus agar (SAID/MRSA). An in vitro diagnostic medical device (IVD)</td>
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<td>Recall for Product Correction</td>
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<td>25/08/2015 Actifuse ABX and Actifuse MIS System</td>
<td>Medical Device</td>
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<tr>
<td>25/08/2015 Edwards Pressure Monitoring Kit &amp; Set, Model Number: PXMK2043</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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<tr>
<td>21/08/2015 DirectView Software versions 5.5 &amp; greater and 5.7 with DR, LLI Auto Stitch option on DRX Evolution with Premium and Full Featured Wall Stands</td>
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<td>Recall for Product Correction</td>
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<td>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)</td>
<td>Medical Device</td>
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<tr>
<td>20/08/2015 Brilliance 64, Ingenuity CT, Ingenuity Core, and Ingenuity Core128 with the following versions:</td>
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<td>Recall for Product Correction</td>
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<td>Recall Action Classification</td>
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<td>20/08/2015</td>
<td>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</td>
<td>Medical Device</td>
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<td>19/08/2015</td>
<td>Alcon 23 Gauge and 25 Gauge Valved entry systems</td>
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<td>Recall for Product Correction</td>
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<td>19/08/2015</td>
<td>Fentanyl Intranasal Spray 600ug/2mL</td>
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<td>19/08/2015</td>
<td>PROFEMUR NECK VAR/VAL 8DG, Long Cobalt Chrome, Part number PHAC1254</td>
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<tr>
<td>17/08/2015</td>
<td>Etoposide (as phosphate) 200mg in 10mL, 20mL, and 165mg in 8.3mL syringe for Intravenous injection</td>
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<tr>
<td>17/08/2015</td>
<td>Xia 3 Titanium Torque Wrench</td>
<td>Medical Device</td>
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<tr>
<td>13/08/2015</td>
<td>DigitalDiagnost, Release 4.1.1.1</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>Extension Set</td>
<td>Medical Device</td>
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<tr>
<td>13/08/2015</td>
<td>Philips Trauma Diagnost X-ray Systems</td>
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<td>13/08/2015</td>
<td>VEPTR Vertical Expandable Prosthetic Titanium Rib</td>
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<td>13/08/2015</td>
<td>Volcano IVUS Ultrasound Imaging System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>12/08/2015</td>
<td>ACUSON SC2000 ultrasound systems with software versions VA16A to VA30A and the Stress Echo Option</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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</tr>
<tr>
<td>12/08/2015</td>
<td>ADVIA Chemistry System – Urea Nitrogen and Urea Nitrogen Concentrated Assays. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
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<tr>
<td>12/08/2015</td>
<td>Arrow International 4Fg Seldinger Conversion Set with Long Sheath</td>
<td>Medical Device</td>
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<tr>
<td>12/08/2015</td>
<td>EXACTRAC Version 6.0.0 through to 6.0.5</td>
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System for Australian Recall Actions

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

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<tr>
<td>29/07/2015</td>
<td>Pharmacy Choice Children’s Paracetamol 6 To 12 Years Concentrated 200ml and Pharmacy Choice Ibuprofen Children’s Suspension</td>
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<tr>
<td>28/07/2015</td>
<td>Artis systems used in conjunction with Artis table</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>28/07/2015</td>
<td>Dimension Creatinine and Dimension Vista Creatinine Assays. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>28/07/2015</td>
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<tr>
<td>28/07/2015</td>
<td>Sureshot Humeral 3.2mm AO Drill</td>
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<td>24/07/2015</td>
<td>Back Table Cover supplied in a limited range of Operating Room Packs</td>
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<td>23/07/2015</td>
<td>Da Vinci Xi Surgical System - Breakage of input disks of Endowrist instruments</td>
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<tr>
<td>23/07/2015</td>
<td>N Latex β2–Microglobulin. An in vitro diagnostic medical device (IVD)</td>
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<td>22/07/2015</td>
<td>ReTurnBelt wipeable</td>
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<td>21/07/2015</td>
<td>iChemVELOCITY Automated Urine Chemistry System using iChemVELOCITY Urine Chemistry Strips</td>
<td>Medical Device</td>
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<tr>
<td>21/07/2015</td>
<td>Medtronic Activa PC, Activa SC, Activa RC, Kinetra and Soletra Implantable Deep Brain Stimulators (DBS)</td>
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<td>21/07/2015</td>
<td>MR ACGD Cabinet FRU X Gradient Cable used with GE MRI System</td>
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<td>21/07/2015</td>
<td>NeoMode software used on Puritan Bennett 980 Series (PB980) Universal Ventilator System</td>
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<td>Medtronic MiniMed 640G Insulin Pumps</td>
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<td>17/07/2015</td>
<td>Siemens e.cam Systems</td>
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<td>14/07/2015</td>
<td>Tumor Localization (TumorLOC) software application used on Philips PET/CT combination diagnostic imaging systems</td>
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<td>Artis systems with SW version VC14J</td>
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<tr>
<td>8/07/2015</td>
<td>iPlan RT Dose, versions 4.0 and 4.1 (including all subversions)</td>
<td>Medical Device</td>
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<td>8/07/2015</td>
<td>Milestone Wand STA Hand Piece model STA-5050-305</td>
<td>Medical Device</td>
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<tr>
<td>8/07/2015</td>
<td>Optional PS500 External Power Supply Unit used in connection with Dräger V Series Ventilators: Infinity V500; Babylog VN500; Evita V300</td>
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<td>Recall for Product Correction</td>
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</tr>
<tr>
<td>8/07/2015</td>
<td>Terry White Chemists Ibuprofen Children's Suspension Ibuprofen 20 mg/mL oral liquid bottle 200 mL</td>
<td>Medicine</td>
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<tr>
<td>7/07/2015</td>
<td>ACUSON S Family Ultrasound Systems utilising the 18L6 HD and/or 6C1 HD biopsy guidelines</td>
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<td>Recall for Product Correction</td>
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</table>

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<th>Recall Action Commencement Date¹</th>
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<th>Recall Action ClassificationⅤ</th>
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<td>ACUSON S1000, ACUSON S2000, or ACUSON S3000 Ultrasound Systems with software version VC30A, VC30B, VC30C, or VC31A</td>
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<td>Recall for Product Correction</td>
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<td>Medline procedure packs containing Unomedical Suction Tubing (Sterile and Non-sterile)</td>
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<td>ADVIA Chemistry Systems - Acetaminophen N-acetylcysteine (NAC). An in vitro diagnostic medical device (IVD).</td>
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<td>Recall for Product Correction</td>
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<tr>
<td>2/07/2015</td>
<td>Chemmart &amp; Pharmacy Choice Ibuprofen Children's Suspension 20mg/mL and Chemmart Children's Paracetamol 6 to12 years Concentrated 200mL 48mg/mL oral liquid bottles, Pack Size 200 mL</td>
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<tr>
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<td>Invivo Expression MRI Patient Monitoring System - Product 865214</td>
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<td>Recall Action Commencement Date</td>
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<td>30/06/2015</td>
<td>Neptune 2 Rovers</td>
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<td>Enbrel etanercept (re) 25 mg powder for injection vial plus diluent syringe</td>
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<tr>
<td>29/06/2015</td>
<td>Pull Reduction Device for Percutaneous Drill Guide 4.3mm (Supplied as part of the VA Distal Femur set)</td>
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<td>SERFAS 90° Energy Probe (90R Probe)</td>
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<td>Abutment Retrieval Instrument Zirconia CC RP/WP</td>
<td>Medical Device</td>
<td>Recall</td>
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<tr>
<td>26/06/2015</td>
<td>All Precision 500D Radiographic and Fluoroscopic (R&amp;F) Systems and Advantx Legacy/Legacy-D Radiographic and Fluoroscopic (R&amp;F) Systems</td>
<td>Medical Device</td>
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<td>i-STAT PT/INR Cartridges</td>
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<td>Single and dual LCD monitor suspensions used on Precision RXi fluoroscopic imaging systems</td>
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<td>Reusable Stripper and Cleaver Accessories used with Sureflex and Aura Laser Fibers</td>
<td>Medical Device</td>
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<td>cCrea A+B Membranes used with ABL800 series blood gas analyser range</td>
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<td>3M ESPE Lava Ultimate CAD/CAM Restorative</td>
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<tr>
<td>23/06/2015</td>
<td>Brainlab Cranial Navigation System (all versions before Cranial 3.0)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>22/06/2015</td>
<td>Artis zee and Artis zeego systems used in conjunction with a triple focus x-ray tube assembly</td>
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<td>Barco Surgical Displays</td>
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<td>ARGON Bone Marrow I-type aspirate/biopsy needles &amp; ARGON Trap-Lok Bone Marrow biopsy needles</td>
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<tr>
<td>19/06/2015</td>
<td>Cook LapSac Surgical Tissue Pouch</td>
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<td>Drager Fabius MRI Anaesthesia Machine</td>
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<td>Lunderquist Extra-Stiff Wire Guide</td>
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<tr>
<td>19/06/2015</td>
<td>Medtronic MiniMed Sure-T infusion sets</td>
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<tr>
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<td>TOPCON – 3D Optical Coherence Tomography 3D OCT-1 MAESTRO machines</td>
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<td>16/06/2015</td>
<td>CEFOTAXIME CT 256 WW F100. An in vitro diagnostic medical device (IVD)</td>
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<td>Paclitaxel Suspension (Abraxane) 207.5mg in 0.9% Sodium Chloride</td>
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<td>Shen Neng Qianbai Biyan Pian - (A Rhinitis Treatment in Traditional Chinese Medicine)</td>
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<tr>
<td>28/05/2015</td>
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<tr>
<td>27/05/2015</td>
<td>LifeCycle for Prenatal Screening v4.0, v4.0 Rev 2 and v4.0 Rev 3. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>27/05/2015</td>
<td>ONCENTRA Brachy version 3.x and 4.x</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>27/05/2015</td>
<td>Surface Applicator Set with Leipzig-style Cone</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/05/2015</td>
<td>ADVIA Centaur TnI-Ultra</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>25/05/2015</td>
<td>Pulsar-35 and Pulsar-18 and peripheral self-expanding Nitinol stent systems (with stent length of 200 mm only)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/05/2015</td>
<td>Teflon Tube T2 Humerus, Sterile</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
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<td>Hospital</td>
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<td>22/05/2015</td>
<td>EPREX (Epoetin alfa) syringes</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>22/05/2015</td>
<td>EVOTECH Endoscope Cleaner and Reprocessor (ECR)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/05/2015</td>
<td>CareFusion - AVEA Ventilator</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>20/05/2015</td>
<td>Berichrom Protein C on Sysmex CA-1500, CA-7000, CS-2000i and CS-5100 instruments. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>20/05/2015</td>
<td>Dimension Vista 500 and 1500 Intelligent Lab System. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>20/05/2015</td>
<td>Philips Model AFFINITI 70 Ultrasound System Versions 1.0.2 or lower with Pediatric Cardiology option</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/05/2015</td>
<td>VITROS Immunodiagnostic Products NT-proBNP Assay. An in-vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/05/2015</td>
<td>Animas 2020 and Animas IR 1200 Insulin Pumps</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Consumer</td>
</tr>
<tr>
<td>18/05/2015</td>
<td>Apex 10mm reamer</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/05/2015</td>
<td>APO-Dipyridamole Aspirin 200mg/25mg capsules in bottles of 60s</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Wholesale</td>
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<tr>
<td>18/05/2015</td>
<td>CHISEL BLADES</td>
<td>Medical Device</td>
<td>Recall</td>
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<td>Hospital</td>
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<tr>
<td>18/05/2015</td>
<td>DuraDiagnost 3.0/4.0 X-ray system</td>
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<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>18/05/2015</td>
<td>Expression MRI Patient Monitoring System</td>
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<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>18/05/2015</td>
<td>PenAdapt</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/05/2015</td>
<td>TCAutomation / enGen Laboratory Automation Systems. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/05/2015</td>
<td>WIZARD2 Gamma Counters</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>15/05/2015</td>
<td>IntelePACS</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/05/2015</td>
<td>Manual Collimator Exchange system in use with an ADAC VERTEX Plus, CARDIO, SOLUS or VERTEX V60 imaging system</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/05/2015</td>
<td>Philips Model AFFINITI 70 Ultrasound System without Pediatric Cardiology option</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/05/2015</td>
<td>Philips Model EPIQ 7 Ultrasound System with Pediatric Cardiology option</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<td>15/05/2015</td>
<td>RAPIDLab 1260/1265 Systems. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/05/2015</td>
<td>High Strength Niuhuang Jiedu Tablets 60’s</td>
<td>Medicine</td>
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<td>Class II</td>
<td>Consumer</td>
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<tr>
<td>14/05/2015</td>
<td>Philips Model AFFINITI 50 Ultrasound System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>14/05/2015</td>
<td>Philips Model EPIQ 7 Ultrasound System without Paediatric Cardiology option</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/05/2015</td>
<td>ReMed devices used for Adaptive Servo-Ventilation (ASV) Therapy</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Consumer</td>
</tr>
<tr>
<td>13/05/2015</td>
<td>Cios Alpha mobile C-arm x-ray system</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/05/2015</td>
<td>Immulite 2000 and Immulite 2000 XPi – Italian Cypress Allergen</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/05/2015</td>
<td>Microtek Medical System Drapes used with da Vinci, da Vinci SI, da Vinci Si/S Systems</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/05/2015</td>
<td>Prius Hospital Bed</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/05/2015</td>
<td>Shiley Neonatal, Paediatric and Long Paediatric Tracheostomy Tube, Cuffless and with TaperGuard Cuff</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/05/2015</td>
<td>Trinder tests on Roche analysers – Hitachi 902, COBAS c111, COBAS c311/501/502/701/702 &amp; COBAS INTEGRA 400 plus/800. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>13/05/2015</td>
<td>ULTRA FAST-FIX Knot Pusher/Suture Cutter, Straight</td>
<td>Medical Device</td>
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<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>12/05/2015</td>
<td>Astral Ventilators</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Consumer</td>
</tr>
<tr>
<td>12/05/2015</td>
<td>Brainlab Navigation Software Spine &amp; Trauma 3D versions 2.0 /2.1 and Navigation Software Cranial / ENT version 2.1</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>12/05/2015</td>
<td>Diego Elite Tubesets</td>
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<td>Hospital</td>
</tr>
<tr>
<td>12/05/2015</td>
<td>Philips Model EPIQ 5 Ultrasound System Versions 1.3.2 or lower without Paediatric Cardiology option</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>12/05/2015</td>
<td>Philips Model EPIQ 5 Ultrasound System with Versions 1.3.2 or lower with Paediatric Cardiology option</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>11/05/2015</td>
<td>MRS Traverse Switch</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/05/2015</td>
<td>Medline Procedure Packs containing Covidien Devon Light Gloves</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/05/2015</td>
<td>Corpatch Easy Paediatric (defibrillator electrodes)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/05/2015</td>
<td>HeartWare HVAD System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>7/05/2015</td>
<td>Invacare Platinum Oxygen Concentrator</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Consumer</td>
</tr>
<tr>
<td>7/05/2015</td>
<td>Sekisui Diagnostics Acetaminophen Reagent. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>6/05/2015</td>
<td>Sapheon (Covidien) VenaSeal Closure System</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/05/2015</td>
<td>MV1031 Gram Crystal Violet 4L. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/05/2015</td>
<td>Remel PathoDx Strep Grouping Kit 60 Test containing Remel PathoDx Strep B Group Latex. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<td>5/05/2015</td>
<td>TFN-ADVANCED Proximal Femoral Nailing System (TFNA)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>4/05/2015</td>
<td>LP rotate, sizes 25-27 cat.1-6.</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>1/05/2015</td>
<td>VITEK2 AST-YS06 &amp; VITEK2 AST-YS07 Test Kits</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/05/2015</td>
<td>V-Sign Sensor</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>30/04/2015</td>
<td>OPTI Blood Gas analysers - An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>30/04/2015</td>
<td>Transwarmer Infant Transport Mattress</td>
<td>Medical Device</td>
<td>Recall</td>
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<td>Hospital</td>
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<tr>
<td>29/04/2015</td>
<td>Tavo ophthalmic Table</td>
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<td>Recall for Product Correction</td>
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<td>Hospital</td>
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### Recall for Australian Recall Actions

<table>
<thead>
<tr>
<th>Recall Action Commencement Date</th>
<th>Product Name/Description</th>
<th>Type of Product</th>
<th>Recall Action</th>
<th>Recall Action Classification</th>
<th>Recall Action Level</th>
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<tbody>
<tr>
<td>28/04/2015</td>
<td>Factor IX coagulation studies on the BCS / BCS XP Automated Blood Coagulation Analyser (Actin, Actin FSL and Pathromtin SL)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>27/04/2015</td>
<td>18F-Fludeoxyglucose Injection</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>27/04/2015</td>
<td>D-Fend/D-Fend+ water traps used with Compact Airway Modules E/M-C(Ai)O(V)(X) and Cardiocap/5 monitors</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>27/04/2015</td>
<td>Talon Grasping Device</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>24/04/2015</td>
<td>DBL Methotrexate 2.5mg tablets in bottles of 30</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>24/04/2015</td>
<td>Devon Light Glove</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>24/04/2015</td>
<td>Invacare TDX series and Storm Series power wheelchairs with 20&quot;-24&quot; width configurations with Formula CG Recline seating system (i.e. Tilt/Recline, Tilt/Recline/Elevate, or Recline only) and a conventional style back</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Consumer</td>
</tr>
<tr>
<td>24/04/2015</td>
<td>Philips Dameca Siesta i TS with an EGM software version lower than 4.0.8 / 7.0.8</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/04/2015</td>
<td>Thermablate Endometrial Ablation System (EAS)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/04/2015</td>
<td>Connecting Screw for Insertion of Dynamic Hip Screw (DHS) Blade</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/04/2015</td>
<td>Dimension Vista Systems LOCI Thyroid Stimulating Hormone. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/04/2015</td>
<td>Oscillating Saw Attachment for Colibri/Colibri II Small Electric Drive</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/04/2015</td>
<td>Siemens Ysio Max, Luminos dRF Max, Luminos Agile Max and Uroskop Omnia Max with software version VE10E</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/04/2015</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
</tbody>
</table>

The TGA publishes Australian recall actions in a searchable database to ensure the public has access to information about therapeutic products that have been recalled from the Australian market. If you are concerned about your health or if you have experienced an adverse event please seek advice from a health professional as soon as possible. Please read all the important information at the beginning of this report.
### System for Australian Recall Actions

<table>
<thead>
<tr>
<th>Recall Action Commencement Date</th>
<th>Product Name/Description</th>
<th>Type of Product</th>
<th>Recall Action</th>
<th>Recall Action Classification</th>
<th>Recall Action Level</th>
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<tbody>
<tr>
<td>22/04/2015</td>
<td>SonoSite PowerPark Dock and Stand Module(s) used with SonoSite Ultrasound Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/04/2015</td>
<td>Accu-Chek Spirit Combo insulin pump and Accu-Chek Spirit insulin pump. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Consumer</td>
</tr>
<tr>
<td>20/04/2015</td>
<td>Birmingham Hip Modular Head (BHMH)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/04/2015</td>
<td>Ki67-MM1 Bond Ready To Use, An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/04/2015</td>
<td>Philips Ultrasound QLAB versions 10.0 with a2DO and/or aCMQ plug-ins installed with Philips Xcelera software</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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<tr>
<td>17/04/2015</td>
<td>Amylase Assay used with ADVIA Chemistry Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/04/2015</td>
<td>Counterfeit Durex branded condoms purchased from Groupon website</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Consumer</td>
</tr>
<tr>
<td>17/04/2015</td>
<td>Different Brands of Pantoprazole Tablets in Blisters of 30’s.</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>17/04/2015</td>
<td>Intuitive Surgical Inc. da Vinci Xi Surgical System Patient Cart Arms</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/04/2015</td>
<td>LEMTRADA (alemtuzumab) 10mg/mL injection concentrated vial</td>
<td>Medicine</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/04/2015</td>
<td>Magellan Robotic System (Catheter controller steering unit)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/04/2015</td>
<td>Harris Oxygen Flowmeter</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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</tr>
<tr>
<td>14/04/2015</td>
<td>Dako Beta-2-Microglobulin PET Kits. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
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<td>Hospital</td>
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<tr>
<td>14/04/2015</td>
<td>Karl Storz Tissue Morcellation System</td>
<td>Medical Device</td>
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</tr>
<tr>
<td>14/04/2015</td>
<td>VITROS Chemistry Systems. An in vitro diagnostic medical device (IVD).</td>
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<td>Recall for Product Correction</td>
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</tr>
<tr>
<td>13/04/2015</td>
<td>Bard Max-Core Disposable Core Biopsy Instrument</td>
<td>Medical Device</td>
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<tr>
<td>13/04/2015</td>
<td>enGen Laboratory Automation Systems. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>13/04/2015</td>
<td>ID-LISS/Coombs Cards. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Recall Action Commencement Date</th>
<th>Product Name/Description</th>
<th>Type of Product</th>
<th>Recall Action</th>
<th>Recall Action Classification</th>
<th>Recall Action Level</th>
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<tbody>
<tr>
<td>13/04/2015</td>
<td>STERIS Caviwave Pro Ultrasonic Cleaning System</td>
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<tr>
<td>10/04/2015</td>
<td>Baxter Irrigation solutions</td>
<td>Medical Device</td>
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<tr>
<td>10/04/2015</td>
<td>Dianee peritoneal dialysis solutions</td>
<td>Medicine</td>
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</tr>
<tr>
<td>10/04/2015</td>
<td>Easyvision Umere Daily Contact Lenses (-6.50)</td>
<td>Medical Device</td>
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<td>Class II</td>
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<tr>
<td>10/04/2015</td>
<td>KARMA Corneal Inlay</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>8/04/2015</td>
<td>Curam Duo Forte 875mg/125mg Tablets 10 strip</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>7/04/2015</td>
<td>18F-Fludeoxyglucose Injection</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<td>2/04/2015</td>
<td>Aegis Standing Sling - Lift, patient transfer, sling/harness/strap</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>2/04/2015</td>
<td>Nobel Replace Conical Connection PMC RP 5.0x13mm</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
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<tr>
<td>1/04/2015</td>
<td>CIDEX OPA Solution Test Strips</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
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<tr>
<td>1/04/2015</td>
<td>Uninterruptible Power Supply (UPS) supplied with Philips Computed Tomography / Advanced Molecular Imaging Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>31/03/2015</td>
<td>Alaris System PC Unit model 8015</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>31/03/2015</td>
<td>Cross-Link Clamp for Rods, 6.0 mm</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>31/03/2015</td>
<td>Edwards Fem-Flex II Femoral Arterial Cannula, sizes 8, 10 &amp; 12 French</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>30/03/2015</td>
<td>CBCII AMBULATING BULB (PK10), 1/8 TROCAR W/DRAIN (PK10), 1/4 TROCAR W/DRAIN (PK10)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>30/03/2015</td>
<td>KA351 - My Mobility Walking Frame with Front Wheels, Large, Aluminium, APO Grey, and</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>27/03/2015</td>
<td>Angular Stable Locking System (ASLS), 5.0 mm, Resorbable (Used with Synthes cannulated titanium intramedullary nails)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>27/03/2015</td>
<td>Bard ConQuest PTA Balloon Dilatation Catheter</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>27/03/2015</td>
<td>Capta Malaria EIA</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>27/03/2015</td>
<td>da Vinci Si EndoWrist One Vessel Sealer and da Vinci Xi EndoWrist Vessel Sealer</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>27/03/2015</td>
<td>Radiometer immunoassay AQT90FLEX Analyser</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>26/03/2015</td>
<td>ADVIA Chemistry Systems Lipase Assay</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/03/2015</td>
<td>Trellis 6 and Trellis 8 Peripheral Infusion System</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>25/03/2015</td>
<td>GE MRI Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>24/03/2015</td>
<td>LCS COMPLETE RPS Knee System</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/03/2015</td>
<td>AngioDynamics Morpheus Smart PICC CT (Central venous catheters)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/03/2015</td>
<td>Hydrophilic Acrylic Single Use Intraocular Lens system packs</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
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<tr>
<td>20/03/2015</td>
<td>FX CorDiax High-Flux dialysers and FX CorDiax Haemodiafilters</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/03/2015</td>
<td>Artis Q/Q.zen systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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<tr>
<td>19/03/2015</td>
<td>Catalys Precision Laser System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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<tr>
<td>19/03/2015</td>
<td>Divercleanse 750ml</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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<td>19/03/2015</td>
<td>Hemodialysis Monitor</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>19/03/2015</td>
<td>Model 5392 Dual-Chamber External Pulse Generator</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/03/2015</td>
<td>RaySearch RayStation 3.5, RayStation 4.0, RayStation 4.5, and RayStation 4.7 (Radiation therapy treatment planning system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/03/2015</td>
<td>Persona Trabecular Metal Tibial Plate, all sizes</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/03/2015</td>
<td>Cobas c 501 / c 502 and COBAS INTEGRA. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tbody>
<tr>
<td>17/03/2015</td>
<td>METAL SHELL, CEM.LESS 'DeltaLox' SCREW FIX., TiNb-COAT (Acetabular shell component used for hip replacement)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/03/2015</td>
<td>Aiming Arm 125deg and Aiming Arm 130deg for TFN-ADVANCED (TFNA) System</td>
<td>Medical Device</td>
<td>Recall</td>
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<td>Hospital</td>
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<tr>
<td>16/03/2015</td>
<td>Patient Specific Radiopharmaceuticals</td>
<td>Medicine</td>
<td>Recall</td>
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<tr>
<td>13/03/2015</td>
<td>Access 2 Immunoassay Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/03/2015</td>
<td>Brilliance CT 64-channel with Essence technology, Brilliance iCT, Brilliance iCT SP, Ingenuity Core, Ingenuity Core128, Ingenuity Elite and Ingenuity CT</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>13/03/2015</td>
<td>EXACTRAC 6.x (Image Guided Radiation Therapy Patient Positioning System)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/03/2015</td>
<td>Remote controls for JUPITER, ARTIS and TruSystem 7500 operating tables</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/03/2015</td>
<td>VITROS 5.1 FS Chemistry Systems using Software Version 2.8 &amp; Below. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>12/03/2015</td>
<td>Getinge 46-Series Washer Disinfector with PACS 300/350</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>12/03/2015</td>
<td>IMMULITE 2000/IMMULITE 2000 XPi water and liquid waste bottles</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>12/03/2015</td>
<td>Kenex ceiling-suspended radiation shields and surgical lamps</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
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<tr>
<td>11/03/2015</td>
<td>Inserter f/TEN</td>
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<tr>
<td>11/03/2015</td>
<td>Q Vax Skin Test</td>
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<tr>
<td>6/03/2015</td>
<td>Dostinex (cabergoline), Cabaser (cabergoline) &amp; Methoblastin (methotrexate) - All Batches</td>
<td>Medicine</td>
<td>Recall for Product Correction</td>
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<tr>
<td>6/03/2015</td>
<td>ONLINE DAT Cannabinoids II / 100 tests / 200 tests</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
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<tr>
<td>6/03/2015</td>
<td>Signature Orthopadics' Logical Ceramic Liner (for use with hip replacement systems)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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<tr>
<td>6/03/2015</td>
<td>Sonidet – Medical Equipment &amp; Instrument Detergent</td>
<td>Medical Device</td>
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<td>Class II</td>
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<tr>
<td>5/03/2015</td>
<td>DePuy Synthes Trauma DHS/DCS Impactor Tip</td>
<td>Medical Device</td>
<td>Recall</td>
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<tr>
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<td>5/03/2015</td>
<td>HALCION (triazolam) &amp; PONSTAN (mefenamic acid) &amp; XANAX (alprazolam) - All Batches</td>
<td>Medicine</td>
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</tr>
<tr>
<td>5/03/2015</td>
<td>Self-Righting Luer Slip Tip Cap, Yellow in the DISC PAC packaging</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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</tr>
<tr>
<td>3/03/2015</td>
<td>AQUAPAK BRITISH and INTL 340 SW, 340 ML W/040B Humidifier Adaptors</td>
<td>Medical Device</td>
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<tr>
<td>3/03/2015</td>
<td>Edwards Lifesciences Heart Reference Sensor</td>
<td>Medical Device</td>
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<tr>
<td>2/03/2015</td>
<td>Cure Sleeve (a dental barrier sleeve for curing light to prevent cross contamination)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>2/03/2015</td>
<td>PVC TUBING X-RAY (includes an x-ray detectable line and is used for securing the perfusion lines during cardiopulmonary bypass)</td>
<td>Medical Device</td>
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<tr>
<td>27/02/2015</td>
<td>ARCHITECT Anti-HBc II Reagent Kit. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
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<tr>
<td>26/02/2015</td>
<td>BD Q-Syte Luer Access Split Septum Device</td>
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<td>26/02/2015</td>
<td>SANDEL Weighted Safety Scalpels</td>
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<td>25/02/2015</td>
<td>Bead Block (Embolic Bead)</td>
<td>Medical Device</td>
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<tr>
<td>25/02/2015</td>
<td>RT12 Tube Rotor-Kit (RT12) &amp; StatSpin MP Centrifuge (SSMP)</td>
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<td>Recall for Product Correction</td>
<td>Class II</td>
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<tr>
<td>24/02/2015</td>
<td>GENESIS II KNEE SYSTEM – Non Porous Tibial Base Plate</td>
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<td>Hazard Alert</td>
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<td>24/02/2015</td>
<td>LFIT V40 Femoral Head</td>
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<td>Hazard Alert</td>
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<td>Hospital</td>
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<tr>
<td>24/02/2015</td>
<td>Philips Anaesthesia Machines Siesta i Breasy, Siesta i Whispa, Dameca MRI 508, Siesta i TS &amp; IntelliSave AX700</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>24/02/2015</td>
<td>Triathlon Distal Capture Assembly</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>23/02/2015</td>
<td>GemLock Long Hex Driver</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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<tr>
<td>23/02/2015</td>
<td>Philips Anaesthesia Machines IntelliSave AX700, Dameca MRI 508, Siesta i Whispa, Siesta iTS &amp; Siesta Breasy</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>23/02/2015</td>
<td>XALKORI (crizotinib 200 mg and 250 mg) Capsules</td>
<td>Medicine</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
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<tr>
<td>Recall Action Commencement Date</td>
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<td>20/02/2015</td>
<td>Philips HeartStart MRx Monitor/Defibrillators</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>20/02/2015</td>
<td>ROPIVACAINE PFIZER Solution for Injection 400 mg/200 mL and 200 mg/100 mL bags</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>19/02/2015</td>
<td>Intuitive Harmonic ACE Instruments (used with the da Vinci Standard, S, and Si Surgical Systems)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>18/02/2015</td>
<td>IMMULITE 2000 and IMMULITE 2000 XPi - GI-MA (CA 19-9) Positive Bias. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/02/2015</td>
<td>LiNA Xcise Laparoscopic Morcellator</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/02/2015</td>
<td>T2100 and T2000 Treadmill power cords</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/02/2015</td>
<td>VITEK 2 system version 7.0.1. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/02/2015</td>
<td>5mm and 8mm Harmonic ACE Instruments IFU (for use with 5mm Harmonic ACE instruments (PNs 400274 and 400275)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/02/2015</td>
<td>AQUARIUS Regional Citrate Anticoagulation (RCA) Hemofiltration Device</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/02/2015</td>
<td>Medicina Orange Enteral Feeding Pump (MD-OP900)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/02/2015</td>
<td>Radiometer ABL90Flex analysers running V3.1MR1 or below</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/02/2015</td>
<td>Allura Xper R7.2.x (Fluoroscopic diagnostic x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/02/2015</td>
<td>CARIOHELP Perfusion System, Software versions prior to 3.4.6.0</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/02/2015</td>
<td>Elecsys CMV IgM assay (04784618190) - Diluent Universal. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/02/2015</td>
<td>PlasmaSORD</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/02/2015</td>
<td>Proteus XR/a X-ray imaging systems manufactured with wall stand model number 2260354.</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Recall Action Commencement Date</th>
<th>Product Name/Description</th>
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<th>Recall Action</th>
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</tr>
</thead>
<tbody>
<tr>
<td>4/02/2015</td>
<td>AK 200 S and AK 200 ULTRA S nocturnal home hemodialysis machines</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Consumer</td>
</tr>
<tr>
<td>4/02/2015</td>
<td>AKINETON, biperiden hydrochloride</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>4/02/2015</td>
<td>Colaspase 10iu in 1mL 0.9% Sodium Chloride</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/02/2015</td>
<td>VITEK 2 System version 7.01. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/02/2015</td>
<td>ADVIA Centaur Systems Progesterone Kits</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/02/2015</td>
<td>Birmingham Hip Resurfacing (BHR) System</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/02/2015</td>
<td>CDAS upgraded Intera MR systems equipped with the Basic Triggering Unit</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/02/2015</td>
<td>IntelliSpace Critical Care &amp; Anaesthesia Information Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/02/2015</td>
<td>SIM System with SIM dock power supply model Franmar FRA012-S05-I</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Retail</td>
</tr>
<tr>
<td>2/02/2015</td>
<td>Puritan Bennett 980 Series Ventilator System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/01/2015</td>
<td>Airlight ROM brace (An Orthosis that encompasses the knee joint)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/01/2015</td>
<td>CADD Medication Cassette Reservoir, 50ml</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/01/2015</td>
<td>DuraDiagnost X-ray System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/01/2015</td>
<td>NEO-MERCAZOLE, carbimazole, 5mg tablets</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>30/01/2015</td>
<td>Philips IntelliVue Information Center (PIIC) IX system (A Centralized Patient Monitoring System)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/01/2015</td>
<td>Siemens Capillary Caps for RAPIDLyte Multicap and Multicap-S Blood Collection Capillaries</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/01/2015</td>
<td>CS 8100 &amp; CS 8100 3D</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Retail</td>
</tr>
<tr>
<td>29/01/2015</td>
<td>DigitalDiagnost Release 4.0.0. and 4.0.1</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
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<th>Recall Action Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>29/01/2015</td>
<td>Medtronic Minimed 640G Infusion Pump used in clinical trials</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Consumer</td>
</tr>
<tr>
<td>29/01/2015</td>
<td>MultiDiagnost Eleva Flat Detector (FD) System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
</tr>
<tr>
<td>29/01/2015</td>
<td>MultiDiagnost Eleva II/TV Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
</tr>
<tr>
<td>29/01/2015</td>
<td>Various Sterile-Packaged Femoral Heads (Various sizes, neck lengths and taper sizes)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II Hospital</td>
</tr>
<tr>
<td>28/01/2015</td>
<td>ADVIA Chemistry Systems Drug Calibrator I for Phenytoin 2 and Phenobarbital 2 Assays. An in vitro Diagnostic Medical Device.</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Retail</td>
</tr>
<tr>
<td>28/01/2015</td>
<td>Brilliance iCT and Brilliance iCT SP with software versions 4.1.0.xxxxx, or 4.1.1.xxxxx, or 4.1.2.xxxxx</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
</tr>
<tr>
<td>23/01/2015</td>
<td>Brainlab Offset Cup Impactor Universal</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I Hospital</td>
</tr>
<tr>
<td>23/01/2015</td>
<td>InterStim &amp; InterStim II</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II Hospital</td>
</tr>
<tr>
<td>22/01/2015</td>
<td>Artis Dialysis System equipped with SW 8.15.06 and 8.33.02</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I Hospital</td>
</tr>
<tr>
<td>22/01/2015</td>
<td>FORUM Software</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I Retail</td>
</tr>
<tr>
<td>22/01/2015</td>
<td>MiniCap with Povidone-Iodine Solution</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I Consumer</td>
</tr>
<tr>
<td>22/01/2015</td>
<td>Xcela PICC with PASV Valve Technology/Kits, BioFlo PICC with Endexo and PASV Valve Technology/Kits</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II Hospital</td>
</tr>
<tr>
<td>20/01/2015</td>
<td>Aequalis Ascent Flex Reversed Cut Guide (Instrument for use in the implantation of joint prostheses)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II Wholesale</td>
</tr>
<tr>
<td>20/01/2015</td>
<td>Integra Mayfield Ultra 360 Base Unit</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
</tr>
<tr>
<td>20/01/2015</td>
<td>Medicina DS03 Silo Dressing 3.0mm – DS04 Silo Dressing 4.0mm – DS05 Silo Dressing 5.0mm – DS06 Silo Dressing 6.0mm</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II Hospital</td>
</tr>
<tr>
<td>20/01/2015</td>
<td>Medicina Keyhole Dressing KDXX</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II Hospital</td>
</tr>
<tr>
<td>20/01/2015</td>
<td>PharmAust 30ml Chlorhexidine in Ethanol 70% (Red Tint)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III Hospital</td>
</tr>
</tbody>
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<tbody>
<tr>
<td>20/01/2015</td>
<td>System 6 Aseptic Battery Kit</td>
</tr>
<tr>
<td>19/01/2015</td>
<td>ACUSON SC2000 ultrasound systems</td>
</tr>
<tr>
<td>19/01/2015</td>
<td>Medicina Low Profile Gastrostomy Button</td>
</tr>
<tr>
<td>19/01/2015</td>
<td>Medicina Nasogastric Plaster NS01 (Nasal Strip)</td>
</tr>
<tr>
<td>19/01/2015</td>
<td>Medicina SILOBAG</td>
</tr>
<tr>
<td>19/01/2015</td>
<td>PowerLED, Hied, Xten, Standop Volista, Hanaulux 3000 range - SA Ceiling Suspension</td>
</tr>
<tr>
<td>19/01/2015</td>
<td>Single Limb Circuit for Pneupac Ventilators, with PEEP Valve</td>
</tr>
<tr>
<td>16/01/2015</td>
<td>MEDPOR Barrier Sheets – Orbital Floor Implant 38mm X 50mm X 1.6mm</td>
</tr>
<tr>
<td>16/01/2015</td>
<td>SONY LMD-1951MD MONITORS</td>
</tr>
<tr>
<td>15/01/2015</td>
<td>Persona (TASP) Tibial Articular Surface Provisional Shim</td>
</tr>
<tr>
<td>15/01/2015</td>
<td>syngo.plaza</td>
</tr>
<tr>
<td>14/01/2015</td>
<td>Brilliance CT 16 Air, 64, Big Bore, iCT, iCT SP, Ingenuity CT, Ingenuity Core, Ingenuity Core128 and Ingenuity Flex</td>
</tr>
<tr>
<td>14/01/2015</td>
<td>Hand-held Barcode Scanner used with VITROS clinical chemistry systems. An in vitro diagnostic medical device (IVD).</td>
</tr>
<tr>
<td>9/01/2015</td>
<td>Maquet demonstration unit fiber-optic Intra-Aortic Balloon Catheter</td>
</tr>
<tr>
<td>7/01/2015</td>
<td>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</td>
</tr>
<tr>
<td>7/01/2015</td>
<td>HeartWare Controller</td>
</tr>
<tr>
<td>7/01/2015</td>
<td>Virazole (ribavirin powder for solution)</td>
</tr>
<tr>
<td>20/01/2015</td>
<td>Medical Device</td>
</tr>
<tr>
<td>19/01/2015</td>
<td>Medical Device</td>
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<tr>
<td>9/01/2015</td>
<td>Medical Device</td>
</tr>
<tr>
<td>7/01/2015</td>
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</tr>
</thead>
<tbody>
<tr>
<td>24/12/2014</td>
<td>Anti-dsDNA Kit. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/12/2014</td>
<td>Cheek Retractor, f/MATRIXMANDIBLE U-shaped, flexible</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/12/2014</td>
<td>Minor Plastics Pack IVF Australia</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/12/2014</td>
<td>Monaco (radiation therapy planning system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/12/2014</td>
<td>Radiometer ABL90Flex analysers running V3.1MR1 or below</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/12/2014</td>
<td>Bending/Cutting Pliers with Nose, for LOCK Plates 2.0</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/12/2014</td>
<td>Dimetapp Daytime/Nightime Liquid Caps capsule blister pack</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>23/12/2014</td>
<td>Enzymatic Creatinine, Cholesterol, Uric Acid, Lactate, and Lipase Assays</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/12/2014</td>
<td>Focal Release 4.80.00</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/12/2014</td>
<td>MEVATRON, PRIMUS, ONCOR and ARTISTE Digital Linear Accelerators</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/12/2014</td>
<td>NCL-L-CD15. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/12/2014</td>
<td>Affinis Inverse inlay ceramys &amp; Affinis Fracture ceramic heads (Total Shoulder System that is designed for treating shoulder conditions)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/12/2014</td>
<td>Basic Custom Procedure Pack</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/12/2014</td>
<td>PF4 IgG assay (Thrombophilia and coagulation inhibitor assay). An in vitro Diagnostic Medical Device (IVD).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/12/2014</td>
<td>RF enabled St. Jude Medical Ellipse, Fortify Assura, Unity Assura, and Quadra Assura Implantable Cardioverter Defibrillators (ICDs) and Assurity and Allure Pacemakers when used with Merlin@home RF Remote Monitoring Transmitter Model EX1150</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/12/2014</td>
<td>Sensei X Robotic Catheter System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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</table>

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<table>
<thead>
<tr>
<th>Recall Action Commencement Date</th>
<th>Product Name/Description</th>
<th>Type of Product</th>
<th>Recall Action</th>
<th>Recall Action Classification</th>
<th>Recall Action Level</th>
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<tbody>
<tr>
<td>19/12/2014</td>
<td>Trellis 8 Peripheral Infusion System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>19/12/2014</td>
<td>Triathlon Tibial Alignment Ankle Clamp EM</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/12/2014</td>
<td>EndoBarrier Gastrointestinal Liner with Delivery System</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/12/2014</td>
<td>Fluoron Gas Tamponade EasyGas SF6</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/12/2014</td>
<td>Jurnista 16 MG 14 Tablets</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>18/12/2014</td>
<td>LENTIS HydroSmart Foldable Intraocular Lenses in Glass Vials</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>18/12/2014</td>
<td>Puritan Bennett 980 Series Ventilator System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>17/12/2014</td>
<td>Saw Palmetto 4600</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>16/12/2014</td>
<td>Alere Actim Partus. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/12/2014</td>
<td>Captia Malaria EIA (An in vitro Diagnostic Medical Device (IVD))</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/12/2014</td>
<td>Depuy Synthes Trauma RIA (Reamer/Irrigator/Aspirator) system</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>15/12/2014</td>
<td>Cartia LOW DOSE ASPIRIN 100mg tablet blister 7’s pack</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>15/12/2014</td>
<td>Ysio Max. Luminos dRF Max and Luminos Agile Max (with software version VE10 including SmarthOrtho license)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/12/2014</td>
<td>AQT90Flex Tnl (troponin) Test Kit. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/12/2014</td>
<td>Artis Q and Artis Q.zen Ceiling Systems (Fluoroscopic angiographic x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>12/12/2014</td>
<td>Artis Zeego Systems (Fluoroscopic angiographic x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>12/12/2014</td>
<td>HemosIL PT-Fibrinogen HS PLUS, An in-vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>12/12/2014</td>
<td>Proteus XR/a X-ray Imaging Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>Recall Action Commencement Date</td>
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<tr>
<td>11/12/2014</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/12/2014</td>
<td>Phadia 1000 Instrument (Allergy testing system). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/12/2014</td>
<td>Alere INRatio &amp; INRatio2 PT/INR Monitor System. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Consumer</td>
</tr>
<tr>
<td>10/12/2014</td>
<td>Eon Mini Implantable Pulse Generator (IPG) Model 65-3788 and Eon Mini Charging System Model 3/21</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/12/2014</td>
<td>Eon/Eon C/ Eon Mini/ Prodigy Neurostimulation Systems and Octrode/ Quattrode Percutaneous Leads and Accessories</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/12/2014</td>
<td>Philips M1783A and M5526A 12 Pin Sync Cables</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/12/2014</td>
<td>QIAsymphony DSP Virus/Pathogen Midi Kit. An in vitro Diagnostic Medical Device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/12/2014</td>
<td>Philips HeartStart MRx Monitor/Defibrillator</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/12/2014</td>
<td>Synthes Small Electric Drive Hand Piece (Drill Surgical System)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/12/2014</td>
<td>Humeral broaches Aequalis (6/6.5 diameter)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/12/2014</td>
<td>Philips HeartStart MRx Monitor/Defibrillators</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/12/2014</td>
<td>Philips HeartStart MRx Monitor/Defibrillator</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/12/2014</td>
<td>Trilogy Bone Screws – 6.5mm X 35mm &amp; 6.5mm X 25mm</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/12/2014</td>
<td>Defibrillation Electrode for Children (Leonhard Lang) used with GE defibrillators</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/12/2014</td>
<td>DRX Revolution Mobile X-Ray System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
</tbody>
</table>
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### System for Australian Recall Actions

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<th>Recall Action Level</th>
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<tbody>
<tr>
<td>27/11/2014</td>
<td>Philips Ultrasound Q-Station 3.0 with a2DQ and/or aCMQ Q-Apps</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>26/11/2014</td>
<td>Iron Plus Capsules</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Wholesale</td>
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<td>26/11/2014</td>
<td>KimVent Microcuff Subglottic Suctioning Endotracheal Tube, 7.0 mm, 7.5 mm, 8.0 mm, 8.5 mm &amp; 9.0 mm</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/11/2014</td>
<td>PF Saline Nasal Spray 30ml</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>24/11/2014</td>
<td>syngo Imaging XS and syngo.plaza (Radiology picture archiving and communication system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/11/2014</td>
<td>Biograph mCT and Biograph mCT Flow systems running VG50A software and equipped with the Adaptive 3D Intervention option</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>21/11/2014</td>
<td>Esprit V1000 and Esprit/V200 Conversion Ventilator</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/11/2014</td>
<td>IMMULITE 2000 and IMMULITE 2000 XPi</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/11/2014</td>
<td>LIAISON Borrelia IgG. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/11/2014</td>
<td>McGrath MAC Video Laryngoscope Blade Size #2</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>21/11/2014</td>
<td>Pico 70 Arterial Blood sampler</td>
<td>Medical Device</td>
<td>Recall</td>
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<tr>
<td>21/11/2014</td>
<td>Silane (dentine adhesive)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
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<tr>
<td>21/11/2014</td>
<td>Sunrise Medical Sunlift Hoist</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>20/11/2014</td>
<td>BrightView XCT SPECT/CT systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>Hospital</td>
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<tr>
<td>20/11/2014</td>
<td>HomeChoice PRO Automated PD System Automated PD System Devices</td>
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<td>Hospital</td>
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<tr>
<td>19/11/2014</td>
<td>3f Enable Aortic Bioprosthesis - Model 8000</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
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<td>Hospital</td>
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<td>18/11/2014</td>
<td>Boston Scientific AUTOGEN DR Implantable Cardioverter-Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>18/11/2014</td>
<td>DePuy Synthes ATTUNE Intuition Distal Femoral Jig</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>14/11/2014</td>
<td>AlignRT patient positioning/tracking video camera system</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>Recall Action Commencement Date</td>
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<td>14/11/2014</td>
<td>CareLink Clinical Therapy Management Software</td>
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<td>Class II</td>
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<tr>
<td>14/11/2014</td>
<td>Rocket IPC Drainage Bottle (A collection device used to collect fluid or air from the pleural cavity)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/11/2014</td>
<td>Alcon INFINITI Ultrasound PAKs - INFINITI Microsmooth Tapered Kelman 30°</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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</tr>
<tr>
<td>13/11/2014</td>
<td>Alere Determine HIV-1/2 Ag/Ab Combo (an in vitro diagnostic medical device)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>13/11/2014</td>
<td>Liquid Specific Protein (LSP) Calibrator. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/11/2014</td>
<td>Revaclear and Revaclear Max Dialysers (Hollow-fibre haemodialysis dialyser)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>13/11/2014</td>
<td>Stellaris PC with Laser System (Cataract extraction/vitrectomy system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>12/11/2014</td>
<td>ArthroCare Corporation HipVac 50 Coblation Wand</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>12/11/2014</td>
<td>Horse Blood Agar. An in vitro Diagnostic Medical Device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
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<tr>
<td>11/11/2014</td>
<td>cCrea A+B Membrane Unit for use on the ABL800 series blood gas analyser range</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>11/11/2014</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>10/11/2014</td>
<td>HemoCue Glucose 201 Microcuvettes single packed</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>7/11/2014</td>
<td>Dimension Vista 500 Intelligent Lab System &amp; Dimension Vista 1500 Intelligent Lab System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>7/11/2014</td>
<td>Gelflex Sterile Eye Wash Normal Saline 10mL Ampoule</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
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<tr>
<td>7/11/2014</td>
<td>STERIS 5085 and 5085SRT Surgical Table</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
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<tr>
<td>4/11/2014</td>
<td>Endo Wrist One Vessel Sealer (INS-410322) for the da Vinci Si (IS3000) Surgical System</td>
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<td>4/11/2014</td>
<td>MammoDiagnost DR</td>
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<tr>
<td>31/10/2014</td>
<td>Anaerobic Agar Plate. An in vitro diagnostic medical device (IVD)</td>
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<td>31/10/2014</td>
<td>Hamilton Active Family SPF 50+ 225mL</td>
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<tr>
<td>31/10/2014</td>
<td>Relief ACP Oral Care Gel supplied separately and in Zm CH 25% Kits</td>
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<tr>
<td>30/10/2014</td>
<td>Mindray V-Series Patient Monitors with 12-lead ECG interpretation capabilities</td>
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<tr>
<td>30/10/2014</td>
<td>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</td>
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<tr>
<td>30/10/2014</td>
<td>Panorama Central Station, software versions 10.0 to 11.3 and patient Monitoring Network</td>
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<tr>
<td>29/10/2014</td>
<td>AFB III Staining Kit (An in vitro diagnostic medical device (IVD))</td>
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<tr>
<td>29/10/2014</td>
<td>Philips IntelliVue Patient Monitors and Philips Avalon Fetal Monitors</td>
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<tr>
<td>29/10/2014</td>
<td>TORISEL temsirolimus 25 mg concentrate for injection vial and diluent vial composite pack</td>
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<tr>
<td>29/10/2014</td>
<td>Zimmer NexGen Trabecular Metal Tibial (Replacement) Impactor Pad Instruments</td>
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<tr>
<td>28/10/2014</td>
<td>Thermo Scientific MAS CardiOImmune XL</td>
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<tr>
<td>28/10/2014</td>
<td>ThermoCool SmartTouch Catheter Family (used to facilitate electrophysiological mapping of the heart and to undertake RF ablations)</td>
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<tr>
<td>24/10/2014</td>
<td>E-Z Gas II Effervescent Granules Antacid/Antiflatulent 4g packet</td>
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<tr>
<td>24/10/2014</td>
<td>Zovirax (aciclovir) Ophthalmic Ointment 30mg/g</td>
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<tr>
<td>23/10/2014</td>
<td>AVS PL SPACER (Used as an aid in spinal fixation)</td>
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<table>
<thead>
<tr>
<th>Type of Product</th>
<th>Recall Action</th>
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<th>Recall Action Level</th>
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<tbody>
<tr>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>Hospital</td>
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<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>Hospital</td>
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### Recall for Australian Recall Actions

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<tbody>
<tr>
<td>23/10/2014</td>
<td>Burinex (Bumetanide) Injection 2mg/4mL (Pack of 5 ampoules)</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/10/2014</td>
<td>Symbia S and T Series camera systems (SPECT/CT nuclear medicine diagnostic imaging system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/10/2014</td>
<td>Thiglycollate Broth 5mL, An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/10/2014</td>
<td>APC Plus Victory Series Twin Upper Left Cuspid -3T/10A with Distal Hook (Unitek Orthodontic Metal Brackets - Orthodontic bracket, metal)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>21/10/2014</td>
<td>IMMULITE, IMMULITE 1000, IMMULITE 2000 and IMMULITE 2000 XPi - Calcitonin Control Module</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/10/2014</td>
<td>50mm Left Standard Ti Mandible</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>17/10/2014</td>
<td>Artis zeego systems with a C - arm (Fluoroscopic X-ray systems)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/10/2014</td>
<td>Sapphire Administration IV Set AP424 (Patient Controlled Analgesia IV set for use with the Sapphire infusion pump)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/10/2014</td>
<td>Surveyor S12 and Surveyor S19 Patient Monitors</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>17/10/2014</td>
<td>UNIVERSAL Modular Electric/Battery Double Trigger Handpiece (Surgical power tool)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/10/2014</td>
<td>ADVIA Centaur and ADVIA Centaur XP (An in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/10/2014</td>
<td>Dimetapp Saline Nasal Drops for Infants</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>14/10/2014</td>
<td>Edwards Lifesciences Vent Catheter</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/10/2014</td>
<td>Leksell Gamma Knife Perfexion (teletherapy device indicated for stereotactic irradiation of head structures)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/10/2014</td>
<td>0.9% Sodium Chloride for Irrigation 2000ml and Water for Irrigation 2000ml</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/10/2014</td>
<td>Allura Xper Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/10/2014</td>
<td>Hudson Nebuliser Adaptor - AQUAPAK</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
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</tr>
</thead>
<tbody>
<tr>
<td>10/10/2014</td>
<td>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</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>10/10/2014</td>
<td>MultiDiagnost Eleva with Flat Detector Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>10/10/2014</td>
<td>PHILIPS MX 16-slice CT System, software: v1.1.3.1167; v1.1.4.21425; v1.1.4.21424; v1.1.4.21422</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>10/10/2014</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>10/10/2014</td>
<td>Sodium Chloride For Injection – MS 0.9% W/V, 50 X 5ML Ampoules</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class I</td>
</tr>
<tr>
<td>9/10/2014</td>
<td>Puritan Bennett 980 Series Ventilator System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>9/10/2014</td>
<td>Selector Tubing Kit for use with CUSA Selector Ultrasonic Aspirators</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>8/10/2014</td>
<td>ADVIA Centaur, ADVIA Centaur XP and ADVIA Centaur CP - BNP Ready Pack Lot 038174</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>8/10/2014</td>
<td>Multiple ProcedurePak Trays with Ecolab-Microtek Medical Basin Liners</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>8/10/2014</td>
<td>Puritan Bennett 980 Series Ventilator System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
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<tr>
<td>7/10/2014</td>
<td>Abbott RealTime Assay Application CD-ROM</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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<tr>
<td>7/10/2014</td>
<td>Calibrator E used for calibration of the ADVIA Centaur Systems Cortisol, Progesterone and Testosterone assays</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
</tr>
<tr>
<td>7/10/2014</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
</tbody>
</table>

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<tr>
<td>7/10/2014</td>
<td>IMRIS Operating Room table (ORT300)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>3/10/2014</td>
<td>AMPLITUDE Orthopaedic Surgical Instruments</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>3/10/2014</td>
<td>Lifemed Urinary Drainage Bag with Pump</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/10/2014</td>
<td>OEC 9800, OEC UroView 2800, OEC MiniView 6800, OEC FlexiView 8800 (mobile fluoroscopic x-ray diagnostic system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>2/10/2014</td>
<td>CLINITEK Status, CLINITEK Status+, and CLINITEK Status Connect Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>2/10/2014</td>
<td>COLGATE TOTAL ORIGINAL toothpaste tube 220g</td>
<td>Medicine</td>
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<td>Class III</td>
<td>Consumer</td>
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<tr>
<td>1/10/2014</td>
<td>Accu-Chek Spirit Combo Insulin Pumps</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Consumer</td>
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<td>1/10/2014</td>
<td>Autostainer Link 48, AS480</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>1/10/2014</td>
<td>Proclear Toric Soft Hydrophilic Contact Lenses</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
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<tr>
<td>1/10/2014</td>
<td>Trident Acetabular System Hemispherical Surgical Protocol &amp; Product Reference Guide</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>30/09/2014</td>
<td>Panbio Q Fever IgM ELISA (An in vitro diagnostic medical device (IVD))</td>
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<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>26/09/2014</td>
<td>MENINGITEC meningococcal serogroup C conjugate vaccine suspension for injection pre-filled syringe</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
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<tr>
<td>26/09/2014</td>
<td>Multiple Models of GE Nuclear Medicine Systems:</td>
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<td>Recall for Product Correction</td>
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<tr>
<td>26/09/2014</td>
<td>Persona Distal Valgus Alignment Guide (supplied as part of the reusable surgical kit)</td>
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<td>Recall for Product Correction</td>
<td>Class II</td>
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<td>26/09/2014</td>
<td>Zimmer Persona Tibial Articular Surface Provisional (TASP) Instruments</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/09/2014</td>
<td>Aeroneb Pro and Solo Nebuliser Systems - FRISO power adapter</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
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</tr>
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<td>25/09/2014</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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<td>25/09/2014</td>
<td>Covidien Medi-Trace Cadence Defibrillation Electrodes</td>
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<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>25/09/2014</td>
<td>Dimension Vista Hemoglobin A1c Flex Reagent Cartridge. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>25/09/2014</td>
<td>Stereotaxic Biopsy Device used with Mammmomat Inspiration Mammmography System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/09/2014</td>
<td>BOC Medical Grade Compressed Air supplied in Size D Cylinders</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/09/2014</td>
<td>Expression Information Portal - IP5 (secondary display control unit for Expression MRI patient monitoring system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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<tr>
<td>24/09/2014</td>
<td>Grifols Australia Perfect Panel cells</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>24/09/2014</td>
<td>IMMULITE/IMMULITE 1000 - Cortisol Assay - An in vitro diagnostic medical device (IVD)</td>
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<td>Recall</td>
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<td>Hospital</td>
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<td>22/09/2014</td>
<td>AcrySoF CACHET PHAKIC Lens</td>
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<td>Hazard Alert</td>
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<td>22/09/2014</td>
<td>Codman Neuro EDS 3 CSF External Drainage Systems</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/09/2014</td>
<td>COGNIS Implantable Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) and TELIGEN DR &amp; VR Implantable Cardioverter-Defibrillators (ICDs)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/09/2014</td>
<td>Premise Universal Restorative Body Syringe and Unidose, Shade A2</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
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<td>19/09/2014</td>
<td>SwitchPoint Infinity 3 - SPI3</td>
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<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/09/2014</td>
<td>Aeroneb Pro/Solo Nebuliser Systems FRIWO power adapter</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/09/2014</td>
<td>m24sp Instrument System (sample extraction system). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
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<td>18/09/2014</td>
<td>Safo Talaris Tibial Impactor</td>
<td>Medical Device</td>
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<td>17/09/2014</td>
<td>ADVIA Centaur/Centaur XP/Centaur CP Systems Hbc Total (Hbct) Assay</td>
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<tr>
<td>17/09/2014</td>
<td>VITROS 4600 Chemistry Systems &amp; VITROS 5600 Integrated Systems Using Software Version 3.0</td>
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<tr>
<td>16/09/2014</td>
<td>ADVIA Centaur Cleaning Solution. An in vitro diagnostic medical device (IVD).</td>
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<tr>
<td>16/09/2014</td>
<td>NaCl, Enzyme Test and Cold Agglutinins</td>
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<td>16/09/2014</td>
<td>VIDAS Anti HBs Total II. An in vitro Diagnostic Medical Device (IVD)</td>
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<td>15/09/2014</td>
<td>942-073, D8088_Crea A, D8089_Crea B Membranes used on the ABL827 blood gas analyser. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
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<td>15/09/2014</td>
<td>Defibrillator/pacer SLIM corpse3</td>
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<td>Class I</td>
<td>Retail</td>
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<td>15/09/2014</td>
<td>Human IgG4 Kit Immage Kit</td>
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<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/09/2014</td>
<td>Optional PS500 External Power Supply Unit Used in connection with Dräger V Series Ventilators</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>15/09/2014</td>
<td>Puritan Bennett 840 Ventilator</td>
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<td>Recall for Product Correction</td>
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<tr>
<td>15/09/2014</td>
<td>Ysio Max, Luminos dRF Max, Luminos Agile Max, Uroskop Omnia Max with software version VE10A to VE10C</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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<td>12/09/2014</td>
<td>Dade Innovin Reagent. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
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<td>12/09/2014</td>
<td>Phenocell A 3%. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>11/09/2014</td>
<td>IntelliSpace Portal, software versions 5.0.0, 5.0.1, 5.0.2, 6.0.0, 6.0.1, 6.0.2</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>10/09/2014</td>
<td>DePuy Charnley Pin Retractor &amp; Handle Set (orthopaedic hip joint replacement instrument)</td>
<td>Medical Device</td>
<td>Recall</td>
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</tr>
<tr>
<td>Recall Action Commencement Date</td>
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<tr>
<td>9/09/2014</td>
<td>Babytherm 8004/8010 and Babytherm 8000WB for newborns (Infant warmers and open infant care units)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
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</tr>
<tr>
<td>9/09/2014</td>
<td>Pinnacle3, software versions 9.0, 9.2, 9.4, 9.6 (Radiation Treatment Planning System)</td>
<td>Medical Device</td>
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<tr>
<td>5/09/2014</td>
<td>MobileDiagnost wDR (Mobile digital x-ray imaging system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>5/09/2014</td>
<td>Phenocell A 3%. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>Hospital</td>
</tr>
<tr>
<td>5/09/2014</td>
<td>Spectra Optia Apheresis System with Software Version 11</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
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<tr>
<td>5/09/2014</td>
<td>Ysio Systems with fixed detector in the wall stand, software version VC10 (Diagnostic digital x-ray system)</td>
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</tr>
<tr>
<td>4/09/2014</td>
<td>Horizon Cardiology Hemo – versions 13.0 and 13.1 (cardiology/cath lab information management system)</td>
<td>Medical Device</td>
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</tr>
<tr>
<td>3/09/2014</td>
<td>Scherbak Weights – 400 gr and 800 gr (used with Scherbak vaginal speculum)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/09/2014</td>
<td>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)</td>
<td>Medical Device</td>
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<tr>
<td>2/09/2014</td>
<td>IntelliSpace PACS 4.4 (Radiology picture archiving and communication system)</td>
<td>Medical Device</td>
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<tr>
<td>2/09/2014</td>
<td>Intuitive Surgical Battery Box of the da Vinci STM and da Vinci SiTM Surgical Systems</td>
<td>Medical Device</td>
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<tr>
<td>1/09/2014</td>
<td>ZOLL ProPadz Sterile Multi-Function Electrodes</td>
<td>Medical Device</td>
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<tr>
<td>29/08/2014</td>
<td>4D Integrated Treatment Console (4DITC) Version: 10 and 11 (Used for accurate treatment delivery by monitoring linear accelerator parameters)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>29/08/2014</td>
<td>Bard DuaLok Breast Lesion Localization Wire</td>
<td>Medical Device</td>
<td>Recall</td>
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<tr>
<td>29/08/2014</td>
<td>Cortex Screw Ø 3.5 mm, self-tapping, length 28 mm, Stainless Steel</td>
<td>Medical Device</td>
<td>Recall</td>
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<td>Hospital</td>
</tr>
<tr>
<td>29/08/2014</td>
<td>Maintenance Solution Amino Acid 4% + Heparin, TE &amp; Zinc</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
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</tr>
</tbody>
</table>
### System for Australian Recall Actions

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<thead>
<tr>
<th>Recall Action Commencement Date</th>
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</thead>
<tbody>
<tr>
<td>29/08/2014</td>
<td>Patient Data Module (PDM) Used with CARESCAPE Monitor B850, B650, or B450 (Multiparameter Patient Monitor)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>29/08/2014</td>
<td>VSMs transesophageal transducer (used for ultrasound imaging)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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</tr>
<tr>
<td>27/08/2014</td>
<td>CLAW and CLAW II Plates (An internal fixation device for the stabilisation of fractured bones and/or bone fragments)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
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<td>Hospital</td>
</tr>
<tr>
<td>27/08/2014</td>
<td>DePuy S-ROM Noiles Rotating Hinge Femur with Pin</td>
<td>Medical Device</td>
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<tr>
<td>27/08/2014</td>
<td>Spectra Optia Apheresis System - Return Line Air Detector (RLAD)</td>
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<td>Recall for Product Correction</td>
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<td>26/08/2014</td>
<td>Omrix Pressure Regulator (Surgical air pipeline regulator)</td>
<td>Medical Device</td>
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<td>Class I</td>
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</tr>
<tr>
<td>22/08/2014</td>
<td>ADVIA Centaur and ADVIA Centaur XP Immunoassay Systems. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>Hospital</td>
</tr>
<tr>
<td>22/08/2014</td>
<td>CentraLink Data Management System V14 (Analyser software for in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>Hospital</td>
</tr>
<tr>
<td>22/08/2014</td>
<td>Precise Treatment Table (A patient treatment support and positioning table for radiation therapy and simulation use.)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>Hospital</td>
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<tr>
<td>22/08/2014</td>
<td>Test Tube Heater - Power Supply Unit</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/08/2014</td>
<td>Vapotherm Disposable Patient Circuit System (Delivers high flow humidified gases via a nasal cannula or other patient interface)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>21/08/2014</td>
<td>Haemoglobin A1c (HbA1c) Flex Reagent Cartridge (An in vitro diagnostic medical device (IVD) used with Dimension Vista Systems)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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<tr>
<td>21/08/2014</td>
<td>Luminos dRF and Luminos dRF Max systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>21/08/2014</td>
<td>TOPPER Xtra Absorbent Dressing Pads, Sterile</td>
<td>Medical Device</td>
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<td>20/08/2014</td>
<td>ADVIA Centaur &amp; ADVIA Centaur XP Immunoassay System (An in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>20/08/2014</td>
<td>Neoflow Flow Sensor and Neoflow Insert</td>
<td>Medical Device</td>
<td>Recall</td>
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<tr>
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<td>20/08/2014</td>
<td>Tegris OR Table Control (Operating room device management system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>18/08/2014</td>
<td>Herculite Ultra</td>
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<td>18/08/2014</td>
<td>HS66 Turbo LTSF Steriliser</td>
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<td>18/08/2014</td>
<td>OXYGEN Sterile Protection</td>
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<td>18/08/2014</td>
<td>Philips HeartStart FR3, software version 2.0 (Automated external defibrillator (AED))</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
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<tr>
<td>18/08/2014</td>
<td>St. Jude Medical Ellipse VR/DR Implantable Cardioverter Defibrillators (ICDs)</td>
<td>Medical Device</td>
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<tr>
<td>18/08/2014</td>
<td>Vanguard 360 Femoral Boss Reamer</td>
<td>Medical Device</td>
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<tr>
<td>14/08/2014</td>
<td>HeartWare Ventricular Assist System batteries</td>
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<tr>
<td>14/08/2014</td>
<td>Monaco and Focal (radiation treatment planning systems)</td>
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<td>14/08/2014</td>
<td>VELCADE (bortezomib) 3.5 mg powder for injection vial</td>
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<tr>
<td>11/08/2014</td>
<td>LIAISON Biotrin Parvovirus B19 IgM</td>
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<td>11/08/2014</td>
<td>Red Back Spider Antivenom 500U Injection Vial</td>
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<tr>
<td>8/08/2014</td>
<td>ADVIA Centaur CP – BNP</td>
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<td>Recall for Product Correction</td>
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<td>8/08/2014</td>
<td>BD Epicenter v6.20A (used in conjunction with Bruker MALDI BioTyper) An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>8/08/2014</td>
<td>Chemistry 1 Calibrator used on Dimension Vista Systems (Magnesium assay calibrator). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
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</tr>
<tr>
<td>8/08/2014</td>
<td>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 &amp; Video System Center (components or parts of endoscopes)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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</tr>
<tr>
<td>8/08/2014</td>
<td>STERIS 4085, 4085 SS and 4085 Feather Weight Leg Section (FLWS) Surgical tables</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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</tr>
</tbody>
</table>

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<tr>
<td>8/08/2014</td>
<td>Symbia T Series and Symbia Intevo Camera System (SPECT/CT diagnostic imaging system)</td>
<td>Medical Device</td>
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<td>8/08/2014</td>
<td>Transpac Monitoring Kits</td>
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<td>Bayer Elevit with Iodine Tablets</td>
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<td>5/08/2014</td>
<td>Ultrafilter U9000 (Used on Gambro Haemodialysis Delivery Systems.)</td>
<td>Medical Device</td>
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<td>Amoxicillin + clavulanic acid 20 &amp; 10 lg discs. An in vitro diagnostic medical device (IVD).</td>
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<td>E.CAM or Symbia E System: Rear Casters of the Collimator Cart</td>
<td>Medical Device</td>
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<td>BD BBL Vancomycin Screen Agar</td>
<td>Medical Device</td>
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<td>31/07/2014</td>
<td>Kodak DirectView DR 7500 (Diagnostic x-ray system)</td>
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<td>31/07/2014</td>
<td>Of Spiggle &amp; Theis PTFE Ventilation Tubes</td>
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<td>31/07/2014</td>
<td>Philips Ultrasound QLAB versions 10.0 and 10.1</td>
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<td>31/07/2014</td>
<td>T-PAL (Transforaminal Posterior Atraumatic Lumbar Cage System)</td>
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<td>30/07/2014</td>
<td>PRISMA, PRISMAFLEX, X-MARS and ADSORBA sets</td>
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<tr>
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<td>Surgical Instruments with flexible shafts</td>
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<tr>
<td>29/07/2014</td>
<td>Sysmex CS-2000i/CS-2100i/CS-5100 Automated blood coagulation analysers. An in vitro diagnostic medical device (IVD)</td>
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<tr>
<td>25/07/2014</td>
<td>Clinical Chemistry ICT Serum Calibrator. An in vitro diagnostic medical device (IVD)</td>
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<tr>
<td>25/07/2014</td>
<td>Discovery XR656 Wall Stand System (X-ray system)</td>
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<tr>
<td>25/07/2014</td>
<td>Expression IP5 Information Portal (Multiparameter patient monitor for use during MRI procedure)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/07/2014</td>
<td>Prinivil (Lisinopril)10mg and 20mg Tablets</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>24/07/2014</td>
<td>CHEMMART PHARMACY IBUPROFEN 200mg Soft Gel capsule blister pack (Pack sizes: 20s, 40s, IOOs)</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
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<tr>
<td>24/07/2014</td>
<td>Codman Certas Programmable Valves (Hydrocephalic valve)</td>
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<tr>
<td>24/07/2014</td>
<td>COSEAL Surgical Sealant 2ml and 4ml</td>
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<tr>
<td>24/07/2014</td>
<td>Panbio Q Fever IgM ELISA. An in vitro diagnostic medical device (IVD)</td>
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<tr>
<td>24/07/2014</td>
<td>VITROS Immunodiagnostic Products CA 19-9 Calibrators and Reagent Packs</td>
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<tr>
<td>22/07/2014</td>
<td>Allura Xper R8.2.0 (Fluoroscopic diagnostic x-ray system)</td>
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<tr>
<td>22/07/2014</td>
<td>Cooper Surgical TransWarmer Infant Transport Mattress (Produces heat through chemical reaction)</td>
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<tr>
<td>21/07/2014</td>
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<tr>
<td>18/07/2014</td>
<td>AVS ARIA Implant Inserter</td>
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<tr>
<td>18/07/2014</td>
<td>Injectomat Agilia Range (Std, MC &amp; TIVA), Volumat Agilia Range (Std &amp; MC)</td>
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<tr>
<td>18/07/2014</td>
<td>Philips Gel-E Donut and Squishon 2 (Gel filled Pillow)</td>
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<tr>
<td>18/07/2014</td>
<td>TXR-ME (Tri-Ex Extraction Balloon with Multiple Sizing)</td>
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<tr>
<td>16/07/2014</td>
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<tr>
<td>16/07/2014</td>
<td>Sonopet Console (Ultrasonic Surgical Aspirator System)</td>
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<tr>
<td>15/07/2014</td>
<td>Minstrel Patient Transfer Lift with Scale</td>
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<tr>
<td>15/07/2014</td>
<td>National Workplace First Aid Kit &amp; Sports &amp; Outdoors First Aid Kit</td>
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<tr>
<td>15/07/2014</td>
<td>Philips Ingenia 1.5T and 3.0T MR Systems</td>
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</tbody>
</table>

The TGA publishes Australian recall actions in a searchable database to ensure the public has access to information about therapeutic products that have been recalled from the Australian market. If you are concerned about your health or if you have experienced an adverse event please seek advice from a health professional as soon as possible. Please read all the important information at the beginning of this report.
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<th>Recall Action Commencement Date</th>
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<td>CARESCAPE respiratory modules E-sCO, E-sCOV, E-sCAIO, E-sCAIOV, E-sCAIOE, E-sCAIOVE &amp; the Airway Gas Option N-CAIO</td>
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<td>Artis Q and Artis Q zen systems (Fluoroscopic X-ray systems)</td>
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<tr>
<td>11/07/2014</td>
<td>Artis zee and Artis zeego systems</td>
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<tr>
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<td>5mL Reaction Vessels used with the m2000sp Instrument. An in vitro diagnostic medical device (IVD)</td>
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<td>10/07/2014</td>
<td>Specular Microscope SP-1P (non-invasive photographic microscope)</td>
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<td>MobileDiagnost wDR (digital x-ray system)</td>
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<td>9/07/2014</td>
<td>VITROS 3600 Immunodiagnostic Systems, VITROS 4600 Chemistry Systems &amp; VITROS 5600 Integrated Systems (Software Versions 3.0 &amp; below)</td>
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<td>8/07/2014</td>
<td>LED Single Bay Battery Charger, supplied with LED Headlight System</td>
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<tr>
<td>8/07/2014</td>
<td>RECLAIM Distal Stem with Taper Sleeve Protector (Press-fit hip femur prosthesis)</td>
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<tr>
<td>8/07/2014</td>
<td>TRIGEN INTERTAN Intramedullary Nail 13MM X 20CM 125D</td>
<td>Medical Device</td>
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<tr>
<td>7/07/2014</td>
<td>Bartels Herpes Simplex Virus Fluorescent Monoclonal Antibody Test. An in vitro diagnostic medical device (IVD).</td>
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<tr>
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<td>HOYA Corporation (PENTAX Medical) – Gas/Water Feeding Valve</td>
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<td>Recall for Product Correction</td>
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<tr>
<td>Recall Action Commencement Date</td>
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<tr>
<td>7/07/2014</td>
<td>Large Clip Applier for use with the da Vinci STM and da Vinci SiTM</td>
<td>Medical Device</td>
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<tr>
<td>7/07/2014</td>
<td>NexGen Complete Knee Solution MIS Total Knee Procedure Stemmed Tibial Component, Precoat</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
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</tr>
<tr>
<td>4/07/2014</td>
<td>3M ESPE Filtek Supreme XTE Flowable Restorative (Dental material)</td>
<td>Medical Device</td>
<td>Recall</td>
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<tr>
<td>4/07/2014</td>
<td>Affinity Four Birthing Bed</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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</tr>
<tr>
<td>4/07/2014</td>
<td>Cordis EMPIRA NC RX PTCA Dilatation Catheter (&quot;75RxxyyyN&quot;) and Cordis EMPIRA RX PTCA Dilatation Catheter (&quot;85RxxyyyS&quot;)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>4/07/2014</td>
<td>Horizon Cardiology Hemo1 – versions 12.2 HF4 and earlier</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>4/07/2014</td>
<td>InTouch Critical Care Bed</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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<tr>
<td>4/07/2014</td>
<td>qube Compact Monitor (Transportable multiparameter patient monitor)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/07/2014</td>
<td>Slide-in Plug Adaptor for Charger used with Haag Streit UK Perkins MKIII Tonometer</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>4/07/2014</td>
<td>Thioglycollate Medium (bacteria culture media). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
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<td>Hospital</td>
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<tr>
<td>3/07/2014</td>
<td>m24sp Instrument System (sample extraction system). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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</tr>
<tr>
<td>3/07/2014</td>
<td>Panthera-Puncher 9, An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>Hospital</td>
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<tr>
<td>2/07/2014</td>
<td>C-Series High Energy Linear Accelerator</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>Hospital</td>
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<tr>
<td>2/07/2014</td>
<td>RAPIDQC Complete Quality Control Material (QC reagent for use with blood gas instruments). An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>Hospital</td>
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<tr>
<td>1/07/2014</td>
<td>Lancet, Low Flow and Micro Flow</td>
<td>Medical Device</td>
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<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>30/06/2014</td>
<td>Damon TMA - Low Friction Archwire (orthodontic wire)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III Retail</td>
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<tr>
<td>30/06/2014</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
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<td>30/06/2014</td>
<td>MSA Hip System</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
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<td>27/06/2014</td>
<td>BrightView XCT and BrightView X- upgraded with the XCT Flat Panel Detector (Gamma camera)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>27/06/2014</td>
<td>Crepe Bandage 5cm x 1.5m</td>
<td>Medical Device</td>
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<td>Class II Hospital</td>
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<td>26/06/2014</td>
<td>Micro-Injection Pipettes for IVF procedures</td>
<td>Medical Device</td>
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<tr>
<td>25/06/2014</td>
<td>ACL Top Family of instruments (haemostasis testing systems). An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
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<td>25/06/2014</td>
<td>DX-D 100 Digital Radiography X-Ray System</td>
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<tr>
<td>24/06/2014</td>
<td>BOC Medical E.P. Grade Oxygen Compressed supplied in Size D Cylinders</td>
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<tr>
<td>24/06/2014</td>
<td>CARESCAPE Monitor B850, B650 or B450 Monitors with V2 software versions (Multiparameter patient monitors)</td>
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<td>24/06/2014</td>
<td>Skin Graft Knife Blades for use with Thackray Watson Cobbett and Braithwaite Skin Graft Knife (Pack of 10 blades)</td>
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<tr>
<td>23/06/2014</td>
<td>ACUSON S Family Ultrasound Systems with software versions VC25D, VC30A, VC30B</td>
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<tr>
<td>18/06/2014</td>
<td>BD FACSCanto 10 colour configuration (Cytometer). An in vitro diagnostic medical device (IVD)</td>
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<td>18/06/2014</td>
<td>HeartSine Technologies Pad-Pak/ Pedi-Pak (contains non-rechargeable battery and defibrillation electrodes for use with the HeartSine Samaritan PAD 350P and 500P Defibrillators)</td>
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<td>Muro 128 5% Ointment (Sodium Chloride Hypertonicity Ophthalmic Ointment, 5%) Tube 3.5g</td>
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<td>Axiom Artis and Artis Zee Systems with hand switch (Fluoroscopic angiographic X-ray system)</td>
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<td>Cortex Screw Ø 1.5 mm, self-tapping, length 8 mm (non-biodegradable orthopaedic bone screw)</td>
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<td>Medtronic Duet External Drainage and Monitoring System (Cerebrospinal fluid drainage system)</td>
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<td>SOLIRIS eculizumab (rmc) Concentrated Solution for Infusion 300mg/30mL</td>
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<tr>
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</tr>
<tr>
<td>6/06/2014</td>
<td>Alere Triage BNP Calibrator for Beckman Coulter</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/06/2014</td>
<td>Guide Wire diameter 3.2mm, length 400mm (Fixation nail guidewire)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/06/2014</td>
<td>Single-width Airway Module E-miniC and Extension Modules N-FC &amp; N-FCREC</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/06/2014</td>
<td>ADVIA Centaur, ADVIA Centaur XP and ADVIA Centaur CP - Troponin Ultra ReadyPack. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/06/2014</td>
<td>Digital Linear Accelerators of type ARTISTE, ONCOR and PRIMUS with Automatic Sequenced Treatment Delivery Option</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/06/2014</td>
<td>Fludeoxyglucose F18, sterile injectable solution, multidose vial</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/06/2014</td>
<td>Puritan Bennett 840 Ventilator</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/06/2014</td>
<td>MENTOR Gel Sizers (Sizer for mammary prosthesis)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/06/2014</td>
<td>AGA Medical Amplatzer Septal Occluder</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/06/2014</td>
<td>DCP 2.0, 7 holes, length 37 mm, Stainless Steel, Sterile (Non-biodegradable orthopaedic fixation plate)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/06/2014</td>
<td>HexaPOD evo RT Systems running iGUIDE 2.0.0 - 2.0.2 (used for accurate patient positioning within a radiation therapy treatment environment)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/06/2014</td>
<td>Horizon Medical Imaging products versions 4.5 up to and including 11.9 and McKesson Radiology 12.0 (Radiology picture archiving and communication system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/06/2014</td>
<td>RAPIDPoint 500 Measurement Cartridges. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/06/2014</td>
<td>Tytin Regular Set (Dental amalgam)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>3/06/2014</td>
<td>VTI Bayonet 20 MHz Doppler Probe (used for the intraoperative and transcutaneous critical evaluation of blood flow)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
</tbody>
</table>
### System for Australian Recall Actions

<table>
<thead>
<tr>
<th>Recall Action Commencement Date</th>
<th>Product Name/Description</th>
<th>Type of Product</th>
<th>Recall Action</th>
<th>Classification</th>
<th>Recall Action Level</th>
</tr>
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<tbody>
<tr>
<td>30/05/2014</td>
<td>5mm Round Fluted Bur</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td></td>
<td>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)</td>
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<tr>
<td>30/05/2014</td>
<td>Accu-Chek Spirit Combo insulin pump</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>30/05/2014</td>
<td>BBL Crystal Enteric/Nonfermenter ID Kit, An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/05/2014</td>
<td>Orbital Rim Plate 1.3, curved, 9 holes, Pure Titanium (Craniofacial fixation plate)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/05/2014</td>
<td>ACUSON S2000 and ACUSON S3000 Ultrasound Systems (software version VC25) or with HELX Evolution (software version VC30A)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>29/05/2014</td>
<td>CARESCAPE Monitor B650</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/05/2014</td>
<td>HAMILTON G5 / S1 ICU ventilators</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/05/2014</td>
<td>Hamilton Galileo Ventilator when used with Flexport Communication Interface Protocol version 1.2</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>28/05/2014</td>
<td>Accu-Chek Mobile Blood Glucose Meter</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Consumer</td>
</tr>
<tr>
<td>28/05/2014</td>
<td>Hamilton Medical G5 / S1 Ventilator, software versions between V2.00 and V2.31</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>27/05/2014</td>
<td>Disposable Ventstar 180cm Circuit (used in connection with the Drager Oxylog 2000 Transport Ventilator)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/05/2014</td>
<td>ThermoCool SF NAV Catheter Family</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/05/2014</td>
<td>Axium Neurostimulator Leads (MN20450-50AU, MN20450-50AU)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/05/2014</td>
<td>HYGROTON Chlorthalidone 25mg Tablets</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Wholesale</td>
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<tr>
<td>23/05/2014</td>
<td>SmartMonitor 2 Professional Series</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
</tbody>
</table>

The TGA publishes Australian recall actions in a searchable database to ensure the public has access to information about therapeutic products that have been recalled from the Australian market. If you are concerned about your health or if you have experienced an adverse event please seek advice from a health professional as soon as possible. Please read all the important information at the beginning of this report.
<table>
<thead>
<tr>
<th>Recall Action Commencement Date</th>
<th>Product Name/Description</th>
<th>Type of Product</th>
<th>Recall Action</th>
<th>Recall Action Classification</th>
<th>Recall Action Level</th>
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</thead>
<tbody>
<tr>
<td>23/05/2014</td>
<td>Tecnis CL Foldable Silicone IOL with OptiEdge Design</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/05/2014</td>
<td>Baxter Peritoneal Dialysis Transfer Sets, Titanium Adapters, Disconnect Caps and Clamshell</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/05/2014</td>
<td>Ingenia, Intera and Achieva MR Systems on software version R5.1.1 and R5.1.2</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/05/2014</td>
<td>Polyurethane Nasogastric Feeding Tube</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/05/2014</td>
<td>syngo Lab Data Manager, Middle-ware for use with in vitro diagnostic medical devices (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/05/2014</td>
<td>Synthes Trauma External Fixation System (Small, Medium, Distraction Osteogenesis (DO) Ring and Large)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/05/2014</td>
<td>Ultrasonic Transducer Kits used with the Access Family of Immunoassay Systems. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/05/2014</td>
<td>MGuard Prime Coronary Stent System Embolic Protective Stent (EPS)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/05/2014</td>
<td>Mobile Shower and Toilet Commode Aquatec Ocean VIP</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>20/05/2014</td>
<td>MobileDiagnost wDR (Mobile x-ray imaging system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/05/2014</td>
<td>MOSAIQ Versions 1.40 through 2.50, inclusive (Oncology information system used to manage workflows for treatment planning and delivery)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/05/2014</td>
<td>Nifehexal (Nifedipine) 20mg Tablets 60 Blister</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>20/05/2014</td>
<td>Tenor without scale (Mobile patient transfer lift)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/05/2014</td>
<td>Wireless Footswitch used in conjunction with AXIOM Arts, Artis Zee and Artis Q Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/05/2014</td>
<td>Ysio Systems (X-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/05/2014</td>
<td>Multiple Krill Oil Capsules Sponsored by Nature's Care</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
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<td>Recall Action</td>
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<tr>
<td>15/05/2014</td>
<td>Single-width Airway Module E-miniC and Extension Modules N-FC &amp; N-FCREC (used with Carescape Monitors B850, B650 and B450, S/5 modular monitors, Engstrom Carestation, Patient Monitor B30, S/5M and FML monitors)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/05/2014</td>
<td>ACUSON SC2000 Ultrasound Systems with Software Version 3.5 (VA35)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/05/2014</td>
<td>G7 Positioning Guide Rod &amp; G7 Positioning Guide Post</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/05/2014</td>
<td>Hill-Rom MC700 General Ward Bed</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Retail</td>
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<tr>
<td>13/05/2014</td>
<td>MAGNETOM Aera (Full Body MRI System)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/05/2014</td>
<td>MiniCap Extended Life PD Transfer Set with Twist Clamp (Peritoneal dialysis tubing set)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Consumer</td>
</tr>
<tr>
<td>12/05/2014</td>
<td>Intuitive Surgical Inc. – 5mm Curved Cannula for Single-Site Instruments for da Vinci Surgical Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/05/2014</td>
<td>MIBG I-131 Therapy Injection (metabolic benzylguanidine labelled as iodine- 131)</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/05/2014</td>
<td>ConMed MacroLyte Premie Dispersive Electrode</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/05/2014</td>
<td>PentaRay Nav Catheter (used for multiple electrode electrophysiological mapping of cardiac structures in the heart)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/05/2014</td>
<td>Sidhil Inspiration Cot</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/05/2014</td>
<td>Tension Band Pins (Internal fixation pins)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/05/2014</td>
<td>Flexi-Seal CONTROL Faecal Management System</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>8/05/2014</td>
<td>Model 5348 Single-Chamber External Pulse Generator</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/05/2014</td>
<td>Receptal System Liners and Canisters</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/05/2014</td>
<td>GLUMA Desensitizer Power Gel (Polymer based dental bonding agent)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>7/05/2014</td>
<td>PATH Thread Cup Adaptor</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
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<td>7/05/2014</td>
<td>Synapse Cardiovascular (CV) Client application, version 4.0.8 (Picture archiving and communication system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/05/2014</td>
<td>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</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>Hospital</td>
</tr>
<tr>
<td>6/05/2014</td>
<td>Lithium Ion Batteries, M4605A and M4607A for use with IntelliVue Patient Monitors</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>5/05/2014</td>
<td>Alere INRatio2 PT/INR Heparin Insensitive Test Strips</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/05/2014</td>
<td>FOLFusor SV 0.5mL/hr used for infusing patient specific compounded Fluorouracil (Fluorouracil compounded for treatment of cancer)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/05/2014</td>
<td>HeartWare Ventricular Assist System batteries</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/05/2014</td>
<td>Medtronic Navigation Sterile Devices (used in a variety of imaged guided, navigated surgical procedures)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/05/2014</td>
<td>Oxoid Antimicrobial Susceptibility Testing Penicillin (P1) Discs (an in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/04/2014</td>
<td>12 Instrument Sterilisation Tray (used for the Conquest Manual Instrument line)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/04/2014</td>
<td>ACUSON SC2000 Ultrasound Systems with software version 3.5 (VA35)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/04/2014</td>
<td>Compact Airway Modules E-CO, E-COV, E-COVX, E-CAIO, E-CAIOV &amp; 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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/04/2014</td>
<td>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))</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
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<td>Recall Action</td>
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<tr>
<td>29/04/2014</td>
<td>RaySearch RayStation, version 4.0.3 (Radiation therapy treatment planning system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>28/04/2014</td>
<td>Percutaneous Sheath Introducer Kits</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>28/04/2014</td>
<td>Philips HeartStart XL+ Defibrillator/Monitor</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>28/04/2014</td>
<td>SynFix-LR Surgical Implant Holder</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>Hospital</td>
</tr>
<tr>
<td>24/04/2014</td>
<td>Bond Ready-To-Use Primary Antibody Thyroglobulin (1D4) (An in vitro Diagnostic Medical Device (IVD))</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/04/2014</td>
<td>Brilliance CT 16, 64, Big Bore iCT, Ingenuity CT, Ingenuity Core, Ingenuity Core128, Ingenuity Flex</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/04/2014</td>
<td>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</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/04/2014</td>
<td>Corneo-scleral Disc (Normothermic)</td>
<td>Biological</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/04/2014</td>
<td>Craniomaxillofacial (CMF) Distraction System (modular family of internal distraction devices to lengthen the mandibular body and ramus)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/04/2014</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/04/2014</td>
<td>FUJIFILM FDR-1000AWS / FDR-2000AWS / FDR-3000AWS V5.1.0001-0007 with Biopsy unit (a component of FUJIFILM Digital Mammography System)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/04/2014</td>
<td>HexaPOD evo RT Couchtop (X-ray powered radiation therapy table)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/04/2014</td>
<td>Otto Bock A200 Power Wheelchair, SKIPPI and SKIPPI PLUS Power Wheelchairs</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>23/04/2014</td>
<td>Xyntha (morocrococ alfa) 500IU Dual Chamber Syringe</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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</tr>
<tr>
<td>17/04/2014</td>
<td>550 TxT Treatment Table used with PRIMUS, ONCOR and ARTISTE Digital Linear Accelerators (LINAC)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/04/2014</td>
<td>Accu-Chek Mobile Blood Glucose Monitoring System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>17/04/2014</td>
<td>ADVIA Centaur, ADVIA Centaur XP and ADVIA Centaur CP</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/04/2014</td>
<td>AQUIRE Data Management System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/04/2014</td>
<td>Colied-Tube INFUSOR System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/04/2014</td>
<td>FOLFusor SV 0.5 ml/hr</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/04/2014</td>
<td>IMPAX RIS 5.8 and higher (Picture archiving and communication system software)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/04/2014</td>
<td>Luminos dRF (Fluoroscopic diagnostic x-ray systems)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/04/2014</td>
<td>MDC PACS Release R2.x and IntelliSpace PACS DCX r3.x (Picture archiving and communication system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/04/2014</td>
<td>Mueller Hinton-HTM (culture media). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/04/2014</td>
<td>SOMATOM Emotion 6 / 16 Slice Configuration and SOMATOM Spirit/Spirit Power Systems (Full-body computed tomography (CT) diagnostic x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/04/2014</td>
<td>syngo Dynamics v9.5 with Sensis-syngo Dynamics Integration (Radiology picture archiving and communication system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/04/2014</td>
<td>Cochlear Baha Soft Tissue Gauge (included in the Cochlear Baha Attract surgical tool kit)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/04/2014</td>
<td>Panda iRes Warmers integrated with Nellcor SpO2</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/04/2014</td>
<td>Centricity PACS RA1000 Workstation versions 3.2 and higher (Picture archiving and communication system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/04/2014</td>
<td>ExacTrac 5.5.5 (Image guided radiation therapy patient positioning system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>14/04/2014</td>
<td>Infant Nasal CPAP Prongs and Bubble CPAP Starter Kits</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/04/2014</td>
<td>DigitalDiagnost (Digital X-ray System)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/04/2014</td>
<td>Extension Tubing in Refill Kits for use with Synchronomed pumps</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/04/2014</td>
<td>MEDRAD Continuum Infusion Pump</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/04/2014</td>
<td>Bayer CANESTEN clotrimazole thrush treatment 6 day cream 35g</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>10/04/2014</td>
<td>EverCross .035” OTW PTA Catheter (Balloon dilatation angioplasty catheter)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/04/2014</td>
<td>LenSx Laser System (used for femtosecond cataract surgery)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/04/2014</td>
<td>Edwards Lifesciences Fem-Flex II Cannulae</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/04/2014</td>
<td>Lipase Reagent (diagnostic good for the quantitation of lipase in human serum or plasma)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/04/2014</td>
<td>ACUSON X700 Ultrasound System with software versions 1.0.00, 1.0.01, 1.0.02, 1.1.00 or 1.1.02</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/04/2014</td>
<td>Cavafix (used for the catheterisation of vena cava)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/04/2014</td>
<td>Dynabeads HLA (Human Leucocyte Antigen) Class II (an in vitro diagnostic medical device)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/04/2014</td>
<td>Potassium 10mmol in 0.225% Sodium Chloride and 10% Glucose (500ml)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/04/2014</td>
<td>enGen Laboratory Automation Systems configured with Data Innovation, LLC Instrument Manager (IM) v8.06</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/04/2014</td>
<td>ICS G2 Clinical Access (used for acquiring 24-72 hours of standard patient waveforms for analysis)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/04/2014</td>
<td>Monitor AC2000 Spring Arm</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/04/2014</td>
<td>Philips Ingenuity Core128 with Software Version 3.5.5 (whole body Computed Tomograph (CT) x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>7/04/2014</td>
<td>VITROS Chemistry Products Specialty Diluent and VITROS Chemistry Products FS Diluent Pack 3</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/04/2014</td>
<td>FELDENE (piroxicam) 10mg Capsules Blister packs of 50s</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>4/04/2014</td>
<td>Kenex suspension arm with radiation shield and/or surgical lamp</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/04/2014</td>
<td>Pipeline Embolization Device and Alligator Retrieval Device</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/04/2014</td>
<td>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</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/04/2014</td>
<td>Discovery MR450, Discovery MR750, Optima MR450w, Optima MR 450w GEM, Discovery MR750w, and Discovery MR750w GEM products (Full body magnetic resonance imaging systems)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/04/2014</td>
<td>Fraxel Dual 1550/1927 Laser Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>2/04/2014</td>
<td>OEC 9900 Workstation Monitor Spring Arm Screws</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>2/04/2014</td>
<td>Technetium-99m Oxidronate HDP (Radioactive Dose prepared as a solution in a syringe for diagnostic imaging)</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/04/2014</td>
<td>ADAC Vertex Classic, Vertex Plus, Vertex V60 and Solus Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/04/2014</td>
<td>ARTIS Zeego (Fluoroscopic angiographic x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/04/2014</td>
<td>Mindray’s V Series Monitoring System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>31/03/2014</td>
<td>Alere Triage BNP Test for Beckman Coulter (intended to measure B-type Natriuretic Peptide levels)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>31/03/2014</td>
<td>Colleague Volumetric Infusion Pumps</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>28/03/2014</td>
<td>ADVIA Centaur Folate Assay</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>28/03/2014</td>
<td>LOVher Herbal Viagra</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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</tr>
<tr>
<td>27/03/2014</td>
<td>Datascope System 98/98XT, CS100/CS100i and CS300 Intra-Aortic Balloon Pumps (IABP)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>27/03/2014</td>
<td>Guide Wire Ø 3.2 mm, length 400 mm (used for the implantation of intramedullary nails)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/03/2014</td>
<td>DePuy S-ROM Nolles Rotating Hinge Femur with Pin (compatible with the MBT revision tibial tray)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/03/2014</td>
<td>IntelliSpace Portal with AutoSPECT Pro reconstruction application (image viewing system for diagnostic imaging, x-ray and computed tomography)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/03/2014</td>
<td>On-Board Imager (OBI) (used with linear accelerators for verification of correct patient position in relation to isocenter and verification of treatment fields)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/03/2014</td>
<td>Philips EPIQ 5 Ultrasound System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/03/2014</td>
<td>Philips EPIQ 7 Ultrasound System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/03/2014</td>
<td>Shape Arm Kit Left and Shape Arm Kit Right (Mounting/positioning system for flat panel monitors)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/03/2014</td>
<td>Cup Removal Instruments (Reusable surgical instrument used to remove an acetabular cup with minimal loss of bone)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Wholesale</td>
</tr>
<tr>
<td>24/03/2014</td>
<td>Threaded Reduction Tool, 2.4mm diameter, self-drilling, 78mm length, with Hexagonal coupling</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/03/2014</td>
<td>Expression Information Portal - IP5 (secondary display control unit for Expression MRI patient monitoring system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/03/2014</td>
<td>H LED and PowerLED Ambient Light Modules (Surgical light)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/03/2014</td>
<td>Stainless Steel Scissor, Universal Shear, Blue Handle</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/03/2014</td>
<td>Zoll X Series Defibrillators with system software version 02.10.02.00 or higher</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>18/03/2014</td>
<td>Dimension Vista Cyclosporine (CSA) Flex Reagent Cartridge and Dimension Vista Cyclosporine (CSAE) Flex Reagent Cartridge</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td></td>
</tr>
<tr>
<td>18/03/2014</td>
<td>Endo-Scrub2 Sheaths and Tubing Set</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td></td>
</tr>
<tr>
<td>18/03/2014</td>
<td>HOTLINE Fluid Warming Sets</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td></td>
</tr>
<tr>
<td>18/03/2014</td>
<td>Latex Test Lungs and Latex Rebreathing Bags</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td></td>
</tr>
<tr>
<td>17/03/2014</td>
<td>Natural-Knee II System with Metal-Backed Patella</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td></td>
</tr>
<tr>
<td>17/03/2014</td>
<td>Philips HeartStart Home and OnSite (HS1) Automated External Defibrillators</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td></td>
</tr>
<tr>
<td>17/03/2014</td>
<td>Symbia T and Symbia T2 Camera System (CT imaging system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td></td>
</tr>
<tr>
<td>17/03/2014</td>
<td>Teleflex Medical CAPIO Sutures</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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<tr>
<td>17/03/2014</td>
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The TGA publishes Australian recall actions in a searchable database to ensure the public has access to information about therapeutic products that have been recalled from the Australian market. If you are concerned about your health or if you have experienced an adverse event please seek advice from a health professional as soon as possible. Please read all the important information at the beginning of this report.
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<td>Recall</td>
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<td>Retail</td>
</tr>
<tr>
<td>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)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
</tbody>
</table>

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<thead>
<tr>
<th>Recall Action Commencement Date</th>
<th>Product Name/Description</th>
<th>Type of Product</th>
<th>Recall Action</th>
<th>Recall Action Classification</th>
<th>Recall Action Level</th>
</tr>
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<tbody>
<tr>
<td>24/01/2014</td>
<td>Puritan Bennett 840 Ventilator and 700 Series (740 and 760) Ventilators</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/01/2014</td>
<td>Activa PC, Activa RC and Activa SC Implantable Deep Brain Stimulators and RestoreUltra and RestoreSensor Implantable Spinal Cord Stimulators</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/01/2014</td>
<td>ACUSON SC2000 Ultrasound Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/01/2014</td>
<td>St. Jude Medical ICD/CRT-D devices programmed to a single VF detection zone with Merlin Programmer software version 17.2.2 rev. 0</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/01/2014</td>
<td>SynchroMed II Implantable Infusion Pump</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/01/2014</td>
<td>Vented Spike with Clearlink (fluid transfer set)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/01/2014</td>
<td>Anspach Short Carbide Cranial Cutting Burrs - 1.5 mm x 7.5 mm Cylindrical Carbide Drum used with Short Attachments</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/01/2014</td>
<td>Mosaic Porcine Aortic Bioprosthesis Model 305 and Medtronic Aortic Obtrators/Sizers and IOEA Charts</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/01/2014</td>
<td>Multiple Manual Pulmonary Resuscitators (Single Use)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/01/2014</td>
<td>Xia 3 Titanium Torque Wrench, Mantis Redux Torque Wrench &amp; Xia Torque Wrench (used for final tightening of the blocker on the head of the pedicle screw during posterior spinal fusion surgery)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/01/2014</td>
<td>BrightView SPECT, BrightView X and BrightView XCT (SPECT/CT diagnostic imaging system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/01/2014</td>
<td>Osteocalcin assay run on IMMULITE 2000 &amp; IMMULITE 2000 XPi analysers. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/01/2014</td>
<td>Sorin Perceval S Post-Dilation Catheter Size M (indicated for in situ post-dilation of the valve after implantation)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/01/2014</td>
<td>Elecsys HIV combi PT assay. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/01/2014</td>
<td>Kodak DirectView DR 7500 System with software version 5.3 (diagnostic x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>Recall Action Commencement Date</td>
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<tr>
<td>16/01/2014</td>
<td>Ceiling mounted rail systems for Liko Overhead Lifts</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Consumer</td>
</tr>
<tr>
<td>16/01/2014</td>
<td>Novocastra Liquid Mouse Monoclonal Antibody. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>16/01/2014</td>
<td>Oxoid Antimicrobial Susceptibility Discs with Vancomycin (VA30). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>15/01/2014</td>
<td>Magnetom Spectra 3.0 T System (MRI system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/01/2014</td>
<td>Thermo Scientific MAS Omni-IMMUNE PRO. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/01/2014</td>
<td>Desktop Pro R7.01 SP2 and Desktop Pro R4.2, R5.0, R5.1, R6.0, R6.1 (Linear accelerator system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/01/2014</td>
<td>Matrix Surgical Laparoscopic Spatula with Cable (Active endotherapy device)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/01/2014</td>
<td>Zymed Holter Converter (Cardiology information system designed for the collection and management of electrocardiography data)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/01/2014</td>
<td>Innova 3100, Innova 3100IQ and Innova 2100IQ Cardiovascular X-ray Imaging Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/01/2014</td>
<td>PET Discovery 600 and PET Discovery 690, with software versions pet_mict_plus.44 and pet_velocity.53 (Nuclear medicine diagnostic system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/01/2014</td>
<td>Precision RXI X-ray Imaging Systems equipped with LCD Video Monitor</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/01/2014</td>
<td>Integrity R1.1, R3.0 and R3.1(digital linear accelerator)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/01/2014</td>
<td>Oxford Advance only manufactured prior to July, 2010 (Prior to serial number 1007L0001)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>7/01/2014</td>
<td>CILAMOX Sugar Free (Amoxycillin) 250mg/5mL Syrup</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>3/01/2014</td>
<td>ACUSON SC2000 Ultrasound Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/01/2014</td>
<td>Journey BCS Knee Replacement System - Femoral Implant</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
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<td>recall_action</td>
<td>recall_action_classification</td>
<td>recall_action_level</td>
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</tr>
<tr>
<td>3/01/2014</td>
<td>Total IgE for use with Immulite, Immulite 1000, Immulite 2000, Immulite 2000 XPi analysers. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/12/2013</td>
<td>Citrate Activated Partial Thromboplastin Time (APTT) Cuvettes. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/12/2013</td>
<td>cobas 4800 PCR Media Kit, cobas 4800 PCR Urine Sample Kit and cobas PCR Female Swab Kit. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/12/2013</td>
<td>STERRAD 100S, STERRAD 50 and STERRAD NX Sterilisation Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/12/2013</td>
<td>Trident Tritanium Acetabular Window Trials Case</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/12/2013</td>
<td>Artis systems running software version VC21B in conjunction with a Large Display</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/12/2013</td>
<td>RAPIDLyte Arterial Blood Sampling Line Draw Syringes</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/12/2013</td>
<td>EVOTECH Endoscope Cleaner and Reprocessor (ECR)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/12/2013</td>
<td>Laparoscopic inserts with tube, 3.00mm</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/12/2013</td>
<td>Pregnancy Iron (30's)</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>19/12/2013</td>
<td>VITEK 2 System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/12/2013</td>
<td>Brilliance iCT with Software Version 4.1.0.19260</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>18/12/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/12/2013</td>
<td>SuperElastic NiTi Archwires (intended to provide force to the teeth to effect movement in order to alter their position)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>17/12/2013</td>
<td>CompoStop Flex 3F T&amp;B - 100/600/1300 - PLT Pooling - processing and leuko reduction system (Blood donor set)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/12/2013</td>
<td>Essenta DR X-ray System (Digital diagnostic X-Ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/12/2013</td>
<td>GEMINI TF 64 PET/CT Systems, software versions 3.5.1 and 3.5.2.1</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/12/2013</td>
<td>Philips Expression Information Portal (IP5) (secondary display control unit for the Expression MRI Patient Monitoring System)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/12/2013</td>
<td>Acuity Central Monitoring Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/12/2013</td>
<td>AQUERE Data Management System. Version 1.54. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/12/2013</td>
<td>BD BACTED FX - Top Unit and Bottom Unit (used to detect bacteria and fungi in clinical specimens)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/12/2013</td>
<td>KAMRA Corneal Inlay (inserted into the natural cornea to treat presbyopia ie, age related hyperopia (far sightedness))</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/12/2013</td>
<td>Optima XR 220amx, Optima XR200amx with Digital Upgrade Mobile X-ray Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/12/2013</td>
<td>APPESE 0.5 ropinirole (as hydrochloride) 0.5mg tablets</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Wholesale</td>
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<tr>
<td>11/12/2013</td>
<td>MEDRAD Veris MR Vital Signs Monitor</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<td>11/12/2013</td>
<td>SOMATOM CT System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>Recall Action Commencement Date</td>
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<td>10/12/2013</td>
<td>CEM Nosecone for use with CUSA Excel/Excel+ Ultrasonic Aspirator</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/12/2013</td>
<td>Eclipse Treatment Planning System, ARIA Radiation Oncology (treatment plan and image management application) and Acuity Radiation Therapy Simulator</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/12/2013</td>
<td>PLUM LifeCare 5000 Series and PLUM XL Family of Infusers</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/12/2013</td>
<td>DRX Revolution Mobile X-Ray System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>9/12/2013</td>
<td>Inflation bulbs used with Safescope Sigmoidoscopes</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/12/2013</td>
<td>Large and Mega Needle Driver Endowrist Instruments for da Vinci Surgical Systems</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/12/2013</td>
<td>Precision 500D, Legacy, Prestilix, Monitrol, RFX, SFX, Tilt-C, Prestige VH, Prestige SI, and Prestige SI (diagnostic fluoroscopic x-ray systems)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>6/12/2013</td>
<td>D-10 Dual Program Reorder Pack (used with D-10 Haemoglobin Testing System). An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>6/12/2013</td>
<td>Viscocel and Viscocel Plus (Hydomethylpropcellulose) 2% Prefilled Syringes 1.5mL and 2.0mL</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>5/12/2013</td>
<td>Dimension Vista Systems - Cyclosporine (CSA) Flex reagent cartridge. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>5/12/2013</td>
<td>Sorin Perfusion System - S5/C5 Heart Lung Machine</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/12/2013</td>
<td>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</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<td>Recall Action Commencement Date</td>
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<td>3/12/2013</td>
<td>Integrity, software version R1.1, 3.0, and R3.1 (Linear Accelerator)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<td>3/12/2013</td>
<td>SANGOFIX IV Administration Set and HEIDELBERG EXTENSION TUBING</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<td>3/12/2013</td>
<td>Volume Imaging System (XVI), software versions 4.2.1 (Electronic Imaging Device (EID) used with radiation therapy treatment)</td>
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<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>2/12/2013</td>
<td>Gemstar Docking Station (Used as an alternate power source for the GemStar infusion pumps and to charge a GemStar battery pack)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>2/12/2013</td>
<td>LH 750 and LH 780 Haematology System. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>2/12/2013</td>
<td>Slimming Factor (also known as Easy Trim, Que She and Chinese Herbal Diet Pills)</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class I</td>
<td>Consumer</td>
</tr>
<tr>
<td>2/12/2013</td>
<td>VITROS Mixing Cup Arrays on VITROS 250 Chemistry Systems &amp; VITROS 350 Chemistry Systems. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>2/12/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/11/2013</td>
<td>Children's Panadol 1-5 years Suspension (paracetamol 24mg/mL) Orange 100 ml and Strawberry 200 ml</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>29/11/2013</td>
<td>Instrument Star Unit ML (Calibration with ICM4) (part of Brainlab Spine &amp; Trauma Navigation System)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/11/2013</td>
<td>Leica M525 F50 Surgical Microscope with XY-Unit (surgical light microscope)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
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<tr>
<td>29/11/2013</td>
<td>Plum A+ Infusion Pump and Software Module</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
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</tr>
<tr>
<td>29/11/2013</td>
<td>UniCel DxH 600 &amp; 800 Coulter Cellular Analysis System. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
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</tr>
<tr>
<td>29/11/2013</td>
<td>XiO versions 4.50 and higher (Radiation therapy treatment planning system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td></td>
</tr>
<tr>
<td>28/11/2013</td>
<td>BrainLab Navigation Software Spine and Trauma 3D 2.0 (intra-operative image guided stereotactic localisation system to enable precision spine and trauma surgeries)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td></td>
</tr>
<tr>
<td>28/11/2013</td>
<td>Calibration Diskette and Assay Data Disks used with VITROS chemistry instruments. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td></td>
</tr>
<tr>
<td>28/11/2013</td>
<td>Monitor AC3000 Spring Arm (component of Draeger ceiling pendant and light systems)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td></td>
</tr>
<tr>
<td>27/11/2013</td>
<td>HT Connect Peripheral Guide Wires (used for percutaneous transluminal Angioplasty (PTA) in peripheral arteries)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
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</tr>
<tr>
<td>27/11/2013</td>
<td>Patient Data Module (PDM) used with B850, B650, B450, Solar 8000i, MacLab / ComboLab (Multifunction patient monitoring)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td></td>
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<tr>
<td>27/11/2013</td>
<td>Patient Side Manipulators - da Vinci S, Si, Si-e Surgical System (robotic surgical unit)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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</tr>
<tr>
<td>27/11/2013</td>
<td>PET Discovery 610 and Discovery 710 with software version pet_coreload.44 and pet_mfk.44</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
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<tr>
<td>26/11/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
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<tr>
<td>26/11/2013</td>
<td>Patient Data Module (PDM) used with B850, B650, B450, Solar 8000i and MacLab / ComboLab (multifunction patient monitor module)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
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<tr>
<td>26/11/2013</td>
<td>Sysmex Automated Blood Coagulation Analyzer CS-2100i and 2000i. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td></td>
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<td>Recall Action Commencement Date</td>
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<tr>
<td>26/11/2013</td>
<td>THUNDERBEAT TB Series Hand Instrument (used in general, laparoscopic and endoscopic surgeries)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/11/2013</td>
<td>Zimmer Periarticular Femoral Cond Buttress Plate and Zimmer Periarticular Distal Lateral Femoral Locking Plate</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>25/11/2013</td>
<td>Micro Well Shuttle Weight used in VITROS 3600 Immunodiagnostic Systems and VITROS 5600 Integrated Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>25/11/2013</td>
<td>Zimmer Trabecular Metal Reverse Shoulder System Glenosphere &amp; Base Plate (Total shoulder replacement prosthesis)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/11/2013</td>
<td>Children's Panadol (paracetamol 100mg/mL) Baby Drops Syringe</td>
<td>Medicine</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>22/11/2013</td>
<td>Modular Finishing Instrument Tray Assembly (used to store, transport and organise instrumentation for the Restoration Modular Instruments Set)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>22/11/2013</td>
<td>Oncaspar (Pegasparargase) 3750IU/5mL Injection Solution (Pack of 1 injection)</td>
<td>Medicine</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/11/2013</td>
<td>REPLY and ESPRIT Pacemakers interrogated using Orchestra and Orchestra Plus Programmers</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/11/2013</td>
<td>STERRAD 100NX (Gas Plasma Steriliser)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/11/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/11/2013</td>
<td>A-642100 fixed offset adaptor (used in external prosthesis)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/11/2013</td>
<td>LIKO SlingBar 350, SlingBar 360, SlingBar Wide 670 and SideBar Standard</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Consumer</td>
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<tr>
<td>21/11/2013</td>
<td>Medfusion 4000 Syringe Infusion Pump</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/11/2013</td>
<td>VITROS 3600, 4600, 5600, 5,1 FS Chemistry Systems, An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>21/11/2013</td>
<td>VITROS Chemistry Products K+ Slides. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/11/2013</td>
<td>Ceiling system for Artis Zee System (Fluoroscopic angiographic digital x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/11/2013</td>
<td>Gemstar Infusion System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>15/11/2013</td>
<td>Atrium Chest drains that contain an Autotransfusion (ATS) System access line (for re-infusion of autologous blood in post operative and trauma blood loss management)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/11/2013</td>
<td>Human IgM Kit for use on SPA Plus. An in vitro Diagnostic Medical Device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>15/11/2013</td>
<td>ONCASP AR (pegaspargase) injection, 750 IU/mL, 5mL vial</td>
<td>Medicine</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/11/2013</td>
<td>STERRAD Boosters and Adaptors (used in STERRAD NX steriliser and contains hydrogen peroxide sterilant)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/11/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/11/2013</td>
<td>Vessix Generator System (portable RF generator used with percutaneous angioplasty balloon catheter to deliver low frequency RF energy into the renal artery)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/11/2013</td>
<td>ZYM B, API Listeria and API NH (bacterial identification reagents and kits). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/11/2013</td>
<td>BFT II Analyser</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/11/2013</td>
<td>Infinity Acute Care System (IACS) Monitoring Solution (Patient monitoring system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
</tbody>
</table>

The TGA publishes Australian recall actions in a searchable database to ensure the public has access to information about therapeutic products that have been recalled from the Australian market. If you are concerned about your health or if you have experienced an adverse event please seek advice from a health professional as soon as possible. Please read all the important information at the beginning of this report.
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<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>12/11/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/11/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall</td>
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<td>Hospital</td>
</tr>
<tr>
<td>8/11/2013</td>
<td>ADAC ARGUS Gamma Camera Systems (Nuclear medicine system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/11/2013</td>
<td>Ansell Sandel Weighted Safety Scalpel</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/11/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/11/2013</td>
<td>Epidural Minipack Systems (Epidural anaesthesia kit)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/11/2013</td>
<td>Fresofol 1% MCT/LCT (propofol) 500mg/50mL Emulsion for Intravenous Injection/Infusion Pre-Filled Syringe</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/11/2013</td>
<td>Imigran Mk II sumatriptan 6mg/0.5mL (as succinate) Injection Syringe</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>8/11/2013</td>
<td>IN.PACT Amphirion Drug-Eluting Balloon (DEB) (used for percutaneous transluminal angioplasty of small peripheral arteries)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/11/2013</td>
<td>ONCASPAR (pegaspargase) injection, 750 IU/mL, 5mL vial</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/11/2013</td>
<td>Teflon Tube T2 Humerus, Sterile (Intended to support the exchange of the Ball Tip Guide Wires for Smooth Tip Guide Wires for nail insertion)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/11/2013</td>
<td>Welch Allyn Propaq LT / Propaq 802 with Nellcor SpO2 (multifunction patient monitor)</td>
<td>Medical Device</td>
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<tr>
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<tr>
<td>6/11/2013</td>
<td>ABL90 FLEX Analyser. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/11/2013</td>
<td>Clinac, Trilogy, Trilogy Tx, Novalis Tx and Unique accelerators, software versions 7.x, 8.x and 9.0. (Linear accelerator system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
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</tr>
<tr>
<td>6/11/2013</td>
<td>PDM module with Frame F5-01 used with CARESCAPE Monitor B850</td>
<td>Medical Device</td>
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</tr>
<tr>
<td>4/11/2013</td>
<td>ClinActiv and ClinActiv Plus Therapy Surface (used to provide pressure relief to aid in the prevention and treatment of pressure ulcers)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>1/11/2013</td>
<td>AxSYM Valproic Acid Reagent (An in vitro diagnostic medical device IVD)</td>
<td>Medical Device</td>
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<td>1/11/2013</td>
<td>Homechoice Pro APD System (peritoneal dialyser)</td>
<td>Medical Device</td>
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<td>Consumer</td>
</tr>
<tr>
<td>1/11/2013</td>
<td>i-STAT PT/INR Cartridge (prothrombin time test used for monitoring patients receiving oral anticoagulation therapy) (An in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall</td>
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<tr>
<td>1/11/2013</td>
<td>Weinmann Medumat Transport Ventilator</td>
<td>Medical Device</td>
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<tr>
<td>31/10/2013</td>
<td>CARESCAPE Monitor B850 (with software versions 1.0.12 and earlier) and CARESCAPE Monitor B650 (with software version 1.1.12 and earlier)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>31/10/2013</td>
<td>MIBGen - Iobenguane [I-123] Injection 2mL and 4mL</td>
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<tr>
<td>30/10/2013</td>
<td>E.cam and Symbia E systems (diagnostic nuclear medicine imaging system)</td>
<td>Medical Device</td>
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<td>30/10/2013</td>
<td>KABIVEN G 19% 1540mL injection bag</td>
<td>Medicine</td>
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<tr>
<td>30/10/2013</td>
<td>TRUEtrack and TRUEbalance Blood Glucose Monitoring Systems</td>
<td>Medical Device</td>
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<td>Consumer</td>
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<tr>
<td>29/10/2013</td>
<td>MDC PACS R2.3 SP2 HF6 and MDC PACS R2.3 SP2 HF7 (Picture, archiving and communication system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>28/10/2013</td>
<td>Vygon Nutrisafe Syringe Feeding Pumps</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
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<tr>
<td>25/10/2013</td>
<td>Luminos dRF and Uroskop Omnia systems with Software Version VD10</td>
<td>Medical Device</td>
<td>Recall Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>25/10/2013</td>
<td>OCTREOTIDE SUN octreotide (as acetate) solution for injection ampoule</td>
<td>Medicine</td>
<td>Recall Correction</td>
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<tr>
<td>25/10/2013</td>
<td>Panbio Barmah Forest Virus IgM ELISA (An in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall Correction</td>
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<tr>
<td>25/10/2013</td>
<td>RayStation 3.0, 3.5, or 4.0 (Radiation therapy treatment planning system)</td>
<td>Medical Device</td>
<td>Recall Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/10/2013</td>
<td>Reliance Endoscope Processing System (EPS) used with FUJINON G5 and G8 Type Flexible GI Endoscopes</td>
<td>Medical Device</td>
<td>Recall Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>25/10/2013</td>
<td>Star Excimer Laser System (used to surgically correct visual refractive error in corneal surgery)</td>
<td>Medical Device</td>
<td>Recall Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/10/2013</td>
<td>SynReam Medullary Reamer Head Ø 8.5 mm (part of the Adolescent Lateral Femoral Nail and SynReam Reaming System Instrument Trays)</td>
<td>Medical Device</td>
<td>Recall Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/10/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/10/2013</td>
<td>Basin Liner within Molnlycke ProcedurePak (surgical procedure packs)</td>
<td>Medical Device</td>
<td>Recall Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/10/2013</td>
<td>CEDIA Tobramycin II Assay (used for quantitative determination of tobramycin in human serum or plasma) (an in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/10/2013</td>
<td>Inzii 12/15mm Retrieval System (used as a receptacle for the collection and extraction of tissues, organs and calculi during laparoscopic procedures)</td>
<td>Medical Device</td>
<td>Recall Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/10/2013</td>
<td>Novacell Battery Charger supplied with the BLS-1000 Light Source set (light source for endoscopic procedures)</td>
<td>Medical Device</td>
<td>Recall Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/10/2013</td>
<td>Trinica Ratchet Handles (included in the Anterior Lumbar Plate (ALP) Instrument Tray)</td>
<td>Medical Device</td>
<td>Recall Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/10/2013</td>
<td>Vivid E9 with Software versions 112.1.0, 112.1.1, and 112.1.3</td>
<td>Medical Device</td>
<td>Recall Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>23/10/2013</td>
<td>Aequalis Reversed II and Reversed Fracture Impactors</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td></td>
<td>(supplied as part of Aequalis Reversed II and Reversed Fracture Instrument sets, YKAD83 &amp; YKAD95)</td>
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</tr>
<tr>
<td>23/10/2013</td>
<td>Brivo CT315/325, Brivo CT385, Optima CT520 and Optima CT540 (all configurations)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/10/2013</td>
<td>ATTAIN HYBRID Guide Wires (used to aid the placement of Medtronic transvenous left ventricular leads in the coronary vasculature)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/10/2013</td>
<td>EPIQ 7 Diagnostic Ultrasound System (software version 1.0, 1.0.1)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/10/2013</td>
<td>OPTEASE Retrievable Vena Cava Filter</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/10/2013</td>
<td>Transradial Artery Access Kits</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/10/2013</td>
<td>Getinge 46-Series Washer Disinfector with PACS 300 module</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>21/10/2013</td>
<td>Straight Adjustable Gastric Band</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/10/2013</td>
<td>GSI Viewer, prior to version 2.00-0M on AW and prior to version 2.20-0B in AW Server</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td></td>
<td>(Picture archiving and communication system, PACS)</td>
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<tr>
<td>17/10/2013</td>
<td>IntelliSpace PACS 4.4 (Picture archiving and communication system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/10/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/10/2013</td>
<td>Optimys Opening Broach Bent (Reusable surgical instrument used for opening the medullary canal)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/10/2013</td>
<td>Crocodile Size 3 Walker (walking aid)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>16/10/2013</td>
<td>TDL6000MC Disposable Diathermy - Spatula tip with handle (Electrosurgical electrode)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/10/2013</td>
<td>da Vinci S Surgical System, IS2000; da Vinci Si Surgical System IS3000</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
</tbody>
</table>

The TGA publishes Australian recall actions in a searchable database to ensure the public has access to information about therapeutic products that have been recalled from the Australian market. If you are concerned about your health or if you have experienced an adverse event please seek advice from a health professional as soon as possible. Please read all the important information at the beginning of this report.
<table>
<thead>
<tr>
<th>Recall Action Commencement Date</th>
<th>Product Name/Description</th>
<th>Type of Product</th>
<th>Recall Action</th>
<th>Recall Action Classification</th>
<th>Recall Action Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>14/10/2013</td>
<td>Discovery NM/CT 670, Optima NM/CT 640, Discovery NM630 and Brivo NM615 (all configurations) (Nuclear Medicine System)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/10/2013</td>
<td>Single-Site Bipolar Maryland and Single-Site Curved Needle Driver (Reusable endotherapy device with an endoscope)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/10/2013</td>
<td>TISSUE-GUARD Family of Products - VASCU-GUARD, DURA-GUARD, PERI-GUARD and SUPPLE PERI GUARD (Xenograft)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Wholesale</td>
</tr>
<tr>
<td>14/10/2013</td>
<td>Volumed VP7000 Premium, Volumed VP7000 Classic Plus, Syramed SP6000 Premium and Syramed SP6000 Classic Plus</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/10/2013</td>
<td>Vygon Purple Nutrisafe Feeding Tube 10 FR</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/10/2013</td>
<td>Philips Expression Information Portal - IPS (Multiparameter patient monitor)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/10/2013</td>
<td>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))</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/10/2013</td>
<td>Lifestent Vascular Stent System (200 mm stent length)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/10/2013</td>
<td>PEB01H Diathermy Pencil (Electrosurgical electrode)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/10/2013</td>
<td>Sapphire Multi Therapy Pump with software Rev09Ver07 (Infusion Pump)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/10/2013</td>
<td>TPS MicroDriver (used for surgical procedures involving drilling, reaming, driving wires or pins, cutting bone and hard tissue)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/10/2013</td>
<td>Avance, Amino, Aisys Anaesthesia Devices (software version 8.00) and Avance CS Anaesthesia Devices (with software version 10.00)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/10/2013</td>
<td>Contoura 1000 and 1080 Beds (used to facilitate management of very obese patients)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/10/2013</td>
<td>Ysio, Luminos Agile, Luminos dRF and Uroskop Omnia Systems with software Versions VB10 and VC10 (diagnostic digital x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
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<tr>
<td>4/10/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/10/2013</td>
<td>Invacare Power Wheelchairs with affected SPJ+ Joysticks and MK6i Driver Controls</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>3/10/2013</td>
<td>BD SoloMed 3-piece syringe with breakable plunger.</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Wholesale</td>
</tr>
<tr>
<td>3/10/2013</td>
<td>Carestream PACS Client Workstation version 11.3.2.0 / 11.3.2.4 / 11.4</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/10/2013</td>
<td>Magstim 90mm High Power Coil (used for diagnostic and therapeutic purposes by stimulating the cortical and peripheral nerves using the magnetic field)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/10/2013</td>
<td>Medtronic CareLink 2090 Programmer (Implantable pacemaker programmer)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>2/10/2013</td>
<td>B20, B30, B40 Patient Monitors (used for ECG monitoring)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/10/2013</td>
<td>ISE Reference Solenoid Valve for AU400, AU480, AU640, AU680, AU2700, AU5400 and AU5800 Chemistry Analyser. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/10/2013</td>
<td>TomoFix Plate Medial Tibia 4 Hole Standard and TomoFix Small Proximal Medial Tibia 4 Hole 112 mm Titanium Sterile</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/10/2013</td>
<td>UniCel DxH 800 and UniCel DxH 600 Coulter Cellular Analysis Systems. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/10/2013</td>
<td>Xia 3 Titanium Torque Wrench &amp; 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)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>27/09/2013</td>
<td>Beckman Coulter LH 750 &amp; 780 Hematology Analysers (An in vitro diagnostic device (IVD))</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>27/09/2013</td>
<td>PICATO ingenol mebutate 0.015% / 0.05% (w/w) gel tube</td>
<td>Medicine</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Wholesale</td>
</tr>
<tr>
<td>25/09/2013</td>
<td>EPIQ 7 Ultrasound system version 1.0 (Intended for diagnostic ultrasound imaging)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
</tbody>
</table>
### System for Australian Recall Actions

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<thead>
<tr>
<th>Recall Action Commencement Date</th>
<th>Product Name/Description</th>
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<th>Recall Action Level</th>
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</thead>
<tbody>
<tr>
<td>25/09/2013</td>
<td>HIV Ag/Ab Combo (CHIV) Assay (used with ADVIA Centaur, ADVIA Centaur XP and ADVIA Centaur CP) (an in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/09/2013</td>
<td>Multiple Zimmer Highly Polished Implants (packaged in a Low Density Polyethylene (LDPE) Bag)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/09/2013</td>
<td>RAPIDPoint 400 Series, RAPIDPoint 500, and RAPIDLab 1200 Series Analysers (diagnostic blood gas analyser)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/09/2013</td>
<td>Stryker Standard Video Cart and Vision Mounting Arm</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/09/2013</td>
<td>NX3 Try-In Gel Syringe Refills, Bleach (dental material used to preview the expected shade of a tooth restoration before final cementation)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>18/09/2013</td>
<td>Sodium Iodide (I-131) Therapy Capsule</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>17/09/2013</td>
<td>BBL MGIT Mycobacteria Growth Indicator Tube</td>
<td>Medical Device</td>
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<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/09/2013</td>
<td>LOCI Cardiac Troponin I Calibrator (used with Dimension EXL Clinical Chemistry Systems)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/09/2013</td>
<td>NC Sprinter RX Balloon Dilatation Catheter ( Angioplasty balloon dilatation catheter)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/09/2013</td>
<td>VERSA-FX II Femoral Fixation System</td>
<td>Medical Device</td>
<td>Recall</td>
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<tr>
<td>13/09/2013</td>
<td>Argyle Single Lumen Polyurethane Umbilical Vessel Catheter</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/09/2013</td>
<td>Artis Systems running Artis VC1x software (Fluoroscopic angiographic diagnostic x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/09/2013</td>
<td>Crocodile Size 3 Walker (walking aid)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>Consumer</td>
</tr>
<tr>
<td>13/09/2013</td>
<td>DRX Revolution Mobile, DRX Mobile Retrofit &amp; DRX Transportable X-ray Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/09/2013</td>
<td>Grifols Australia AHG Cards. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
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<td>Hospital</td>
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<tr>
<td>13/09/2013</td>
<td>Panbio Barmah Forest Virus IgM ELISA. An in vitro diagnostic medical device (IVD).</td>
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<td>Hospital</td>
</tr>
<tr>
<td>13/09/2013</td>
<td>Ureterorenoscope 8703-524 (rigid ureterorenoscope)</td>
<td>Medical Device</td>
<td>Recall</td>
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<td>Hospital</td>
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<tr>
<td>12/09/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/09/2013</td>
<td>Cobas b 101 HbA1c Test (used to test for diabetes)</td>
<td>Medical Device</td>
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<tr>
<td>11/09/2013</td>
<td>Engstrom Ventilator &amp; Aspire View, Aisys and Avance Anaesthesia Machines</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/09/2013</td>
<td>FMS Intermediary Tubing with One-Way Valve (used with FMS Fluid Management Systems in a surgical setting by personnel trained in arthroscopy)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/09/2013</td>
<td>Vented Spike Adaptor</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
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</tr>
<tr>
<td>10/09/2013</td>
<td>CARDOHELP-I (Heart-lung bypass system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>Hospital</td>
</tr>
<tr>
<td>9/09/2013</td>
<td>Bellatek Zirconia Abutments</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>9/09/2013</td>
<td>Biomet 3i Dental Implants</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>9/09/2013</td>
<td>Standard SlingBar 450</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>6/09/2013</td>
<td>BD Epilor Plastic BD Luer-Lok Loss of Resistance (LOR) Syringe (7mL) (Used in conjunction with an epidural needle for identifying epidural space)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/09/2013</td>
<td>BrightView XCT</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/09/2013</td>
<td>Brilliance CT Big Bore Oncology, Brilliance CT Big Bore Radiology and Brilliance CT 16 (Air), software version 3.6.0</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/09/2013</td>
<td>Howard Wright Limited Hospital Beds and Stretchers</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/09/2013</td>
<td>Leica Ceiling Mounts MSF-1, MS-1F and MC-1F (Used for mounting surgical microscopes)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/09/2013</td>
<td>ADVIA 1200, 1650, 1800 and 2400 Clinical Chemistry Systems. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/09/2013</td>
<td>Paclitaxel suspension (Abraxane) 150mg in Bag Vialflex</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
</tbody>
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</tr>
</thead>
<tbody>
<tr>
<td>5/09/2013</td>
<td>Robicomb Liceguard Comb</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>4/09/2013</td>
<td>Easypod Auto Injector, model 5.1 (Used to inject SAIZEN growth hormone under the skin)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>3/09/2013</td>
<td>Application Instrument for Sternal ZipFix</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>2/09/2013</td>
<td>Inspira Air Balloon Dilation System (Bronchial balloon catheter)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/08/2013</td>
<td>BacT/ALERT PF Plus Culture Bottle. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/08/2013</td>
<td>Free T3 Assays for use on the IMMULITE, IMMULITE 1000, IMMULITE 2000 and IMMULITE 2000 XPi analysers. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/08/2013</td>
<td>Little Coughs</td>
<td>Medicine</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>29/08/2013</td>
<td>COGNIS Implantable Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) and TELIGEN DR &amp; VR Implantable Cardiomyocyte-Defibrillators (ICDs)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/08/2013</td>
<td>GENESIS II PS Articular Inserts (internal tibial component for knee prosthesis)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>28/08/2013</td>
<td>DigitalDiagnost - EasyUpgrade DR (Diagnostic digital x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>28/08/2013</td>
<td>Gas/Water Feeding Valve – PTX-OF-B194 (Used with PENTAX GI Video Endoscopes - 90/90K series and 110/K10 series )</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>27/08/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/08/2013</td>
<td>Berichrom Heparin (used in the quantitative and/or qualitative determination of tests associated with the coagulation cascade) (An in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
</tbody>
</table>
## System for Australian Recall Actions

<table>
<thead>
<tr>
<th>Recall Action Commencement Date</th>
<th>Product Name/Description</th>
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</tr>
</thead>
<tbody>
<tr>
<td>26/08/2013</td>
<td>Centricity PACS RA1000 Workstation (Picture Archiving and Communication System)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/08/2013</td>
<td>Zimmer Trabecular Metal Reverse Glenosphere Distractor</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/08/2013</td>
<td>Zimmer Trabecular Metal Reverse Glenosphere Helmet, 35mm/40mm</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/08/2013</td>
<td>Advantx, Innova 2000, Innova 2100 IQ, Innova 3100, Innova 4100, Innova 4100 IQ Cardiovascular X-ray imaging systems equipped with Video Monitor Suspension (Fluoroscopic, angiographic x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/08/2013</td>
<td>SLE 5000 Ventilator</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/08/2013</td>
<td>Endowrist Instruments and Accessories for the da Vinci Surgical Systems (Used in endoscopic procedures)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/08/2013</td>
<td>Sterile K-Wire and Steinmann Pin Products (Typically used for temporary fixation of bones in the extremities)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/08/2013</td>
<td>Colleague P1.7 CXE Single Channel Pump and Colleague P1.7 CXE Triple Channel Pump (Infusion Pump)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/08/2013</td>
<td>EasyLink Data Management System, all versions (used for connecting multiple IVD instruments to Laboratory Information System (LMS))</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/08/2013</td>
<td>OtisMed ShapeMatch Cutting Guides (used to assist in the positioning of knee arthroplasty components and in guiding the marking of bone before cutting)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/08/2013</td>
<td>Sterile Chlorhexidine Gluconate/Alcohol Swabs, Sterile Alcohol Swabs and Sterile Povidine Iodine Swabs</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Wholesale</td>
</tr>
<tr>
<td>20/08/2013</td>
<td>Ingenuity TF PET/CT</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>20/08/2013</td>
<td>Of Spiggle &amp; Thesis PTFE Ventilation Tubes - Fluoroplastic shepard button and Fluoroplastic collar button (Tympanostomy tubes used to ventilate the middle ear subsequent to otitis media)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
</tbody>
</table>

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<tr>
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<th>Recall Action Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>19/08/2013</td>
<td>Discovery MR450, MR750 and Optima MR450w MRI System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/08/2013</td>
<td>SIGMA Fixed Bearing Tibial Inserts - PLI, Cruciate Retaining, Posterior Stabilised (used as part of SIGMA Knee System)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/08/2013</td>
<td>Ceiling Supply Units (CSU) 80xx/CSU60xx (Used for positioning of medical gas and vacuum systems)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/08/2013</td>
<td>Phosphorus Reagent. An in vitro diagnostic medical device (IVD). (Used for the quantitation of phosphorus in human serum, plasma or urine)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/08/2013</td>
<td>Vitamin D3 Streuli 300,000IU/mL Ampoules (pack of 10)</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/08/2013</td>
<td>Oxoid Antimicrobial Susceptibility Discs with Augmentin (Amoxycillin and Clavulanic acid - AMC3). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/08/2013</td>
<td>Tec 6 and Tec 6 Plus Vaporizers (Used to vaporize anaesthetic agent Desflurane)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/08/2013</td>
<td>LifeCycle for Prenatal Screening software. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/08/2013</td>
<td>3M Scotchcast Wet or Dry Cast Padding</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/08/2013</td>
<td>E-Z Clean, L-Wire Laparoscopic Electrode Split Stem, 45cm (Single use electrosurgical electrode)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/08/2013</td>
<td>Liquichek Sedimentation Rate Control, Level 2. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/08/2013</td>
<td>MX 16-Slice (Full body CT system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/08/2013</td>
<td>4.0mm x 15mm Small Peripheral Cutting Balloon (Monorail &amp; Over-the-Wire) Microsurgical Dilatation Device (used for Percutaneous Transluminal Angioplasty of obstructive lesions in peripheral vessels) and 4.00mm x 15mm Flextome Cutting Balloon (Monorail &amp; Over-the-Wire) Microsurgical Dilatation Device (used in patients with coronary vessel disease)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/08/2013</td>
<td>Abraxane nanoparticle albumin-bound paclitaxel 100 mg powder for injection (suspension) vial</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
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</tr>
<tr>
<td>9/08/2013</td>
<td>Fluoprep (Mounting medium for immunofluorescence microscopy) - An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/08/2013</td>
<td>Secondary 19&quot; Touchscreen - TEGRIS System (Operating room device management system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/08/2013</td>
<td>Bio-Absorbable Suture Anchors (Soft tissue fixation device)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/08/2013</td>
<td>Fabius Anaesthesia Machine</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/08/2013</td>
<td>General Purpose 9 French Temperature Probe, Disposable, 400 Series</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/08/2013</td>
<td>HemoCue Hb 201 Microcuvettes (an in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/08/2013</td>
<td>Portex Blue Line Disposable Inner Cannula, 7mm (Reusable tracheostomy tube)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/08/2013</td>
<td>PyroTITAN Humeral Resurfacing Arthroplasty (CHRA)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/08/2013</td>
<td>Zoo Master Pouch 15 5H 3/8&quot; Heavy Elephant Elastics (Elastomeric component used with orthodontic brackets)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>7/08/2013</td>
<td>8mm Vector TAS Screw and Vector TAS Starter Kit (Orthodontic anchoring screw)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>6/08/2013</td>
<td>ORTHO BioVue System Cassettes (blood typing and compatibility tests). An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/08/2013</td>
<td>Allura Xper FD10 F and Allura FD10/10 (diagnostic, fluoroscopic x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/08/2013</td>
<td>Bond Polymer Refine Red Detection System. An in vitro diagnostic medical device (Immunohistochemical staining kit)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/08/2013</td>
<td>HemoCue Glucose 201 RT Microcuvettes, single pack. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/08/2013</td>
<td>Phenocell C 0.8% and Phenocell C 3%. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>2/08/2013</td>
<td>STERRAD 100NX Cassette (Used to provide hydrogen peroxide sterilant used in the STERRAD NX Steriliser)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
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</tr>
</thead>
<tbody>
<tr>
<td>2/08/2013</td>
<td>ViewPoint 6 Versions 6.2, 6.2.1, 6.3 and 6.31 including OB Pro-Expert Reporting (Ultrasound image management software)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/08/2013</td>
<td>Anastaflo Intravascular Shunt (Carotid artery shunt)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/08/2013</td>
<td>Medtronic Xomed Instrument Trays</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>31/07/2013</td>
<td>ACL Top Family of analysers used with HemosIL APTT reagent (an in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>31/07/2013</td>
<td>Durolane 3ml (synovial fluid supplementation substance)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>31/07/2013</td>
<td>Oxoid Antimicrobial Susceptibility Testing Discs MEM10 (Meropenem), CT0774B (An in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/07/2013</td>
<td>ADVIA Centaur Folate ReadyPack, Lot 071218 Kit Lots (an in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/07/2013</td>
<td>LPS (Limb Preservation System) Lower Extremity Dovetail Intercalary Component (internal femoral component)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/07/2013</td>
<td>VITROS Chemistry Products MicroSlides (an in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/07/2013</td>
<td>Cell Marque CDX-2 (EPR2864Y*) antibody 7ml - an in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/07/2013</td>
<td>FujiFilm Digital Mammography System AMULET (FDR MS-1000)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/07/2013</td>
<td>HypoMon Alarm System (alarm for sleep time hypoglycemic episodes)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>29/07/2013</td>
<td>VariVac InLine Adjustable Vacuum Wound Drainage System with bottle</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/07/2013</td>
<td>C-Qur, C-Qur TacShield and C-Qur V-Patch (used for tissue reinforcement during surgery)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/07/2013</td>
<td>Octagam 5% 10g/200mL</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/07/2013</td>
<td>Brilliance iCT and iCT SP up to and including Software Version 3.2.5</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/07/2013</td>
<td>Compat Nasogastric Feeding Tube 8Fr, 10Fr and 12Fr</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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</tbody>
</table>

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<thead>
<tr>
<th>Recall Action Commencement Date</th>
<th>Product Name/Description</th>
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<tr>
<td>24/07/2013</td>
<td>Contoura 380 and 480 Bed</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>24/07/2013</td>
<td>Fluorocore 2+ Fast Set Core Build Up Dental Material, Syringe- Blue Coloured</td>
<td>Medical Device</td>
<td>Recall</td>
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<td>Retail</td>
</tr>
<tr>
<td>24/07/2013</td>
<td>HemoCue Urine Albumin Microcuvettes (an in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/07/2013</td>
<td>Optimark (gadoversetamide) Injection bottle 5mL, (Used in magnetic resonance imaging)</td>
<td>Medicine</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
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</tr>
<tr>
<td>24/07/2013</td>
<td>Sterile Disposable Syringe 3mL - Luer Slip</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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</tr>
<tr>
<td>23/07/2013</td>
<td>Cobas 4800 HPV Amplification/Detection Reagents, 240 tests and 960 tests</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/07/2013</td>
<td>Dimension Vista RF Flex Reagent Cartridge (an in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>22/07/2013</td>
<td>MX8000 IDT 16 Slice CT Scanner</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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<tr>
<td>22/07/2013</td>
<td>PROMUS Element Plus MONORAIL Everolimus-Eluting Coronary Stent System</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>19/07/2013</td>
<td>Clearlink System Solution Set (Infusion administration set)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/07/2013</td>
<td>D788 pCO2 Membrane (catalogue number 942-063) used with Radiometer ABL700 and ABL800 series analysers (An in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/07/2013</td>
<td>Medtronic Navigation Framelink (used with Medtronic Navigation StealthStation S7 and i7 systems or a Medtronic Planning Station for image guided surgery)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>19/07/2013</td>
<td>Normal Saline with Phenol (NSP) in 4.5mL fill</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>19/07/2013</td>
<td>PTFE GRAFTS – ADVANT VXT, FLIXENE, FLIXENE w/IFG, ADVANTA SST with expiration between April 2017 and May 2018</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/07/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/07/2013</td>
<td>Air Liquide Medical Oxygen</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
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<tr>
<td>Recall Action Commencement Date</td>
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<td>18/07/2013</td>
<td>Febridol Paracetamol 500mg, 100 tablet bottle</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class I</td>
<td>Consumer</td>
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<tr>
<td>17/07/2013</td>
<td>Disposable Breathing Circuit Kit</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/07/2013</td>
<td>Frameless SRS QA Target Pointer (Component of Brainlab Stereotactic System used for patient positioning during stereotactic radiosurgery or radiotherapy procedures using a linear accelerator)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>16/07/2013</td>
<td>Active Care 1015-1 Swivel Sliding Transfer Bench</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/07/2013</td>
<td>Fine-Medium Buchanan Pluggers (Dental instrument used during endodontic procedures)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>16/07/2013</td>
<td>Monaco RTP System (Radiation Treatment Planning System Software)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/07/2013</td>
<td>Mullins Transseptal Catheter Introducer 7 French Sheath</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>15/07/2013</td>
<td>Life Standard Package Cavity Liner (Calcium Hydroxide)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>15/07/2013</td>
<td>Medrad Hand Controller Sheaths (used with Avanta Pedestal Mount Injection System and Avanta Table Mount Injection System)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/07/2013</td>
<td>Alaris System PC Unit (PCU) model 8015, software version 9.12</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<td>11/07/2013</td>
<td>Medline Cardiac Pack (which includes Edwards LifeSciences Suction Wand)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/07/2013</td>
<td>Olympus OFP-2 Flushing Pump (used with endoscopic irrigation)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/07/2013</td>
<td>Locking Screw Stardrive 2.4mm and 2.7mm (self-tapping, 12 mm length, stainless steel, Orthopaedic bone screw)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>10/07/2013</td>
<td>Triathlon Tibial Alignment Ankle Camp Extramedullary (Referencing Instrument supplied with Triathlon Total Knee Arthroplasty procedure kit)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
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<tr>
<td>10/07/2013</td>
<td>Zimmer NexGen Micro Knee Implants (Femur, Patella, Articular Surface) and Provisionals</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>9/07/2013</td>
<td>ADVIA Chemistry Systems, Alkaline Phosphate (ALPAMP) Reagent Kits</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
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<tr>
<td>9/07/2013</td>
<td>CT0003B AMP10 Amoxicillin Antimicrobial Susceptibility Testing Discs (An in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/07/2013</td>
<td>HemoCue Glucose 201 Microcuvettes, single packed (an in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/07/2013</td>
<td>Liaison Control Mumps IgG (an in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/07/2013</td>
<td>AirSep Impulse Elite OCD (oxygen conserving device)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>5/07/2013</td>
<td>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</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/07/2013</td>
<td>Medtronic MiniMed Insulin Reservoirs</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Consumer</td>
</tr>
<tr>
<td>5/07/2013</td>
<td>Riata and Riata ST Silicone Endocardial Defibrillation Leads</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/07/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/07/2013</td>
<td>NordiPen used with 5mg, 10mg and 15mg Norditropin SimpleXx cartridges</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>4/07/2013</td>
<td>SynchroMed II and SynchroMed EL Implanted Infusion Pump</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/07/2013</td>
<td>SynchroMed II and SynchroMed EL Implanted Infusion Pump</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>4/07/2013</td>
<td>SynchroMed II and SynchroMed EL Implanted Infusion Pump</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>4/07/2013</td>
<td>Thymoglobuline (rabbit anti-human thymocyte immunoglobulin) 25 mg powder for infusion vial</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/07/2013</td>
<td>ADVIA Centaur Homocysteine (HCY) Assay used with the ADVIA Centaur, Centaur XP, and Centaur CP systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/07/2013</td>
<td>Aliquot Syringe Delivery System Kits (orthopaedic surgical kit, used to place injectable synthetic cortical bone void filler in weak or diminished bone)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/07/2013</td>
<td>All Digital Accelerators with Electrons and Beam Modulator, MLCi/MLCi2, Agility or Asymmetric Heads</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>Hospital</td>
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</tbody>
</table>

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<td>3/07/2013</td>
<td>GEHC Discovery NM/CT 670 Nuclear Medicine System</td>
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<tr>
<td>3/07/2013</td>
<td>Medisafe Scope Pre-Clean Sponge Kit</td>
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<tr>
<td>3/07/2013</td>
<td>OASYS Midline Occipital Plate (Intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (Occiput –T3))</td>
<td>Medical Device</td>
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</tr>
<tr>
<td>2/07/2013</td>
<td>Edwards Lifesciences Suction Wand (Used during cardiac surgery for the suction of excessive fluid from the pericardium)</td>
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<td>Recall</td>
<td>Class I Hospital</td>
</tr>
<tr>
<td>28/06/2013</td>
<td>BD MAX Instruments. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
</tr>
<tr>
<td>28/06/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
</tr>
<tr>
<td>28/06/2013</td>
<td>PSA Assays for use on Immulite, Immulite 1000, Immulite 2000 and Immulite 2000 XPI analysers (an in vitro diagnostic medical device)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II Hospital</td>
</tr>
<tr>
<td>28/06/2013</td>
<td>Red Blood Cell Antibody Identification Reagent - Phenocell C 0.8% and Phenocell C 3%. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III Hospital</td>
</tr>
<tr>
<td>27/06/2013</td>
<td>Cementless Columbus Knee System</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II Hospital</td>
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<tr>
<td>27/06/2013</td>
<td>Niti-S Biliary Covered Stent (Flare-Type) Nagi/Pseudocyst 10mm x 3cm</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II Hospital</td>
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<tr>
<td>26/06/2013</td>
<td>Consulta CRT-P (Implantable cardiac pacemaker)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
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<tr>
<td>26/06/2013</td>
<td>Herbs of Gold Olive Leaf Oral Liquid</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II Wholesale</td>
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<tr>
<td>26/06/2013</td>
<td>Liposomal Amphotericin (AMBISOME) 50mg in 50ml 5% glucose infuser device</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class I Hospital</td>
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<tr>
<td>26/06/2013</td>
<td>Maquet Heater Unit</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
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<tr>
<td>26/06/2013</td>
<td>OSSEOTITE Certain PREVAIL 2 Implant 5/4 x 11.5mm</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II Hospital</td>
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<td>25/06/2013</td>
<td>Aquarius GEF08200 Device, V4 Software</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
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<td>25/06/2013</td>
<td>Mini RPE Screw Assembly (Orthodontic Appliance System)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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<tr>
<td>25/06/2013</td>
<td>Morphine Sulphate solution, 50mg in 50mL 0.39% Sodium Chloride Syringe (Compound patient specific medicine)</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
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<td>25/06/2013</td>
<td>Reduction Instrument for Spondylothesis, standard, for Matrix 5.5</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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<tr>
<td>24/06/2013</td>
<td>Cholestahealth Powder</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
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<tr>
<td>21/06/2013</td>
<td>BD Stem Cell Control Kit (used with BD FACSCanto flow cytometers). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
</tr>
<tr>
<td>20/06/2013</td>
<td>Infinia, VG, VG Hawkeye and Helix nuclear medical systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
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<tr>
<td>20/06/2013</td>
<td>Perfect Pool 10x10mL, an in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
</tr>
<tr>
<td>19/06/2013</td>
<td>AMBISOME (amphotericin B) 50 mg powder for injection vial</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class I</td>
</tr>
<tr>
<td>19/06/2013</td>
<td>AMH Gen II ELISA Kit. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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<tr>
<td>19/06/2013</td>
<td>Biograph mCT systems running the VG40A or VG40B software</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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<tr>
<td>19/06/2013</td>
<td>Transpedicular Schanz Screw (Bone screw for internal spinal fixation system)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>18/06/2013</td>
<td>Dynamic Locking Screw Stardrive 3.7mm self tapping, length 22-70mm and 5.0mm, length 32-90 mm, Cobalt Chrome (CoCrMo) sterile</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
</tr>
<tr>
<td>18/06/2013</td>
<td>HeartStart MRx Monitor / Defibrillator</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
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<tr>
<td>18/06/2013</td>
<td>V60 Non-invasive Ventilators</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>17/06/2013</td>
<td>Ceftriaxone (as Sodium) Powder for Injection 1g</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class I</td>
</tr>
<tr>
<td>17/06/2013</td>
<td>Deep Brain Stimulation (DBS) Leads (implantable, neurological electrode stimulator)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
</tr>
<tr>
<td>14/06/2013</td>
<td>Abbott Medical Optics (AMO) STAR Excimer Laser System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
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</tr>
<tr>
<td>14/06/2013</td>
<td>Alaris GP, GP Guardrails, GP Plus &amp; GP Plus Guardrails Infusion Pumps</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>14/06/2013</td>
<td>EZTest steam and Smart-Read EZTest steam Biological Indicators</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>14/06/2013</td>
<td>Medtronic Consulta CRT-P (Implantable cardiac pacemaker)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
</tr>
<tr>
<td>13/06/2013</td>
<td>5L and 10L Prolystica Ultra Concentrate Alkaline Detergent</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>13/06/2013</td>
<td>IH-1000. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>13/06/2013</td>
<td>INFUSE/LT Cage Bone Graft Kit (Used for spinal fusion procedures)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I</td>
</tr>
<tr>
<td>13/06/2013</td>
<td>Intuitive Surgical 5mm Cannula and 5mm Flared Cannula (Reusable endotherapy cannula)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>12/06/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>12/06/2013</td>
<td>Diclocil (dicloxacillin sodium) 500mg capsules</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>12/06/2013</td>
<td>Elements Motor and TF Adaptive Starter Kit (Dental motor used with endodontic rotary instruments)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
</tr>
<tr>
<td>12/06/2013</td>
<td>Medtronic Paradigm Insulin Infusion Sets</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>6/06/2013</td>
<td>APEX Arthroscopy Tubing Set, One Connection</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>6/06/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>6/06/2013</td>
<td>Coiled Tube Baxter Infusors (Portable Elastomeric Infusion Systems)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
</tr>
<tr>
<td>6/06/2013</td>
<td>MEVATRON, PRIMUS, ONCOR and ARTISTE Digital Linear Accelerators</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>6/06/2013</td>
<td>Sonopet Console (Ultrasonic Surgical Aspirator System)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
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<tr>
<td>4/06/2013</td>
<td>DePuy ReClaim Reamer Extension (Supplied as part of the ReClaim modular revision hip system kit)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>4/06/2013</td>
<td>DX-D 100 (Mobile diagnostic x-ray generator)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>3/06/2013</td>
<td>Elekta XVI X-Ray Volume Imager (Electronic Portal Imaging Device (EPID) used with radiation therapy treatment)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>3/06/2013</td>
<td>Vitamin A Ampoules</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>31/05/2013</td>
<td>Bone Fragments - Milled irradiated femoral head</td>
<td>Biological</td>
<td>Hazard Alert</td>
<td>Class II</td>
</tr>
<tr>
<td>31/05/2013</td>
<td>Brilliance CT Systems and Gemini &amp; Precedence Systems utilising Brilliance CT</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>31/05/2013</td>
<td>Monaco RTP System (Radiation Treatment Planning System Software)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>30/05/2013</td>
<td>Glenosphere Orientation Guide Instrument used with the Delta EXTEND Reverse Shoulder System.</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
</tr>
<tr>
<td>30/05/2013</td>
<td>Medrad Veris MR Vital Signs Monitor - Power cable</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>30/05/2013</td>
<td>Neptune 2 Rover Ultra and Neptune Bronze Rover (Mobile unit used as surgical fluid/smoke waste management system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>29/05/2013</td>
<td>8 mm Fenestrated Bipolar Forceps used with da Vinci Standard System (IS1200)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>29/05/2013</td>
<td>ECHELON 60mm Endoscopic Linear Cutter Reloads, Black (Reload cartridge with two 60mm long triple-staggered lines of staples)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
</tr>
<tr>
<td>29/05/2013</td>
<td>Edwards Lifesciences QuickDraw Venous Cannula</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
</tr>
<tr>
<td>29/05/2013</td>
<td>G-6-PDH Control Kits, Normal. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>29/05/2013</td>
<td>Intuitive Surgical EndoWrist Instrument Hot Shears Monopolar Curved Scissors</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>29/05/2013</td>
<td>MIA16 Minimally Invasive Attachment used with the Anspach</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
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<tr>
<td>28/05/2013</td>
<td>Medacta Femoral Stems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>24/05/2013</td>
<td>Checking Dilator 24-492-15-01 (Dilator, De Bakey, 0 1.5mm, 19cm)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>24/05/2013</td>
<td>DBL Metronidazole Intravenous Infusion, Infusion bag 500mg in 100mL</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>24/05/2013</td>
<td>Dimension Vista 500 &amp; Dimension Vista 1500 Analysers with Software versions 3.4 or 3.5.1 (An in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>24/05/2013</td>
<td>GlideScope Video Laryngoscope Blades GVL3, GVL4 and GVL5</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
</tr>
<tr>
<td>24/05/2013</td>
<td>MammoDiagnost DR with software release 2.1 (mammography system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
</tr>
<tr>
<td>24/05/2013</td>
<td>PET VCAR Application Software (installed on Advantage Workstation and AW Server versions: Advantage Workstation 4.6, Volume Share 5 enhanced - vxtl.11.3, vxtl.11.3 ext1, or vxtl.11.3 ext2 AW Server 2.0, Volume Share 5 enhanced - vxtl.11.3, vxtl.11.3 ext1, or vxtl.11.3 ext2)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>24/05/2013</td>
<td>PYRENEES Constrained plate 2 Level 36mm</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>22/05/2013</td>
<td>ADVIA Chemistry Total Protein 2 reagent (Urine) (UPRO_2). An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>22/05/2013</td>
<td>Alere DDS2 Test Kits (Drug screening test system). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
</tr>
<tr>
<td>22/05/2013</td>
<td>syngo Lab Data Manager Version VA11B and VA12A. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>21/05/2013</td>
<td>CT0003B AMP10 Ampicillin Antimicrobial Susceptibility Testing Discs. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
</tr>
<tr>
<td>20/05/2013</td>
<td>Blackmax, Micromax, Xmax Ansprech Pneumatic Drill Systems / Hoses without a pressure relief valve (PRV)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>20/05/2013</td>
<td>GAMMA3 Long Nail Kit R2.0 LEFT (Intramedullary Nail for fracture fixation)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
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<tr>
<td>20/05/2013</td>
<td>Zimmer Air Dermatome (Air powered surgical skin grafting device)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>17/05/2013</td>
<td>Access 2 Immunoassay System with Software Version 3.4, An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>17/05/2013</td>
<td>ARCHITECT STAT High Sensitive Troponin-I Calibrators and Controls</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
</tr>
<tr>
<td>17/05/2013</td>
<td>Codman Certas Programmable Valves (Hydrocephalic valve)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I</td>
</tr>
<tr>
<td>17/05/2013</td>
<td>Dimension Chemistry Wash</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>17/05/2013</td>
<td>Integra Ojemann Cortical Stimulator (Electrical antiseizure brain stimulator)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>17/05/2013</td>
<td>Receptal 1000 mL liner and canister used with the Laerdal Suction Unit</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>16/05/2013</td>
<td>1.5T Signa HDxt, 3.0T Signa HDxt, Signa Vibrant MR Systems (Magnetic Resonance Imaging Systems)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>16/05/2013</td>
<td>Berichrom PAI (Plasmin activator inhibitors). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
</tr>
<tr>
<td>16/05/2013</td>
<td>Carbon dioxide absorbent canister for use with the Aespire, Aespire View, Avance, Avance CS2, Alys, ADU, 9100, M900, M904, 9300 anaesthesia systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>16/05/2013</td>
<td>IH-1000 Immunohaematology Analyser. An in vitro Diagnostic Medical Device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>16/05/2013</td>
<td>LifeCare P5 Premium Bed with side rails</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>15/05/2013</td>
<td>HeartWare Controller</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>15/05/2013</td>
<td>Viper &amp; Viper Plus Powerchairs</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
</tr>
<tr>
<td>13/05/2013</td>
<td>BrightView SPECT (single photon emission computed tomography system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>13/05/2013</td>
<td>Epix and Direct Drive Laparoscopic Grasper</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>10/05/2013</td>
<td>1000mL Receptal System (waste disposable suction system)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
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<tr>
<td>10/05/2013</td>
<td>BioMend Absorbable Collagen Membrane/Wound Dressing</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>10/05/2013</td>
<td>Medtronic NIM Flex EMG Endotracheal Tube</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
</tr>
<tr>
<td>10/05/2013</td>
<td>Sterile Adapter for use with the da Vinci Si, da Vinci Si-e (robotic surgical system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>10/05/2013</td>
<td>Versaport Bladeless Optical 5mm Trocar with Fixation Cannula (Abdominal and thoracic trocar)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>9/05/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>9/05/2013</td>
<td>CoaguChek XS, CoaguChek XS Plus and CoaguChek XS Pro. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>9/05/2013</td>
<td>Cortex Screw 3.5mm, self-tapping, length 60mm, Stainless Steel, sterile (Orthopaedic non-biodegradable bone screw)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
</tr>
<tr>
<td>9/05/2013</td>
<td>Guide Wire 2.5mm, with drill tip, length 300mm Cobalt-Chrome Alloy (Orthopaedic fixation nail guidewire)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>9/05/2013</td>
<td>Soft Tissue Retractor, small, extendible</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>9/05/2013</td>
<td>STF Load Check Indicators (ultrasonic bath efficacy indicator)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>9/05/2013</td>
<td>T4 Zipper Toga (XL - Tall) (Operating room gown)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>7/05/2013</td>
<td>A-dec 311 Chair and A-dec 361 Support Centre</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>7/05/2013</td>
<td>AU2700/AU2700 Plus and AU5400 Clinical Chemistry Analysers, an in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>7/05/2013</td>
<td>Aurum Amiodarone 30mg/mL Pre-Filled Syringe</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>7/05/2013</td>
<td>Cautery Pen Push Button PTFE Coated blade</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
</tr>
<tr>
<td>7/05/2013</td>
<td>ProcedurePak - Mater Day Hip Arthroscopy Pack</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>6/05/2013</td>
<td>Hill-Rom VersaCare VC 755 Bed</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
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<tr>
<td>3/05/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>3/05/2013</td>
<td>Brainlab Cranial Navigation System, all versions</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>3/05/2013</td>
<td>Elecsys Beta-CrossLaps. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>3/05/2013</td>
<td>Mini C-arm, models InSight and InSight 2 (Fluoroscopic x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>2/05/2013</td>
<td>Dimension TACR (Tacrolimus) Flex Reagent Cartridge (DF107), An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
</tr>
<tr>
<td>1/05/2013</td>
<td>LIGACLIP 10mm M/L Endoscopic Rotating Multiple Clip Applier (metal ligating clip applier)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
</tr>
<tr>
<td>30/04/2013</td>
<td>Elekta Integrity R3.0 Digital Linear Accelerator</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>30/04/2013</td>
<td>Masimo Rad-8 Pulse Oximeters</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>30/04/2013</td>
<td>PANTA Arthrodesis Nail &amp; PANTA XL Arthrodesis Nail (Intramedullary tibial nail)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>30/04/2013</td>
<td>Tensioner (Instrument used for general orthopaedic repairs using implants like cerclage wires, cables and crimps/clamps)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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<tr>
<td>30/04/2013</td>
<td>VIDAS D-Dimer Exclusion II (An in vitro medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>29/04/2013</td>
<td>Discovery MR450, MR750, MR750w and Optima MR450w products, running software versions DV22.0_V02, DV22.1_V01, DV23.0_V01 (MRI System)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>29/04/2013</td>
<td>Electrosurgery Probe Plus II (Electrosurgical electrodes) &amp; Laparoscopic Banding Kit</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>29/04/2013</td>
<td>Trima Accel Automated System (Apheresis unit)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>26/04/2013</td>
<td>Zilver PTX Drug-Eluting Peripheral Stent</td>
<td>Medical Device</td>
<td>Recall</td>
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<tr>
<td>24/04/2013</td>
<td>ACUSON SC2000 System (Ultrasound cardiovascular imaging system) when used with VSM Transducer (which includes revision 4 of the MPI board)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>24/04/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall</td>
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</tr>
<tr>
<td>24/04/2013</td>
<td>RPM Respiratory Gating System, version v1.7.5 with 3D Option (Patient respiratory monitoring system used with radiation therapy systems)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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<tr>
<td>23/04/2013</td>
<td>BBL DrySlide Oxidase Kit. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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<tr>
<td>23/04/2013</td>
<td>BD Vacutainer Multiple Sample Luer Adapter</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>23/04/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
</tr>
<tr>
<td>23/04/2013</td>
<td>LCP Distal Femoral Plate 4.5/5.0, right, 19 holes, length 436 mm, Titanium Alloy (TAN), sterile (Orthopaedic fixation plate)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
</tr>
<tr>
<td>23/04/2013</td>
<td>VITROS Immunodiagnostic Products CK-MB Calibrators. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>22/04/2013</td>
<td>Biograph mCT Systems with VG40 Software (Diagnostic imaging system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>22/04/2013</td>
<td>Confidence Spinal Cement System Kit</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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<tr>
<td>22/04/2013</td>
<td>Constellation Pneumatic Handpiece, DSP (Ophthalmic surgical instrument handle)</td>
<td>Medical Device</td>
<td>Recall</td>
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</tr>
<tr>
<td>22/04/2013</td>
<td>DuraGen Dural Graft Matrix, DuraGen Plus Dural Regeneration Matrix &amp; DuraGen Suturable Dural Regeneration Matrix (Dura mater grafts indicated for the repair or primary closure of dura (brain and spinal chord) for regeneration)</td>
<td>Medical Device</td>
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<tr>
<td>Recall Action Commencement Date</td>
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<tr>
<td>22/04/2013</td>
<td>NeuraGen Nerve Guide (Indicated for the repair of peripheral nerve discontinuities); NeuraWrap Nerve Protector (Indicated to provide nerve protection following peripheral nerve surgery)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
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<tr>
<td>22/04/2013</td>
<td>OxyCap Adult CO2 Sampling Oxygen Mask</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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<tr>
<td>22/04/2013</td>
<td>Panbio Dengue IgM Capture ELISA, An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>22/04/2013</td>
<td>SYNCHRON Systems Lactate (LACT), An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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<tr>
<td>19/04/2013</td>
<td>iPlan RT Dose version 4.0 and 4.1 (including all subversions) (Radiation therapy treatment planning system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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<tr>
<td>19/04/2013</td>
<td>Liquichek ToRCH Plus IgM Control - Positive (An in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall</td>
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<tr>
<td>19/04/2013</td>
<td>MatrixORTHOGNATHIC Screws; MatrixMANDIBLE Screws; MatrixMIDFACE; MatrixNEURO Screws (Non-sterile and sterile screws supplied as part of a craniofacial fixation plate kit)</td>
<td>Medical Device</td>
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<tr>
<td>19/04/2013</td>
<td>Nicolet EEG Wireless Amplifier</td>
<td>Medical Device</td>
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<tr>
<td>19/04/2013</td>
<td>PCA LifeCare Infusion System</td>
<td>Medical Device</td>
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<tr>
<td>19/04/2013</td>
<td>Respond Wires (Orthodontic wire)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
</tr>
<tr>
<td>19/04/2013</td>
<td>Streptex Group D Latex agglutination reagent R30950901, An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
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<tr>
<td>19/04/2013</td>
<td>Tissue Liberator Blade Up (Forceps)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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<tr>
<td>18/04/2013</td>
<td>IMPAX 5.2 DB Server, version 5.2 (Picture archiving and communication system, PACS)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
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<tr>
<td>18/04/2013</td>
<td>Optima MR430s and MSK 1.5T Extreme (MRI System)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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<tr>
<td>18/04/2013</td>
<td>Philips HeartStart MRx Monitor/Defibrillator</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
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<tr>
<td>18/04/2013</td>
<td>YUNO Table Extension device</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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<tr>
<td>17/04/2013</td>
<td>Dimension Tacrolimus (TACR) Flex Reagent Cartridge (An in vitro diagnostic medical device used with Dimension Clinical Chemistry Systems)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
</tr>
<tr>
<td>17/04/2013</td>
<td>Elekta Integrity Digital Linear Accelerator, version 1.1</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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<tr>
<td>17/04/2013</td>
<td>EnSeal G2 SuperJaw (Used for bipolar coagulation and mechanical transection of tissue during laparoscopic and open procedures)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>17/04/2013</td>
<td>Pulmonary Valve Transplant</td>
<td>Biological</td>
<td>Hazard Alert</td>
<td>Class I</td>
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<tr>
<td>17/04/2013</td>
<td>SAFETY Blood Collection Sets</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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<tr>
<td>16/04/2013</td>
<td>Optima CT660, Brivo CT385, Discovery PET/CT 610 and Discovery PET/CT 710 Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>16/04/2013</td>
<td>Torix Disposable Toric IOL Marking and Alignment System</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
</tr>
<tr>
<td>15/04/2013</td>
<td>ADVIA Chemistry Systems Liquid Specific Protein Calibrator (an in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
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<tr>
<td>15/04/2013</td>
<td>Dimension Clinical Chemistry Systems HB1C Flex Reagent Cartridge (An in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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<tr>
<td>15/04/2013</td>
<td>SJM Confirm External Patient Activator Model DM2100A</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
</tr>
<tr>
<td>12/04/2013</td>
<td>All GemStar Family of Infusers: GemStar Infusion System - Single Therapy, GemStar 7 Therapy Infusion System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>12/04/2013</td>
<td>All GEMSTAR Family of Infusers: GemStar Infusion System - Single Therapy, GemStar 7 Therapy Infusion System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>12/04/2013</td>
<td>All GEMSTAR Family of Infusers: GemStar Infusion System - Single Therapy, GemStar 7 Therapy Infusion System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>12/04/2013</td>
<td>DHS/DCS Screw, sterile (Orthopaedic bone screw, non bio-degradable)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>12/04/2013</td>
<td>EVOTECH Endoscope Cleaner and Reprocessor (ECR) System (Endoscope disinfecting unit)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>12/04/2013</td>
<td>EVOTECH Endoscope Cleaner and Reprocessor (ECR) System (Endoscope disinfecting unit)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
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<tr>
<td>12/04/2013</td>
<td>FreeStyle InsuLinx Blood Glucose Meter (An in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
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<tr>
<td>11/04/2013</td>
<td>All GemStar Family of Infusers: GemStar Infusion System - Single Therapy, GemStar 7 Therapy Infusion System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>9/04/2013</td>
<td>ExacTrac (Image guided radiation treatment therapy patient positioning system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>9/04/2013</td>
<td>HbA1c Flex Reagent Cartridge (An in vitro diagnostic medical device (IVD) used with Dimension Vista Systems)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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<tr>
<td>8/04/2013</td>
<td>Newport HT70 and HT70 Plus Ventilator</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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<tr>
<td>8/04/2013</td>
<td>PSV Sets (Scalp Vein), Hard, 27Gx 3/4&quot; ISO CE</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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<tr>
<td>5/04/2013</td>
<td>AcrySof CACHET Phakic Lens (Used for the reduction or elimination of myopia)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
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<td>5/04/2013</td>
<td>Imagine Instant Pregnancy Test</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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<tr>
<td>5/04/2013</td>
<td>syngo WorkFlow MLR with version VB30C_FP1, VB30E, VB35A, VB36A and &quot;Portal Radiologist&quot; license (radiology information system used to process data)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
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<tr>
<td>4/04/2013</td>
<td>cobas 8000 modular analyser series, control unit software version 03-03 (An in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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<tr>
<td>4/04/2013</td>
<td>DASH, PDM and Tram models (Multiparameter patient monitor)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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<tr>
<td>4/04/2013</td>
<td>Locking screw 3.5mm, self tapping, length 55mm, stainless steel, sterile (Orthopaedic bone screw, non-biodegradable)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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<tr>
<td>4/04/2013</td>
<td>STERRAD 100NX and STERRAD 200 Sterilisation Systems</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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<td>4/04/2013</td>
<td>Stryker Suction Irrigation Tips (general purpose irrigation/aspiration units)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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</tr>
<tr>
<td>3/04/2013</td>
<td>epoc BGEM Test Card (blood gas, electrolyte and metabolite test card panel), An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall</td>
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<tr>
<td>28/03/2013</td>
<td>AQURE POC Management System, software versions 1.4.0 to 1.5.3 (An in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
</tbody>
</table>

The TGA publishes Australian recall actions in a searchable database to ensure the public has access to information about therapeutic products that have been recalled from the Australian market. If you are concerned about your health or if you have experienced an adverse event please seek advice from a health professional as soon as possible. Please read all the important information at the beginning of this report.
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<tbody>
<tr>
<td>28/03/2013</td>
<td>AU5800 Clinical Chemistry Analyser: all instrument serial numbers with software version 4.11 and prior (An in vitro diagnostic medical device (IVD))</td>
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<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>28/03/2013</td>
<td>Biomet Oxford Uni Toffee Hammer (Reusable surgical instrument used to insert or remove pins, nails etc)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>28/03/2013</td>
<td>Blue Free Strand ORTHOCORD Sutures: Orthocord Blue without needles; Orthocord Blue &amp; Violet without needles; Orthocord Blue &amp; 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 orthopeadic procedures)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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</tr>
<tr>
<td>28/03/2013</td>
<td>CARDOHELP-1, software version 3.3.0 (Heart-lung bypass system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>28/03/2013</td>
<td>cobas 4800 - z 480 (Real time PCR sample preparation, amplification and detection instrument). An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
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<tr>
<td>28/03/2013</td>
<td>Fluoron Gas Tamponades (Intraocular injection of ophthalmic gases)</td>
<td>Medical Device</td>
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<tr>
<td>28/03/2013</td>
<td>HemoCue Glucose 201 RT and Glucose 201 DM RT Systems (An in vitro diagnostic medical device (IVD) for the quantitative detection of blood glucose)</td>
<td>Medical Device</td>
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<tr>
<td>28/03/2013</td>
<td>PROSTIVA RF Model 8930 Generator (Used for minimally invasive treatment for patients with lower urinary tract symptoms due to benign prostatic hyperplasia (BPH))</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>Hospital</td>
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<tr>
<td>28/03/2013</td>
<td>Pulp Canal Sealer EWT Standard, Pulp Canal Sealer EWT Bulk Powder Refill (Root canal sealing material)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>27/03/2013</td>
<td>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</td>
<td>Medical Device</td>
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<td>27/03/2013</td>
<td>Medtronic Paradigm Insulin Pump</td>
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<td>27/03/2013</td>
<td>One Touch Verio IQ Blood Glucose Monitoring System</td>
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<td>25/03/2013</td>
<td>CentraLink Database Management System, version 14.0.4 (An in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>25/03/2013</td>
<td>Oxoid Antimicrobial Susceptibility Testing discs for Ampicillin (AMP10). An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
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<td>25/03/2013</td>
<td>Oxoid Antimicrobial Susceptibility Testing discs for Ertapenem (ETP10). An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
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<tr>
<td>25/03/2013</td>
<td>Reinforced Endotracheal Tubes - Murphy, Magill, Murphy with stylet &amp; Magill with stylet</td>
<td>Medical Device</td>
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<tr>
<td>22/03/2013</td>
<td>Elekta PreciseTreatment Table (Intended as a universal patient treatment support and positioning table for radiation therapy and simulation use)</td>
<td>Medical Device</td>
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<td>Hospital</td>
</tr>
<tr>
<td>22/03/2013</td>
<td>Take 1 Advanced Medium SuperFast (Dental silicone impression material)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>21/03/2013</td>
<td>Kimguard Container Filters 7.5in (19cm) round &amp; 9x9in (23x23cm) square (Used for wrapping medical devices prior to sterilisation)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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</tr>
<tr>
<td>21/03/2013</td>
<td>Philips IntelliVue Information Center iX (PIIC iX) software release A.01.XX (Central patient monitoring station)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>20/03/2013</td>
<td>ML 301 Examination Lamp</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>19/03/2013</td>
<td>BD HLA-B27 Kit (An in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall</td>
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<td>Hospital</td>
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<tr>
<td>19/03/2013</td>
<td>FEMME-TAB ED 20/100 levonorgestrel 100mcg ethinylestradiol 20mcg film-coated blister pack (Oral contraception)</td>
<td>Medicine</td>
<td>Recall</td>
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</tr>
<tr>
<td>19/03/2013</td>
<td>MX PGE2 3/4 Gellhorn Pessary</td>
<td>Medical Device</td>
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</tr>
<tr>
<td>19/03/2013</td>
<td>RegenerOss Allograft Block Max/Mand Blocks</td>
<td>Biological</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/03/2013</td>
<td>VITROS Chemistry Products PHBR Slides (An in vitro diagnostic medical device (IVD) for the quantitative measure of phenobarbital)</td>
<td>Medical Device</td>
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<td>Hospital</td>
</tr>
<tr>
<td>15/03/2013</td>
<td>AMS 800 Artificial Urinary Sphincter Control Pumps</td>
<td>Medical Device</td>
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<td>Hospital</td>
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<tr>
<td>Recall Action Commencement Date</td>
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<td>15/03/2013</td>
<td>Avance CS2 Anesthesia Carestation</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
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<tr>
<td>15/03/2013</td>
<td>MAQUET QUADROX-i Oxygenators (excluding HLS) and Blood Outlet Connectors</td>
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<td>Recall for Product Correction</td>
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<td>Hospital</td>
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<tr>
<td>15/03/2013</td>
<td>Medtronic NIM TriVantage EMG Endotracheal Tube</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/03/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/03/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/03/2013</td>
<td>IMMULITE 2500 IGF-I (An in vitro diagnostic medical device (IVD))</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>Hospital</td>
</tr>
<tr>
<td>14/03/2013</td>
<td>ML 301 Examination Lamp</td>
<td>Medical Device</td>
<td>Recall</td>
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<td>Retail</td>
</tr>
<tr>
<td>13/03/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>13/03/2013</td>
<td>Archer 0.035 inch (0.89mm) Super Stiff Guidewire</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>13/03/2013</td>
<td>D-dimer Test kit for AQT90 Flex (An in vitro diagnostic medical device (IVD) used as an aid in the diagnosis of venous thromboembolism)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>12/03/2013</td>
<td>ConMed Linvatec VP1600 HD Still Capture Image System (Endoscopic video imaging system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/03/2013</td>
<td>IntelliSpace Portal software version 4.0.2 (Used to remotely access data from networked computers for diagnostic viewing) used with URL PACS integration</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>8/03/2013</td>
<td>Aquae Dry Mouth Gel Hypromellose Oral gel 20mg/g</td>
<td>Medical Device</td>
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<td>Class III</td>
<td>Wholesale</td>
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<td>Recall Action Commencement Date</td>
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<tr>
<td>8/03/2013</td>
<td>Artis Zeego systems (angiographic fluoroscopic digital diagnostic x-ray system) with software Artis VC20x/VC21A/VD10x that have a DSA license installed</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/03/2013</td>
<td>Columbia Ultima Bath Chair</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>8/03/2013</td>
<td>ExacTrac versions 6.0.1 and 6.0.2 only (Image Guided Radiation Therapy Patient Positioning System)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/03/2013</td>
<td>ISKD – Intramedullary Skeletal Kinetic Distractor (Limb Lengthener)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/03/2013</td>
<td>LIFEPAK CR Plus and LIFEPAK EXPRESS Automated External Defibrillators (AED)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Retail</td>
</tr>
<tr>
<td>7/03/2013</td>
<td>Switch Point Infinity 3 (SPI3) (Computer Interface)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/03/2013</td>
<td>Technetium-99m Technescan Sestamibi (Compound radioactive dose prepared from a kit as a solution in a syringe for diagnostic imaging)</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/03/2013</td>
<td>TRIATHLON Baseplate Impactor/Extractor (Included in the reusable Triathlon primary or revision knee implantation kits)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/03/2013</td>
<td>Artis Zeego Systems (Fluoroscopic angiographic x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/03/2013</td>
<td>Transpedicular Schanz Screw, 6.2mm with dual core, length 190/45mm. Titanium alloy (TAN), dark blue (Bone screw for internal spinal fixation system)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/03/2013</td>
<td>Brilliance 64, software version 4.0.0.22621 and Ingenuity CT, software version 4.0.0.25621 (Whole body computed tomography x-ray systems)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/03/2013</td>
<td>Maxcem Elite (Dental cement)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
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<tr>
<td>1/03/2013</td>
<td>Bone Fragments - Milled irradiated femoral head</td>
<td>Biological</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>28/02/2013</td>
<td>BiCision (electrosurgical thermofusion and dissection system)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>28/02/2013</td>
<td>Chlorhexidine 0.5% in Alcohol 70%</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Wholesale</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
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<tr>
<td>28/02/2013</td>
<td>Dash 3000/4000/5000 (multiparameter patient monitor)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td></td>
<td>&amp; Dash Port 2 (docking station for Dash 3000/4000/5000)</td>
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<tr>
<td>27/02/2013</td>
<td>All Plum A+ Family of Infusers: Plum A+Single Channel Infusion Pump, Plum A+ and A+3 Infusion Pumps with MedNet Software</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>27/02/2013</td>
<td>All Plum A+ Family of Infusers: Plum A+Single Channel Infusion Pump, Plum A+ and A+3 Infusion Pumps with MedNet Software</td>
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<td>27/02/2013</td>
<td>All Plum A+ Family of Infusers: Plum A+Single Channel Infusion Pump, Plum A+ and A+3 Infusion Pumps with MedNet Software</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td>Hospital</td>
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<tr>
<td>26/02/2013</td>
<td>RaySearch RayStation 3.0 (Radiation treatment planning and analysis software)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/02/2013</td>
<td>Abbott Molecular m 2000sp instrument. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/02/2013</td>
<td>ADEPT 12/14 Modular Head (Used as femoral head component in metal on metal (MoM) total hip arthroplasty)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/02/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/02/2013</td>
<td>Dade Actin FSL Activated Pro Thromboplastin Time (APTT) Reagent. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/02/2013</td>
<td>Drug 4 Cal (KC460) &amp; Drug 4 Cal (KC460A) for use with the Dimension Vista System. In vitro diagnostic medical devices (IVD).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/02/2013</td>
<td>HOYA One-Piece Intraocular Lenses (IOL)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/02/2013</td>
<td>IPAD Defib Pad, CU-CUA0512F (used with I-PAD NF 1200 Defibrillator)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Retail</td>
</tr>
</tbody>
</table>

The TGA publishes Australian recall actions in a searchable database to ensure the public has access to information about therapeutic products that have been recalled from the Australian market. If you are concerned about your health or if you have experienced an adverse event please seek advice from a health professional as soon as possible. Please read all the important information at the beginning of this report.
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</tr>
</thead>
<tbody>
<tr>
<td>22/02/2013</td>
<td>Oxoid Antimicrobial Susceptibility Testing Discs for Gentamicin (CN10). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
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<tr>
<td>22/02/2013</td>
<td>Oxoid Antimicrobial Susceptibility Testing Discs for Norfloxacin (NOR10). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
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</tr>
<tr>
<td>22/02/2013</td>
<td>Restylane SubQ Lidocaine (Used for facial tissue augmentation)</td>
<td>Medical Device</td>
<td>Recall</td>
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</tr>
<tr>
<td>22/02/2013</td>
<td>VITEK 2 60/XL and VITEK 2 Compact systems (In vitro diagnostic medical devices (IVD) used Bacterial identification and antibiotic sensitivity system)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>For Product Correction</td>
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<tr>
<td>22/02/2013</td>
<td>Z Hyalin Multipack and Z Hyalin Plus Multipack</td>
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<td>21/02/2013</td>
<td>FIAB Ultrasound Transmission and IPL Transparent Gel</td>
<td>Medical Device</td>
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<tr>
<td>21/02/2013</td>
<td>Vitrea Enterprise Suite: Vitrea, Vitrea X and VitreaCore (Tool for analysis of diagnostic images)</td>
<td>Medical Device</td>
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<td>For Product Correction</td>
<td>Hospital</td>
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<tr>
<td>20/02/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall</td>
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</tr>
<tr>
<td>20/02/2013</td>
<td>MuscleBack Energy Magnesium Complex 150 g Powder</td>
<td>Medicine</td>
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<tr>
<td>20/02/2013</td>
<td>Oxoid Xpect Legionella Test Kit (R24680), an in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
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<tr>
<td>19/02/2013</td>
<td>Philips HeartStart XL+ Defibrillator / Monitor (manual defibrillator)</td>
<td>Medical Device</td>
<td>Recall</td>
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<tr>
<td>18/02/2013</td>
<td>Enzymatic Creatinine (EZCR) Flex Reagent Cartridge &amp; Phosphorus (PHOS) Flex Reagent Cartridge for use on the Dimension Clinical Chemistry System. In vitro diagnostic medical devices (IVDs)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>For Product Correction</td>
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<tr>
<td>18/02/2013</td>
<td>Kinevac (sincalide for injection) 5mcg (5mL vial)</td>
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<td>Recall</td>
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<tr>
<td>15/02/2013</td>
<td>Bone Unprocessed - Whole femoral head non-irradiated allograft</td>
<td>Biological</td>
<td>Hazard Alert</td>
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<tr>
<td>15/02/2013</td>
<td>KWIQ-QC Acid Fast Stain Slides (Microbiology quality control slides). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
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<tr>
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<tr>
<td>15/02/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
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<tr>
<td>15/02/2013</td>
<td>Vitrea Enterprise Suite : Vitrea, VitreaAdvanced, VitreaCore (VitalConnect) and Vitrea fx (Tool for analysis of diagnostic images)</td>
<td>Medical Device</td>
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<tr>
<td>14/02/2013</td>
<td>CLOPIDOQREL RBX clopidogrel (as hydrogen sulfate) 75 mg tablets</td>
<td>Medicine</td>
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<tr>
<td>13/02/2013</td>
<td>LifeCycle for Prenatal Screening, software versions V3.0, v3.1, v3.2, v4.0. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
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<tr>
<td>12/02/2013</td>
<td>Artis Zee/Zeego Systems equipped with A 100 plus generator (Fluoroscopic angiographic digital x-ray system)</td>
<td>Medical Device</td>
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<tr>
<td>12/02/2013</td>
<td>Monaco, Release 3.20.00 - 3.20.01 (Radiation Treatment Planning System)</td>
<td>Medical Device</td>
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<tr>
<td>11/02/2013</td>
<td>Deep Brain Stimulation (DBS) Leads (implantable, neurological electrode stimulator)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>11/02/2013</td>
<td>SureSigns Patient Monitors, Model VS2+</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>8/02/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<td></td>
</tr>
<tr>
<td>8/02/2013</td>
<td>Iconos R200 C20, Iconos R200 T20, Iconos R100, Iconos RHD, Luminos RF Classic, Luminos Fusion, Luminos Select (Fluoroscopic diagnostic x-ray systems)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
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<tr>
<td>7/02/2013</td>
<td>Allura Xper FD20 Biplane / FD20 Biplane OR table (Fluoroscopic angiographic digital x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I Hospital</td>
<td></td>
</tr>
<tr>
<td>7/02/2013</td>
<td>Ceramic Insertion Tool Assembly (Supplied as part of the reusable orthopaedic surgical procedure kit)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I Hospital</td>
<td></td>
</tr>
<tr>
<td>6/02/2013</td>
<td>Reflotron Hb Test Strips, an in vitro diagnostic medical device (IVD) intended for the quantitative measurement of haemoglobin in venous blood samples</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
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</tr>
<tr>
<td>6/02/2013</td>
<td>UniCel DxI 800 Access Immunoassay Systems, UniCel DxI 600 Access Immunoassay Systems, UniCel DxC 660i, 680i, 860i, 880i SYNCHRON Access Clinical System. In vitro diagnostic medical devices (IVDs)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/02/2013</td>
<td>MAQUET Heart Lung Machine - HL30 (Heart-lung bypass system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/02/2013</td>
<td>Medtronic Navigation O-Arm Imaging System (Digital fluoroscopic diagnostic portable x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/02/2013</td>
<td>Eclipse Treatment Planning System, (Radiation therapy treatment planning system), version 11</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/02/2013</td>
<td>Berman Angiographic Balloon Catheters</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/02/2013</td>
<td>FCR Go 2 (FCR-MB201) X-Ray System (Digital general purpose mobile diagnostic x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/02/2013</td>
<td>Fenwal Transfer Pack 150ml with spike coupler (Blood collection/cell-culture container)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>1/02/2013</td>
<td>Gambro Conventional Bloodlines: BL200 BD Pre Post, BL208 BD &amp; BL223PB (dialysis/haemodialysis tubing set)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>31/01/2013</td>
<td>Artis Zee Systems equipped with a card collimator</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>31/01/2013</td>
<td>HeartStart Automated External Defibrillator (AED)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Retail</td>
</tr>
<tr>
<td>31/01/2013</td>
<td>ISOLINE 2CR6 and 2CT6 Implantable Defibrillation Leads</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>31/01/2013</td>
<td>Level 1 Fast Flow Fluid Warmers with and without Air Detection</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/01/2013</td>
<td>AcroMetrix PeliSpy Sero Control Type 36 and Type 38. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/01/2013</td>
<td>Apex (Multileaf collimator used with Elekta linear accelerators)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/01/2013</td>
<td>ACUSON S2000 Automated Breast Volume Scanner (ABVS)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
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</tr>
<tr>
<td>29/01/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>25/01/2013</td>
<td>Clopine Suspension - Clozapine 50mg/ml 100ml bottle</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>25/01/2013</td>
<td>Hand Switch for Electric Pen Drive (electrical drive for use with a range of surgical attachments)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/01/2013</td>
<td>Razit 20 rabeprazole sodium 20mg enteric coated tablets blister pack of 28's</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>25/01/2013</td>
<td>Venti and Discovery NM 530c (Full body computed tomography (CT) system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>25/01/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/01/2013</td>
<td>Confidence Spinal Cement System 11cc Plus Kit, Confidence Spinal Cement System Kit</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/01/2013</td>
<td>Corneal Grafts</td>
<td>Biological</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/01/2013</td>
<td>Medtronic Adrian Symplicity Catheter System</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/01/2013</td>
<td>Mizuho OSI 5855 Orthopedic Table Top</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/01/2013</td>
<td>VITROS Vapor Adsorption Cartridge. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/01/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/01/2013</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
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</thead>
<tbody>
<tr>
<td>8/01/2013</td>
<td>ARCHITECT Testosterone Reagent, ARCHITECT Testosterone Calibrators and ARCHITECT Testosterone Controls. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/01/2013</td>
<td>BBL Crystal Enteric/Non-fermenter ID Kit, An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/01/2013</td>
<td>Giraffe Incubator and Giraffe OmniBed with Servo Oxygen Control System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/01/2013</td>
<td>QHVB Pulmonary Allograft Conduit (Human cardiovascular tissue)</td>
<td>Biological</td>
<td>Hazard Alert</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/01/2013</td>
<td>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</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/01/2013</td>
<td>Quadra Trial Broach size 0</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/01/2013</td>
<td>Bunnell Life Pulse Patient Circuits (Used with Life Pulse High Frequency Ventilator)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>4/01/2013</td>
<td>Plum A+ Infusion Pump; Plum A+ Infusion Pump with Hospital MedNet Software; Plum A+3 Infusion Pump with Hospital MedNet Software</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>2/01/2013</td>
<td>4&quot; Goldvac UltraClean Blade, Single Use ABC Needle, 1&quot; UltraClean Needle &amp; Blade with extended insulation and 6&quot; UltraClean Blade (Electrosurgical system electrodes &amp; accessories)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>2/01/2013</td>
<td>A.5650.5 LEM non-sterile haemorrhoid suction bander and Latex gravorings</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>24/12/2012</td>
<td>ADVIA Centaur and ADVIA Centaur XP HBsAg II Assay. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/12/2012</td>
<td>AutoTac Delivery Handle 400-200 and AutoTac Titanium Tack Starter Kit 400-270 (Dental membrane fixation kit)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>24/12/2012</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/12/2012</td>
<td>ELS Cannulae (Part of intravenous catheterisation kit)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
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<tr>
<td>24/12/2012</td>
<td>Fill-In Refill A1 and A2 (temporary crown/bridge)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>24/12/2012</td>
<td>Lumenis VersaCut Tissue Morcellator (soft tissue extraction)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/12/2012</td>
<td>Nobel Replace CC NP 3.5 x 10mm implant (Dental Implant Endosseous)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>24/12/2012</td>
<td>Urinary Catecholamines by HPLC Reagent Kits, Automated Method on Gilson ASPEC. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/12/2012</td>
<td>A3/A5 Anesthesia Delivery System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/12/2012</td>
<td>Cook Medical Zilver PTX Drug-Eluting Peripheral Stent (peripheral artery stent)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/12/2012</td>
<td>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.</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class I</td>
<td>Retail</td>
</tr>
<tr>
<td>20/12/2012</td>
<td>Dimension Clinical Chemistry System, Total Iron Binding Capacity. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/12/2012</td>
<td>Animas 2020 Insulin Infusion Pumps (ambulatory infusion pump)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Consumer</td>
</tr>
<tr>
<td>19/12/2012</td>
<td>cobas Product System Manager (PSM) (Analyser software), all versions. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/12/2012</td>
<td>Liaison Biotrin Parvovirus B19 IgM (testing kit). An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/12/2012</td>
<td>MobileDiagnost wDR (digital diagnostic X-ray imaging system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>18/12/2012</td>
<td>SYNCHRON Systems Glucose (GLU) cartridge Reagent. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/12/2012</td>
<td>AU5800 Clinical Chemistry Analyzer, software versions 4.05 and prior. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>17/12/2012</td>
<td>LSX Files, 25mm (Powered endodontic rasp)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
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<tr>
<td>14/12/2012</td>
<td>Belmont Instrument Corporation Rapid Infuser (high flow, warming infusion pump).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I Hospital</td>
</tr>
<tr>
<td>14/12/2012</td>
<td>NARDIL phenelzine 15mg (as sulphate) 100 tablet bottle</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III Wholesale</td>
</tr>
<tr>
<td>14/12/2012</td>
<td>UCFP Flex Reagent Cartridge (Urinary / Cerebrospinal fluid protein assay) used with Dimension Vista Systems. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III Hospital</td>
</tr>
<tr>
<td>13/12/2012</td>
<td>Philips IntelliVue Information Centre and Philips IntelliVue Information Centre IX (Central patient monitor unit)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I Hospital</td>
</tr>
<tr>
<td>10/12/2012</td>
<td>ARCHITECT Active-B12 (Holotranscobalamin). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
</tr>
<tr>
<td>10/12/2012</td>
<td>Oxoid Anti-microbial Susceptibility Testing Disc for Nitrofurantoin. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II Hospital</td>
</tr>
<tr>
<td>7/12/2012</td>
<td>ARIA Radiation Oncology System (information system), versions: 11.0 below 11.0.55, Build 11.02.28 and 11.0.34</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I Hospital</td>
</tr>
<tr>
<td>7/12/2012</td>
<td>Corpuls Defibrillator (Automated defibrillator). Software version 2.0.0 and 2.0.2</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I Retail</td>
</tr>
<tr>
<td>7/12/2012</td>
<td>DigitalDiagnost (Digital diagnostic X-Ray System). All systems with Eleva software version 3.0.x</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
</tr>
<tr>
<td>7/12/2012</td>
<td>Radiometer TCM4 series analyser base units (Transcutaneous and non invasive blood gas analysers)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I Hospital</td>
</tr>
<tr>
<td>7/12/2012</td>
<td>X-Ray detectable tracer thread included on patient swab / bandage (swabs are included in Sterile Suture, Catheter and Lumbar Puncture Kits)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II Hospital</td>
</tr>
<tr>
<td>6/12/2012</td>
<td>DBB-06, DBB-07 Haemodialysis Device (haemofiltration dialysis unit)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I Hospital</td>
</tr>
<tr>
<td>6/12/2012</td>
<td>DigitalDiagnost (Digital diagnostic X-Ray System) with software version 2.0.2 and 2.0.2SP1</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
</tr>
<tr>
<td>6/12/2012</td>
<td>MagNA Pure 96. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
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<tr>
<td>5/12/2012</td>
<td>AMH Gen II ELISA (clinical chemistry substrate, Anti-Mullerian Hormone assay). An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>5/12/2012</td>
<td>Crutches - Forearm Ergo Grip Tall and Forearm Ergo Grip Adult (one arm, walking aid crutch)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>5/12/2012</td>
<td>DualHemo Mcable for use with the Infinity Acute Care System (IACS) (Patient monitoring system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>5/12/2012</td>
<td>Siroclave Dental Sterilisers (moist heat autoclave)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>4/12/2012</td>
<td>TumorLOC (intensity projection dataset software) use with: Brilliance CT Big Bore, EBW, GEMINI LXL, GEMINI TF 16, GEMINI TF 64 &amp; GEMINI TF Big Bore (radiology systems)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>4/12/2012</td>
<td>Vatech X-Ray System, models: Pax-500, Pax-Uni3D, pax-Reve3D and Duo3D and Picasso 3D (Dental x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>4/12/2012</td>
<td>Z Hyalin Multipacks and Z Hyalin Plus Multipacks (aqueous/vitreous (eye) humour replacement medium kit)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>3/12/2012</td>
<td>Coverstainer Slide Rack (automated staining instrument). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>3/12/2012</td>
<td>Liko Sabina and Capella Sit-to-Stand Mobile Lifts</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>30/11/2012</td>
<td>Artis Zeego Systems (Fluoroscopic diagnostic x-ray system for angiographic procedures) with SW revision VC14, VC20 &amp; VC21 in conjunction with a specific technical configuration</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>30/11/2012</td>
<td>IH-Com Kit Full version (Data management and Result Interpretation Software for ABO blood grouping). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>30/11/2012</td>
<td>Velcade 1mg powder for injection (VELCADE bortezomib 1mg powder for injection vial)</td>
<td>Medicine</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>29/11/2012</td>
<td>Advanced Perfusion System 1 (heart-lung bypass machine)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>29/11/2012</td>
<td>Welch Allyn Schiller AG 1500 Monitor (multi parameter patient monitor)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
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<tr>
<td>28/11/2012</td>
<td>Clinical Chemistry Phenobarbital Reagent. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>28/11/2012</td>
<td>DigitalDiagnost (Digital diagnostic X-Ray System) All systems with Eleva software version 2.1.3</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>28/11/2012</td>
<td>ENSEAL G2 Curved and Straight Tissue Sealer Devices (used in endoscopic procedures)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>28/11/2012</td>
<td>Phenobarbital Reagent (used with ADVIA Chemistry System). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>27/11/2012</td>
<td>2.7mm Self-Tapping Cortex Screw (internal fixation device)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>27/11/2012</td>
<td>Active Knee System - Patella Insert (Used as a component in total knee replacement)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
</tr>
<tr>
<td>27/11/2012</td>
<td>DR0850M, Oxoid Staphytect plus 100 tests (used for the identification of Staphlococcus aureus). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>26/11/2012</td>
<td>Ardis Inserter (intended for delivery of the Ardis interbody spacer into the prepared disc space)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>23/11/2012</td>
<td>Brilliance 64 system with software version 4.00xx516 and Ingenuity CT system running software version 4.00xx518 (full body CT systems)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>23/11/2012</td>
<td>GlideScope Video Laryngoscope Blades GVL3, GVL4 and GVL5 (used for intubation)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
</tr>
<tr>
<td>23/11/2012</td>
<td>Replace Select Tapered TiU RP 4.6x16mm (fully imbedded dental implant)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
</tr>
<tr>
<td>23/11/2012</td>
<td>Table pallet for use with Discovery NM/CT 670 &amp; Discovery NM630 (Diagnositc full body CT X-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>22/11/2012</td>
<td>Alaris GP Large Volumetric Pump (general purpose infusion pump)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>22/11/2012</td>
<td>Biomet 2.5MM offset tibial tray adaptor (tibial component of knee joint prosthesis)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
</tr>
<tr>
<td>22/11/2012</td>
<td>Coffee Shape Slimming Green Coffee</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
</tr>
</tbody>
</table>

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<thead>
<tr>
<th>Recall Action Commencement Date</th>
<th>Product Name/Description</th>
<th>Type of Product</th>
<th>Recall Action</th>
<th>Recall Action Classification</th>
<th>Recall Action Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>22/11/2012</td>
<td>MEDRAD Avanta Hand Controller Sheath (multi-phase contrast medium injection system)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>22/11/2012</td>
<td>Steris Reliance 130L Cart Washer (decontamination washer utensil)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/11/2012</td>
<td>Amvisc Plus 0.8mL (Aqueous/vitreous humour replacement medium (eye))</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/11/2012</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/11/2012</td>
<td>Immulite / Immulite 1000 XPi IGF-1 and Immulite 2000 / Immulite 2000 XPi IGF-1. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/11/2012</td>
<td>MOBICATH Bi-Directional Guiding Sheath, small curve (used to introduce cardiovascular catheters)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/11/2012</td>
<td>Nihon Kohden Defibrillator (semi-automated defibrillator)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/11/2012</td>
<td>Adult Circuit Tubing (Oxygen therapy delivery system)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/11/2012</td>
<td>&quot;PROFEMUR R&quot; PROX BODY PLASMA SPRAYSTD3 (femoral component of a hip joint prosthesis)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/11/2012</td>
<td>ACL ELITE, ACL ELITE PRO, ACL 8000, ACL 9000 and ACL 10000 (coagulation analysers)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>15/11/2012</td>
<td>A-dec 200 Dental Chair (examination chair)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>15/11/2012</td>
<td>SonoSite NanoMaxx Ultrasound System, version 60.80.101.025</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
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<tr>
<td>14/11/2012</td>
<td>Rayner T-Flex Aspheric 623T Intraocular Lens (Posterior chamber intraocular lenses)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Wholesale</td>
</tr>
<tr>
<td>14/11/2012</td>
<td>YUNO Extension Device (used to support and stabilise the patient's body during a surgical procedure)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/11/2012</td>
<td>DRX-1 System Console (radiation therapy digital imager)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/11/2012</td>
<td>VIPER 8, 9 &amp; 10mm Large Diameter Polyaxial Screws, Lengths 70, 80 &amp; 100 mm (To provide immobilisation and stabilisation of spinal segments in the treatment of instabilities or deformities of the thoracic, lumbar, and sacral spine)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/11/2012</td>
<td>VITROS Chemistry Products HPT Reagent. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/11/2012</td>
<td>Access hLH Calibrators used with Access Immunoassay Systems. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/11/2012</td>
<td>Mammmomat Inspiration (diagnostic mammography X-Ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>9/11/2012</td>
<td>AU5800 diluted detergent tank used with AU5800 Clinical Chemistry Analyser. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/11/2012</td>
<td>ADVIA Centaur/Centaur XP/ Centaur CP HbcTotal (HbcT) Kits. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/11/2012</td>
<td>Micro Curved Attachment (MCA) and MCA Cutting Burrs (Intended for use in delicate bone in otologic (ear) procedures such as cochleostomy)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/11/2012</td>
<td>Multiple assays used with ADVIA Centaur, ADVIA Centaur XP, ADVIA Centaur CP Systems: Theophylline 2, Procalcitonin, Folate, DHEA-SO4, 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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/11/2012</td>
<td>Spacelabs Healthcare Qube Compact Monitor (Multi parameter transportable patient monitor)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/11/2012</td>
<td>STERRAD CYCLESURE 24 Biological Indicators (sterilisation process indicator)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
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<tr>
<td>6/11/2012</td>
<td>Haag-Streit International - Tonometer Measuring Prisms (an ophthalmic device used to measure eye ocular pressure/tension).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Retail</td>
<td></td>
</tr>
<tr>
<td>5/11/2012</td>
<td>BioPlant Curved Syringe, multiple doses, BioPlant Intro Pack (synthetic dental bone grafts)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Retail</td>
<td></td>
</tr>
<tr>
<td>2/11/2012</td>
<td>PAD 300/PAD 300P Public Access Defibrillators (PAD) (Semi-automated defibrillator)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I Retail</td>
<td></td>
</tr>
<tr>
<td>1/11/2012</td>
<td>Cobas 8000 Patient sample and control recovery on Cobas c 701/702 modules (clinical chemistry analyser). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>1/11/2012</td>
<td>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).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>1/11/2012</td>
<td>Dimension Vista ALP Calibrator (clinical chemistry enzyme). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III Hospital</td>
<td></td>
</tr>
<tr>
<td>1/11/2012</td>
<td>Lactate membrane for ABL700 series and ABL800 series blood gas analysers (Part 942-066, D7077) . An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>31/10/2012</td>
<td>Cordis ExoSeal Vascular Closure Device (femoral artery compression device)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>31/10/2012</td>
<td>FlexiView 8800 Mobile C-Arms (Mobile, general-purpose, diagnostic, fluoroscopic x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>31/10/2012</td>
<td>HeartWare Sterile Surgical Tool Sets (Supplied as part of the HeartWare Ventricular Assist System, artificial heart (HVAS))</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III Hospital</td>
<td></td>
</tr>
<tr>
<td>31/10/2012</td>
<td>OEC 6800 MiniView C-arms (Mobile, general-purpose, diagnostic, fluoroscopic x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>31/10/2012</td>
<td>SureSafe Wraps and Drapes</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>30/10/2012</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I Hospital</td>
<td></td>
</tr>
</tbody>
</table>

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<tr>
<td>30/10/2012</td>
<td>Liquid Assayed Multiquant Premium (multi analyte control material). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/10/2012</td>
<td>OriGen Syringe DMSO (Used for Research Use Only)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/10/2012</td>
<td>Encore 26 Advantage Kit &amp; Encore 26 Advantage Kit, 5 pack (Used to perform general intravascular procedures)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/10/2012</td>
<td>Essenta DR Compact (Digital diagnostic X-Ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/10/2012</td>
<td>Monitore B20 or B40 Software version VSP-A. 1.10 (or earlier) (Multiparameter Patient Monitor)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/10/2012</td>
<td>Muscletech Hydroxystim 3s, 18s, 110s and 200s Capsules</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class I</td>
<td>Consumer</td>
</tr>
<tr>
<td>29/10/2012</td>
<td>Nihon Kohden Defibrillator CardioLife, Model Number: TEC 5521 &amp; 5531 (Semi-automated defibrillator)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/10/2012</td>
<td>Jurlique Grapefruit Essential Oil 10mL</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>26/10/2012</td>
<td>SS500 Hi-Lo Bed (General Purpose Bed)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>24/10/2012</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/10/2012</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/10/2012</td>
<td>CT0034B Nitrofurantoin 100ug F100 Antimicrobial Susceptibility Discs. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/10/2012</td>
<td>GE Corometrics Owik Connect Plus Spiral Electrodes (single use electrodes used for electrocardiographs)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/10/2012</td>
<td>ORT100 Neurosurgical Table (for Intra-operative MRI Suites)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
</tbody>
</table>
## System for Australian Recall Actions

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<table>
<thead>
<tr>
<th>Recall Action Commencement Date</th>
<th>Product Name/Description</th>
<th>Type of Product</th>
<th>Recall Action Classification</th>
<th>Recall Action Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>23/10/2012</td>
<td>PSX Proximate Skin Staple Extractor (staple remover)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>23/10/2012</td>
<td>Resuscitation Systems with blender field upgrade installed in GE Giraffe and Panda Warmers (infant radiant warmer)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>23/10/2012</td>
<td>syngo WorkFlow SLR (Radiology workflow software). Product versions: VA31A SP1, VA31A SP2 &amp; VA31A SP3</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>22/10/2012</td>
<td>BacT/ALERT 3D B.40.xx Firmware (Automated blood culture incubator/growth detector). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>22/10/2012</td>
<td>Elecsys Thyroglobulin assay used with the Elecsys Modular Analytics analysers An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>22/10/2012</td>
<td>Quantiferon (QFT) Gold Tubes, QFT Gold Untised Pack, TB Ag Tubes 100ct, QFT Gold Tubes (Nil &amp; TB &amp; Mitogen) High Altitude. An in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>22/10/2012</td>
<td>Various mass spectrometers - Quattro micro, ACQUITY TQD, Quattro Premier XE, Xevo TQ; In vitro diagnostic medical devices (IVD's)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>19/10/2012</td>
<td>Blooms Melt (weight loss formula), 60 Vege Capsules</td>
<td>Medicine</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
</tr>
<tr>
<td>18/10/2012</td>
<td>Apex K2 Modular Hip Replacement System (total joint prosthesis)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
</tr>
<tr>
<td>18/10/2012</td>
<td>MOSAIQ (Radiation Oncology Information System). All releases pre version 2.41</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>16/10/2012</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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<tr>
<td>16/10/2012</td>
<td>StreamLAB Automation Solutions (Clinical Chemistry Sample Processors). An in-vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>11/10/2012</td>
<td>Canon CXDI-70C Wireless and CXDI-80C Wireless (Computed Radiographic System)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
</tr>
<tr>
<td>11/10/2012</td>
<td>DigitalDiagnost (Digital Diagnostic X-ray System)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
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<tr>
<td>11/10/2012</td>
<td>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 not intrinsic to the stability of the bony structure)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
</tr>
<tr>
<td>11/10/2012</td>
<td>Plum A+ Pump Version 11.6 and Plum A+ Pump Version 13.4 Med Net ABG Driver (general purpose infusion pump)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>11/10/2012</td>
<td>Zoo Pack Elastics Master Pack 2E 3/16 Hvy Kangaroo (Orthodontic elastic bands)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
</tr>
<tr>
<td>10/10/2012</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
</tr>
<tr>
<td>10/10/2012</td>
<td>IMMULITE 2000 / IMMULITE 2000 XPI ACTH Control module (Used for the detection of Adrenocorticotropic hormone). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
</tr>
<tr>
<td>10/10/2012</td>
<td>INFANRIX HEXA injection composite pack (pre-filled syringe and vial)</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>10/10/2012</td>
<td>Mobile Detector Holder for DigitalDiagnost System (Digital diagnostic x-ray System). Models: Single Detector, Dual Detector, Release 3</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
</tr>
<tr>
<td>10/10/2012</td>
<td>Siemens AX System (Digital fluoroscopic x-ray system) fitted with MAVIG PORTEGRA 2 System (Radiation protection system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>5/10/2012</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>4/10/2012</td>
<td>Cancellous Bone Impactor 6.0mm, Flattened (Supplied as part of the bone internal fixation system implantation kit)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>4/10/2012</td>
<td>Durom Acetabular Component (Used for metal on metal hip replacements)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
</tr>
<tr>
<td>4/10/2012</td>
<td>Surecan Angled Needle (Non-coring needle for access ports)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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<tr>
<td>4/10/2012</td>
<td>Triathlon CR/PS Inserts &amp; ASYM Patella, Brunswick Captive Cemented Cup, Avon Patella Medium &amp; Patella Femoral Joint, HMRS Humerus Bearing, MRH Bumper Neutral/3 Degrees &amp; Tibial Inserts, Scorpio CR Tibial Insert &amp; Medialised Patella, Duracon PCA Femoral, Patella &amp; Constrain Inserts, Scorpio PS Tibial &amp; Flex PS/+PS/+PCS Inserts (total knee, hip, shoulder components) and Artisan Bone Plug</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>4/10/2012</td>
<td>Typhim Vi Vaccine 25ug/0.5mL Solution for Injection (Salmonella typhi Vi polysaccharide)</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
</tr>
<tr>
<td>3/10/2012</td>
<td>Brilliance CT Big Bore with Software Versions 2.4.7 or 2.4.8 (Full body CT system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>3/10/2012</td>
<td>Dimension Vista IRON Flex reagent cartridge. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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<tr>
<td>3/10/2012</td>
<td>Spring Arm (Intended for use as a ceiling mounted device to support or position equipment in the patient area)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>2/10/2012</td>
<td>Birmingham Hip Modular Head (Used as part of a Total Conventional Hip Replacement system)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
</tr>
<tr>
<td>2/10/2012</td>
<td>HLS Cannulae (Used for the cannulation of suitable vessels during extra corporeal circulation as inflow or outflow cannula)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>28/09/2012</td>
<td>Hospira LifeCare 4200 Patient-Controlled Analgesia (PCA) Infuser, PCA with MedNet Software Infusers (general purpose infusion pump).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>28/09/2012</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
</tr>
<tr>
<td>27/09/2012</td>
<td>MX 16-Slice (Full body CT system) oil accumulator within gantry</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>27/09/2012</td>
<td>TempSpan CMT (Temporary composite dental cement)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
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<tr>
<td>26/09/2012</td>
<td>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</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>26/09/2012</td>
<td>BD MAX (6 channel) Instruments (Automated specimen preparation and PCR amplification/detection instrument). An in-vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>26/09/2012</td>
<td>HeartStart XL Defibrillator Battery / Monitor, model M3516A (manual defibrillator).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
</tr>
<tr>
<td>26/09/2012</td>
<td>IMMULITE /IMMULITE 1000 Osteocalcin Control Module (Clinical chemistry hormones). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>26/09/2012</td>
<td>Spectra Optia Apheresis System</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>25/09/2012</td>
<td>Osseotite NT Certain Implant 5mm x 10mm (endosseous dental implant)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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<tr>
<td>25/09/2012</td>
<td>VenoCath Drum Cartridge Catheter (intravascular catheter)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
</tr>
<tr>
<td>24/09/2012</td>
<td>Standard Cranial Reference Array (used with Vector Vision Cranial Navigation System)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
</tr>
<tr>
<td>21/09/2012</td>
<td>Bolton Surgical - Sims Speculum D/E Insulated Large 33 x 38 mm 18.5cm</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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<tr>
<td>21/09/2012</td>
<td>Brilliance CT 6, 16, MX8000 v. EXP and GEMINI Dual Oil Accumulator within the Gantry (combination diagnostic imaging system (PET/CT)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
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<tr>
<td>21/09/2012</td>
<td>Invacare I-Fit Shower Chair</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
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<tr>
<td>21/09/2012</td>
<td>Sorin SS/C5 Perfusion System: SS Single Roller Pump 150 and SS Double Roller Pump 85 (Heart-lung Bypass System)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
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<tr>
<td>21/09/2012</td>
<td>Zimmer A.T.S. 3000 Automatic Tourniquet System (used to temporarily occlude blood flow during surgery)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
</tr>
<tr>
<td>20/09/2012</td>
<td>Patient Labels for Zimmer orthopaedic implants manufactured prior to March 2010.</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
</tr>
</tbody>
</table>

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<tr>
<td>20/09/2012</td>
<td>SIFROL (pramipexole HCl) Tablets 0.125mg 30's, SIFROL (pramipexole HCl) Tablets 0.25mg 100's, SIFROL (pramipexole HCl) Tablets 1mg 100's</td>
<td>Medicine</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>20/09/2012</td>
<td>Soft-Core Obturators (Warm bonded endodontic obturation system obturator)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>19/09/2012</td>
<td>Genscreen HIV Ag/Ab Ultra. An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/09/2012</td>
<td>Patient Specific Active Medication Rolls containing SERENACE 0.5mg Tablets</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class I</td>
<td>Consumer</td>
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<tr>
<td>14/09/2012</td>
<td>Flex Large 4 Coil for MAGNETOM Skyra, Verio, Spectra and Biograph mMR (Full body MRI System)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/09/2012</td>
<td>INHALO CD Cylinder (Medical oxygen), Product Code: 400CD</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/09/2012</td>
<td>SPIRALOK Anchors (suture anchors used to reattach soft tissue to bone in orthopaedic surgery)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/09/2012</td>
<td>Stellaris PC Vision Enhancement System (Cataract Extraction/Vitrectomy System)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/09/2012</td>
<td>SureSigns VSi/VS2 Patient Monitors (multparameter patient monitor)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>13/09/2012</td>
<td>B. Braun Infusomat Space Infusion System (infusion pump)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/09/2012</td>
<td>Serenate (haloperidol) 0.5mg tablet bottle</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class I</td>
<td>Consumer</td>
</tr>
<tr>
<td>12/09/2012</td>
<td>Arthrex and Andreas Hettich Rotofix 32A Centrifuge, An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/09/2012</td>
<td>Immulite 2000, 2000 Xpi EBV-EBNA IgG Assay; An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/09/2012</td>
<td>V60 Non Invasive Ventilators (adult mechanical ventilator)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/09/2012</td>
<td>ClearLink System BURETROL Solution Set with 150ml ClearLink Burette (Ball-Valve Drip Chamber) (Administration sets for the infusion of intravenous solutions and blood)</td>
<td>Medical Device</td>
<td>Recall</td>
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<tr>
<td>7/09/2012</td>
<td>Eclipse Treatment Planning System, (radiation therapy treatment planning system). Versions: 8.9 and 10</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>7/09/2012</td>
<td>GH3 Lifting Hanger (patient lift)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>6/09/2012</td>
<td>Mystic Pump with M-Style Mushroom Cup, Pack Size 1</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>6/09/2012</td>
<td>Remel Xpect Clostridium difficile Toxin A/B. An vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>5/09/2012</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>5/09/2012</td>
<td>Multiple Topiramate Sandoz 60 HDPE tablet bottle, various concentrations</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
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<tr>
<td>5/09/2012</td>
<td>Octagam 10% 20g/200mL Human Normal Immunoglobulin (solution for intravenous infusion)</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/09/2012</td>
<td>Water Filters on Cavitron Scalers and Air Polishing Units (ultrasonic peridontic scaler)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>4/09/2012</td>
<td>Brilliance 6, 10, 16, 40, 64 and Brilliance CT Big Bore Systems with a Multifunction Footswitch (Full body CT diagnostic system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/09/2012</td>
<td>DBL Irinotecan hydrochloride injection via 100mg/5ml</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/09/2012</td>
<td>Integra CT-compatible Intubation Head Ring Assembly (HRAIM), (used to stabilise the head during an imaging procedure) Catalogue Number : HRAIM</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/09/2012</td>
<td>Mahurkar Acute Lumen Catheters, labelled with Non-DEHP Symbol. (Closed loop, haemodialysis catheter)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>3/09/2012</td>
<td>PREVI Isola System. An in vitro diagnostic medical device (IVD)</td>
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<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/09/2012</td>
<td>Timesco Laryngoscope Handle Contact Discs (used in intubation procedures)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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</tr>
<tr>
<td>31/08/2012</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>31/08/2012</td>
<td>ADVIA Centaur and ADVIA Centaur XP (Immuno-assay analysers). An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/08/2012</td>
<td>Affinity Four Birthing Bed</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/08/2012</td>
<td>Clear Canal (ear wax removal kit)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>30/08/2012</td>
<td>Low Profile Abutment Hexed Castable Cylinder, Model LPCCC1</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/08/2012</td>
<td>Spacelabs Healthcare Integrated Module Housing (Used for accommodating additional modules to the patient monitor whenever needed)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/08/2012</td>
<td>Surecan Safety II (Needles with special bevel for implantable access ports).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>29/08/2012</td>
<td>Sharpoint IQ Geometry Slit Knives (Ophthalmic surgical implement intended to make precise incisions in eye tissue)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>28/08/2012</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>28/08/2012</td>
<td>Syntel Vascular Catheters and Syntel Biliary Catheters (embolectomy catheter)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>27/08/2012</td>
<td>Canon CXDA - 70C Wireless Computed radiographic system</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/08/2012</td>
<td>BiCNU (Carmustine 100mg powder vial for IV injection)</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/08/2012</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
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<tr>
<td>23/08/2012</td>
<td>ACTIFUSE ABX Synthetic Bone Substitute (artificial bone graft)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/08/2012</td>
<td>DRX Evolution System (digital diagnostic x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>23/08/2012</td>
<td>Intuitive Surgical Version 12 Tip Cover for 8mm Monopolar Curved Scissors (endotherapy scissors)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>22/08/2012</td>
<td>GUIDELINER Intravascular Guiding Catheter</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
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<tr>
<td>22/08/2012</td>
<td>Thymoglobuline (rabbit anti-human thymocyte immunoglobulin) 25mg Powder for infusion vial</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/08/2012</td>
<td>AEZ Mini Distal Cutter w/ Hold Short (Used to cut archwires during orthodontic treatment)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
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<tr>
<td>21/08/2012</td>
<td>Armada 35 and Armada 35LL percutaneous transluminal angioplasty (PTA) catheter (balloon dilation catheter)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/08/2012</td>
<td>CANESTEN clotrimazole thrush treatment 6 day cream 1% w/w cream tube</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class III</td>
<td>Wholesale</td>
</tr>
<tr>
<td>21/08/2012</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>21/08/2012</td>
<td>Dimension Clinical Chemistry System - Haemoglobin A1c (HbA1c), An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/08/2012</td>
<td>Cavitec (A dental material indicated for use as a cavity liner, eg. pulp capping.)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
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<tr>
<td>16/08/2012</td>
<td>Xia 3 Torque Wrench and Mantis Redux Torque Wrench (Supplied as part of Xia 3 instrument tray)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
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<tr>
<td>14/08/2012</td>
<td>Digital Linear Accelerators fitted with X-ray Volume Imaging (XVI)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/08/2012</td>
<td>Halo Flex Energy Generators (Endotherapy electrosurgical unit)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>14/08/2012</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
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<tr>
<td>14/08/2012</td>
<td>Welch Allyn KleenSpec Disposable Vaginal Speculum</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>13/08/2012</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Consumer</td>
<td></td>
</tr>
<tr>
<td>13/08/2012</td>
<td>Pentax PTX-EG-387UTK Ultrasound Video Gastroscope (flexible gastroduodenoscope)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>13/08/2012</td>
<td>Post Fuse Assembly with Power Wheelchairs (electronic wheelchair)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Consumer</td>
<td></td>
</tr>
<tr>
<td>10/08/2012</td>
<td>Calibrator B from ADVIA Centaur FSH Assay (used with ADVIA Centaur or ADVIA Centaur XP System), An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>10/08/2012</td>
<td>Calibrator B from ADVIA Centaur Prolactin Assay (used with ADVIA Centaur CP System), An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>10/08/2012</td>
<td>Jenx Ltd Headrest Brackets (An externally applied orthopaedic frame for standing).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Consumer</td>
<td></td>
</tr>
<tr>
<td>10/08/2012</td>
<td>L-Gell Ultrasound Transmission Gel – 5ltr &amp; 250mls</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II Retail</td>
<td></td>
</tr>
<tr>
<td>10/08/2012</td>
<td>Lomb Scalpel Blade</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>10/08/2012</td>
<td>PCA Empty Sterile vials with injector. (Intravenous fluid container).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>10/08/2012</td>
<td>Vital Signs Disposable General Purpose 9 French Temperature probes</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I Hospital</td>
<td></td>
</tr>
<tr>
<td>9/08/2012</td>
<td>E1-Tapered 10 degree +3mm Liner 32/39 (hip joint prosthesis, acetabular component)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>9/08/2012</td>
<td>Eon, Eon Mini and Brio Implantable Pulse Generator (IPG) (Implantable Spinal Cord and Deep Brain Stimulators)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class I Hospital</td>
<td></td>
</tr>
<tr>
<td>9/08/2012</td>
<td>NC and RC screw for Cares Abutment, Zr02 and IFU</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II Hospital</td>
<td></td>
</tr>
<tr>
<td>9/08/2012</td>
<td>TempBond NE (temporary dental cement)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III Retail</td>
<td></td>
</tr>
<tr>
<td>8/08/2012</td>
<td>Brilliance 64 and Ingenuity CT systems with software version 4.0.0.xx379 (Full body diagnostic CT X-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I Hospital</td>
<td></td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
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<tr>
<td>8/08/2012</td>
<td>Carescape Monitor B650 (Multiparameter patient monitor)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/08/2012</td>
<td>Carescape Monitor B850, all software versions (multiparameter patient monitor)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/08/2012</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/08/2012</td>
<td>Dash 3000/4000/5000 Patient Monitor with software version 6.0 and later (multiparameter patient monitor)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/08/2012</td>
<td>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</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>8/08/2012</td>
<td>Substrate buffer used with LIFECODES PAK12 and LIFECODES PF41gG Kits, An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/08/2012</td>
<td>ADVIA Centaur HIV 1/O/2 Enhanced (EHIV) reagent kit, An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/08/2012</td>
<td>Agility (An integral beam limiting device used with linear accelerators)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/08/2012</td>
<td>Alaris LVP module (model 8100) (General purpose infusion pump)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/08/2012</td>
<td>Allersearch Economist Forte Nebuliser (non heated nebuliser)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>6/08/2012</td>
<td>Apex Modular Hip Stem Size 4/11.5 (Internal joint prosthesis, femoral component)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/08/2012</td>
<td>ARCHITECT Toxo IgG; An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/08/2012</td>
<td>Cobas 4800 BRAF V600 Mutation Test (acquired genetic alteration IVD), An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/08/2012</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
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</tr>
<tr>
<td>6/08/2012</td>
<td>Innova 2121IQ and Innova 3131IQ Cardiovascular X-Ray Imaging Systems (diagnostic fluorescent angiography x-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/08/2012</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/08/2012</td>
<td>SMR L2 Metal Back Glenoid Component (part of the total shoulder glenoid replacement)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/08/2012</td>
<td>Captura Disposable Biopsy Forceps (endothorpe forces, flexible, single use)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/08/2012</td>
<td>Eon Mini and Brio Implantable Pulse Generators (IPG) (Implantable Spinal Cord and Deep Brain Stimulators)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/08/2012</td>
<td>Essenta DR Compact (General purpose X-ray system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>2/08/2012</td>
<td>Keypad of Alaris LVP module (Component of a general purpose infusion pump); Module Model: 8100</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>30/07/2012</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>27/07/2012</td>
<td>Afinion AS100 Analyser, CRP and CRP Control; An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>27/07/2012</td>
<td>Extrude Wash (Dental impression material)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>27/07/2012</td>
<td>Onyx Liquid Embolic System (LES), (Used for embolization of intracranial aneurysms and lesions in the peripheral and neurovasculature).</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>27/07/2012</td>
<td>syngo Dynamics (Radiology picture archiving and communication system); Version 9.5</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
</tbody>
</table>

The TGA publishes Australian recall actions in a searchable database to ensure the public has access to information about therapeutic products that have been recalled from the Australian market. If you are concerned about your health or if you have experienced an adverse event please seek advice from a health professional as soon as possible. Please read all the important information at the beginning of this report.
<table>
<thead>
<tr>
<th>Recall Action Commencement Date</th>
<th>Product Name/Description</th>
<th>Type of Product</th>
<th>Recall Action</th>
<th>Recall Action Classification</th>
<th>Recall Action Level</th>
</tr>
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<tbody>
<tr>
<td>27/07/2012</td>
<td>syngo Imaging XS (Radiology picture archiving and communication system). Version VA70A or higher</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>27/07/2012</td>
<td>syngo Plaza (Radiology picture archiving and communication system)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/07/2012</td>
<td>GemStar Docking Station (Used as an alternate power source for the GemStar pump and to charge a GemStar battery pack)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>26/07/2012</td>
<td>HemoCue Glucose 201 RT and 201 DM RT Systems. A point of care in vitro diagnostic medical device (IVD).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>24/07/2012</td>
<td>SAIZEN somatropin (rmc) solution for injection multidose cartridge</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>20/07/2012</td>
<td>44R82 Tube Clamp Adapter (Prosthetic component part)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>20/07/2012</td>
<td>AEZ Mini Distal Cutters w/ Hold Long (Used to cut archwires during orthodontic treatment)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>20/07/2012</td>
<td>Animas Insulin Infusion Pump (ambulatory insulin infusion pump), models - IR 2020, 1200</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Consumer</td>
</tr>
<tr>
<td>20/07/2012</td>
<td>Birdie, Birdie Compact and Flamingo Lifters (Patient Lifters)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Consumer</td>
</tr>
<tr>
<td>19/07/2012</td>
<td>4.5mm Dyonics Bonecutter Electroblade (used during arthroscopic procedures for simultaneous soft and osseous tissue resection using mechanical action and coagulation via RF energy)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/07/2012</td>
<td>Brilliance series 6, 16, 40, 64, CT Big Bore, iCT and iCT SP (CT systems)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/07/2012</td>
<td>CSL Rh(D) IMMUNOGLOBULIN VF (human) 250 IU injection vial</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Sponsor</td>
</tr>
<tr>
<td>19/07/2012</td>
<td>Discovery Tray - Child and Small Sizes (A disposable foam tray used for topical oral fluoride applications)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>19/07/2012</td>
<td>Philips HeartStart MRx cardiac monitor / defibrillator, model number: M3536A with R.03.03 software and 12 Lead option (manual defibrillator)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/07/2012</td>
<td>Philips HeartStart MRx cardiac monitor / defibrillator, model numbers: M3535A, M3536A, M3536M4, M3536M5, and M3536M6 (manual defibrillator)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
<td>Product Name/Description</td>
<td>Type of Product</td>
<td>Recall Action</td>
<td>Recall Action Classification</td>
<td>Recall Action Level</td>
</tr>
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</tr>
<tr>
<td>19/07/2012</td>
<td>Philips HeartStart MRx cardiac monitor / defibrillators, models:M3535A, M3536A, M3536J, M3536M, M3536MC, M3536M1, M3536M2, M3536M3, M3536M4, M3536M5 and M3536M6 (manual defibrillator)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/07/2012</td>
<td>Shiley Reusable Cannula Cuffed Tracheostomy Tubes, Product codes: 8FEN, 8LPC, 8LPC-S</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>19/07/2012</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>16/07/2012</td>
<td>GENTECH molybdenum (99Mo) / technetium (99mTc) sterile generator for production of sodium pertechnetate (99mTc) injection multi dose vial (Used to produce metastable isotope99mTc from a decaying Molybdenum-99 bound onto a generator column)</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/07/2012</td>
<td>Bowl Surgical Drape</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/07/2012</td>
<td>Leukine sargramostim (Liquid Injection) 500mcg/mL vial</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>13/07/2012</td>
<td>Mirage, Silverspeed, X-celerator &amp; X-pedion Guidewires, Hyperform &amp; Hyperglide Occlusion Balloon Catheters and Guidewires (Supplied in Procedure Packs)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/07/2012</td>
<td>Alaris PC Unit (General purpose infusion pump)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class I</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/07/2012</td>
<td>CT1133S Cephalexin 100ug CL100 Antimicrobial Susceptibility Discs (Used for antimicrobial susceptibility testing), An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/07/2012</td>
<td>Dimension RxL Reagent Management System (RMS) Power Cord Plug; An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/07/2012</td>
<td>Portapres NiMh battery pack (Device to continuously measure blood pressure)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>12/07/2012</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Hospital</td>
</tr>
<tr>
<td>Recall Action Commencement Date</td>
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<td>Recall Action</td>
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<td>Recall Action Level</td>
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</tr>
<tr>
<td>11/07/2012</td>
<td>AcrySof CACHET Phakic Lens (Intraocular lens used for the reduction or elimination of myopia)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/07/2012</td>
<td>STERRAD 100S System Cassettes (To provide the hydrogen peroxide sterilant used in the STERRAD Steriliser)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>11/07/2012</td>
<td>ULTRA Fabric Reinforced Surgical Gown, X-Large; MICROCOOL Breathable Gown, with SECURE-FIT, with Towel, X-Large</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>6/07/2012</td>
<td>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)</td>
<td>Medical Device</td>
<td>Hazard Alert</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/07/2012</td>
<td>Alginot (dental impression material); All product lots within shelf life</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>5/07/2012</td>
<td>Elekta Monaco rel. 3.10.00 through 3.20.00 &amp; Focal rel. 4.64.00 through 4.70.00 (Radiation Therapy Treatment Planning System)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/07/2012</td>
<td>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)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class III</td>
<td>Retail</td>
</tr>
<tr>
<td>5/07/2012</td>
<td>STERRAD CYCLESURE 24 Biological indicators within Validation Kits - Product codes: 14324, 20253, 20228, 20232 (sterilisation process indicator)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>5/07/2012</td>
<td>Twinfix Ultra Ti Suture Anchor, 5.5mm (used to attach the end or ends of a synthetic or natural ligament to bone)</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>3/07/2012</td>
<td>Matrix Surgical Laparoscopic Spatula with cable (active endotherapy device).</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>2/07/2012</td>
<td>Eclipse Treatment Planning System (Radiation treatment planning system); Version 8.5, 8.6, 8.9, 10 &amp; 11</td>
<td>Medical Device</td>
<td>Recall</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
<tr>
<td>2/07/2012</td>
<td>Laryngoscope Handles (LED) (Item No 08-100) and Laryngoscope Fibre Optic Blades (Item No 08-101)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
</tbody>
</table>
System for Australian Recall Actions

<table>
<thead>
<tr>
<th>Recall Action Commencement Date</th>
<th>Product Name/Description</th>
<th>Type of Product</th>
<th>Recall Action</th>
<th>Recall Action Classification</th>
<th>Recall Action Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>2/07/2012</td>
<td>SEBIFIN terbinafine (as hydrochloride) 250 mg tablet, blister packs of 42 tablets</td>
<td>Medicine</td>
<td>Recall</td>
<td>Class II</td>
<td>Retail</td>
</tr>
<tr>
<td>2/07/2012</td>
<td>VITROS Chemistry Products DGXN Slides; An in vitro diagnostic medical device (IVD)</td>
<td>Medical Device</td>
<td>Recall for Product Correction</td>
<td>Class II</td>
<td>Hospital</td>
</tr>
</tbody>
</table>

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