



IRISH MEDICINES BOARD

FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- DECEMBER 2011

| Product | Manufacturer | Type of Action taken by Manufacturer | FSN Issue Date | Is the Irish market affected? |
|---|--------------------------------|---|------------------|-------------------------------|
| ARCHITECT Cyclosporine | Abbott Laboratories | Advice regarding the use of the device | 23 November 2011 | Yes |
| Lifeguard® trolleys (stretchers) | ArjoHuntleigh | Advice regarding a device modification | 08 December 2011 | Yes |
| Pegasus® Ultra-Lo Low Height Electric Bed Frame | ArjoHuntleigh | Advice regarding changes/updates made to instructions for use | 23 December 2011 | Yes |
| COULTER® LH 780 Analyzer, COULTER® LH 750 Analyzer, COULTER® LH 500 Series System | Beckman Coulter | Advice regarding the use of the device | 30 November 2011 | Yes |
| SYNCHRON System(s) Multi Calibrator Diskette | Beckman Coulter | Advice regarding a device removal | 15 December 2011 | Yes |
| Delta, Delta XL, Vista XL, Gamma XXL and Kappa product | Draeger | Advice regarding a software upgrade | 28 October 2011 | Yes |
| Digital Accelerator | Elekta | Advice regarding a device modification | 14 December 2011 | Yes |
| Dash® 3000/4000/5000 Patient Monitors | GE Healthcare | Advice regarding the use of the device | 08 November 2011 | Yes |
| Senographe 2000D | GE Healthcare | Advice regarding the use of the device | 14 December 2011 | Yes |
| Definium 8000 and Discovery XR650 Patient Barrier | GE Healthcare | Advice regarding a device modification | 21 December 2011 | Yes |
| CardioImmune XL Liquid Assayed Cardiac Marker Control | Microgenics Corporation | Advice regarding a device removal | 14 December 2011 | Yes |
| Diagnostic Ultrasound Endoscope PENTAX EG-3870UTK | Pentax / Hitachi | Advice regarding the use of the device | 10 October 2011 | Yes |
| AXIS and IRIX SPECT systems | Philips | Advice regarding a device modification | 15 November 2011 | Yes |
| therascreen KRAS PCR Kit | Qiagen | Advice regarding a device removal | 26 October 2011 | Unknown |
| syngo®RT Oncologist 4.2 | Siemens | Advice regarding a software upgrade | 06 December 2011 | Yes |
| AXIOM Artis/Artis zee systems | Siemens | Advice regarding a device modification | 22 December 2011 | Yes |
| AXIOM Aristos FX plus Systems | Siemens | Advice regarding a device modification | 14 December 2011 | Yes |
| Clinitest hCG | Siemens Healthcare Diagnostics | Advice regarding a device removal | 19 December 2011 | Yes |
| Graseby MR10 Neonatal Respiration Monitor | Smiths Medical | Advice regarding a device modification | 05 December 2011 | Yes |
| EON Mini and Brio | St Jude Medical | Advice regarding the use of the device | 19 December 2011 | Yes |
| Eon, Eon Mini, and Deep Brain Stimulation Brio Implantable Pulse Generators (IPGs) | St Jude Medical | Advice regarding the use of the device | 19 December 2011 | Yes |
| TRIDENT 10 Degree Poly Inserts | Stryker | Advice regarding a device removal | 21 December 2011 | Yes |
| Rotaflex and Theracare electrically adjustable beds | Theraposture | Advice regarding changes/updates made to instructions for use | 17 August 2011 | Yes |
| Eclipse Treatment Planning Syst | Varian | Advice regarding the use of the device | 01 December 2011 | Yes |
| FrameArray Module (of the Optical Guidance Platform) | Varian | Advice regarding a device modification | 07 December 2011 | Yes |
| Varian Treatment versions 6.6.5034, 6.6.5042, 6.6.5046, 6.6.5048, 6.6.5051 and 6.6.5052 | Varian | Advice regarding the use of the device | 14 December 2011 | Yes |

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| Clinac, Trilogy, Trilogy Tx, and Novalis Tx linear accelerators | Varian Medical Systems | Advice regarding the use of the device | 12 December 2011 | Yes |
| Anchorlok Soft Tissue Anchor | Wright Medical EMEA | Advice regarding a device removal | 23 September 2011 | Yes |