



## IRISH MEDICINES BOARD

## FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- JULY 2012

Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Is the Irish market affected?
Architect iVancomycin Reagent	Abbott Laboratories	Advice regarding the use of the device	21 March 2012	Yes
STERRAD CycleSure 24 Biological Indicator	Advanced Sterilization Products Inc.	Advice regarding a device removal	05 July 2012	Yes
ACRYSOF® CACHET™ Phakic Lens	Alcon Laboratories Inc	Advice regarding changes/updates made to instructions for use	02 July 2012	Yes
Animas Insulin Pump	Animas	Advice regarding the use of the device	16 July 2012	Yes
Volumed µVP7000 Premium, Volumed µVP7000 Classic Plus, Volumed µVP7000 Lite; Syramed µSP6000 Premium, Syramed µSP6000 Classic Plus	Arcomed A.G.	Advice regarding a device modification	07 June 2012	Yes
Pegasus® UltraLo Low Height Electric Bed Frame	ArjoHuntleigh	Advice regarding changes/updates made to instructions for use	19 June 2012	Yes
Minstrel, Minerva, Excelsior, Gemini Patient Lifts	ArjoHuntleigh / Medibo	Advice regarding the use of the device	03 July 2012	Yes
Afinion CRP System	Axis Shield	Advice regarding the use of the device	01 June 2012	Yes
Access Folate Calibrators, PN A14207	Beckman Coulter Inc	Advice regarding a device removal	19 July 2012	Yes
Access Folate Calibrators, PN A98033	Beckman Coulter Inc	Advice regarding a device removal	19 July 2012	Yes
VIDAS EBV VCA-EA IgG	BioMerieux	Advice regarding a device removal	05 July 2012	Yes
CT Asphina 409 MP Lenses	Carl Zeiss Meditec	Advice regarding a device removal	11 July 2012	Yes
Cefndy Healthcare X220 & X221 (including X312 & X313) Bariatric Commodes	Cefndy Healthcare	Advice regarding a device modification	20 February 2012	Yes
MEDSTREAM Pump	Codman	Advice regarding a software upgrade	20 June 2012	Yes
Conveen catheter valve, Simpla catheter valve, Catheter	Coloplast	Advice regarding a device removal	17 November 2011	Yes
Legendair & Support Ventilators	Covidien	Advice regarding a device modification	09 July 2012	Yes
Shiley Reusable Cannula cuffed tracheostomy tubes	Covidien	Advice regarding a device removal	23rd July 2012	Yes
GE Healthcare MR Products	GE Healthcare	Advice regarding a software upgrade	10 July 2012	Yes
Carescape Monitor B650	GE Healthcare	Advice regarding the use of the device	27th July 2012	Yes
Carescape Monitor B850	GE Healthcare	Advice regarding the use of the device	27th July 2012	Yes
Perimeter OCTOPUS 101	Haag Streit International	Advice regarding the use of the device	06 July 2012	Yes
KWIK-QC Gram Stain Slides	Microbiologics	Advice regarding a device removal	29 May 2012	Yes
Olympus HD AUTOCLAVABLE CAMERA	Olympus	Advice regarding a device modification	08 June 2012	Yes
4R82 Tube Clamp Adapter, 34mm, Titanium	Ottobock	Advice regarding a device removal	27 July 2012	Yes

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Foliodress gown	Paul Hartmann AG	Advice regarding a device removal	23 July 2012	Yes
HeartStart MRx Defibrillator	Philips	Advice regarding changes/updates made to instructions for use	01 June 2012	Yes
ABL800 and ABL700	Radiometer	Advice regarding a software upgrade	20 July 2012	Yes
AQT90 Flex	Radiometer	Advice regarding a software upgrade	26 July 2012	Yes
Data Station AMPLILINK	Roche Diagnostics	Advice regarding the use of the device	03 July 2012	Yes
Ropox Hudson Shower Bed	Ropox A/S	Advice regarding a device modification	13 January 2012	Yes
Syngo Imaging XS	Siemens AG Healthcare Sector	Advice regarding a software upgrade	12 July 2012	Yes
ADVIA Centaur & Centaur XP Syphilis Assay	Siemens Healthcare Diagnostics	Advice regarding the use of the device	18 July 2012	Yes
Third Generation TSH assay	Siemens Healthcare Diagnostics	Advice regarding a device removal	01 June 2012	Yes
Silentia Screen System	Silentia AB	Advice regarding changes/updates made to instructions for use	26 June 2012	Yes
Sim.LED 5000 and 7000	Simeon Medical	Advice regarding a device modification	24 July 2012	Yes
Twinfix Ultra Ti Suture Anchors	Smith and Nephew	Advice regarding a device removal	04 July 2012	Yes
EON MINI, BRIO	St Jude Medical	Advice regarding a device removal	26 July 2012	Yes
EON, EON Mini, Brio	St Jude Medical	Advice regarding the use of the device	26 July 2012	Yes
Riata and Riata ST silicone-only defibrillation leads	St. Jude Medical	Advice regarding the review of patient results/patient recall/sample retesting is required	13 July 2012	
Radiofrequency (RF) Cannulae	Stryker	Advice regarding a device removal	25 July 2012	Yes
ABG II Modular Stems and ABG II Modular Necks Rejuvenate Modular Stems and Rejuvenate Modular Necks	Stryker Orthopaedics	Advice regarding a device removal	28 June 2012	Yes
Detex X-Ray Detectable Tied 5 Gauze Swab BP	Synergy Health UK	Advice regarding a device removal	07 June 2012	Yes
Oxoid Antimicrobial Susceptibility Testing Disc	ThermoFisher Scientific	Advice regarding a device removal	29 June 2012	Yes
3D Optical Coherence Tomography, Viewer Software for the OCT	TOPCON Corporation	Advice regarding the use of the device	25 May 2012	Yes
AES Ankle Prosthesis	Transysteme	Advice regarding a device removal	12 June 2012	Yes
neria steel cannula infusion sets	Unomedical	Advice regarding the use of the device	12 June 2012	Yes
GH3 Lifting Hanger	V. Guldmann A/S	Advice regarding changes/updates made to instructions for use	11 July 2012	Yes
VENTIlogic LS / VENTIlogic plus	Weinmann Medical Technology	Advice regarding a device modification	20 June 2012	Yes