



IRISH MEDICINES BOARD

FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- NOVEMBER 2011

Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Is the Irish market affected?
FreeGo Enteral Pump	Abbott Laboratories	Advice regarding a device modification	16 November 2011	Yes
i-STAT cTnl cartridges	Abbott Point of Care	Advice regarding a device removal	01 September 2011	Yes
ALBAcheck BGS Whole Blood Controls	Alba Bioscience	Advice regarding the use of the device	15 November 2011	Yes
Femtosecond Laser Systems	AMO Manufacturing	Advice regarding the use of the device	14 October 2011	Yes
Contoura® 880 series hospital bed frames	ArjoHuntleigh	Advice regarding a device modification	28 October 2011	Yes
Access Immunoassay Systems Ostase Calibrator, QC and Reagent Kits	Beckman Coulter Inc	Advice regarding a device removal	09 November 2011	Yes
OSSEOTITE CERTAIN IMPLANT 3.25 X 13MM	Biomet 3i	Advice regarding a device removal	04 November 2011	Yes
DXA Software with the DICOM Option version 4.2.0 through 4.3.1.	CooperSurgical	Advice regarding a software upgrade	28 September 2011	Yes
Avaira™ Sphere contact lenses.	CooperVision	Advice regarding a device removal	17 November 2011	Yes
SUPER TORQUE® MB Angiographic Catheter	Cordis	Advice regarding the use of the device	24 November 2011	Yes
LigaSure™ Dolphin tip sealer/divider (LS1500 LigaSure™ Dolphin Tip Sealer/Divider, 37cm, LS1520 LigaSure™ Dolphin Tip Sealer/Divider, 20cm)	Covidien	Advice regarding a device removal	14 November 2011	Yes
Bard® EnCor® Biopsy Probes	C. R. Bard, Inc.	Advice regarding a device removal	15 November 2011	Yes
Confidence Diamond Tip Introducer Needle	DePuy Spine Inc.	Advice regarding a device removal	01 April 2011	Yes
Endres Riviera Bathlift	Drive Medical	Advice regarding changes/updates made to instructions for use	09 August 2011	Yes
GE Centricity Critical Care	GE Healthcare	Advice regarding a software upgrade	02 November 2011	Yes
SafeSheath® CSG® Coronary Sinus Guide Braided Core Hemostatic Introducer, SafeSheath® Worley Telescopic Braided Series & Situs LDS 2 Lead Delivery System	GE Healthcare	Advice regarding a device removal	16 November 2011	Yes
Dash® 3000/4000/5000 Patient Monitors	GE Medical Systems Information Technologies	Advice regarding the use of the device	08 November 2011	Yes
Senographe DS Senographe Essential	GE Medical Systems SCS	Advice regarding a software upgrade	21 November 2011	Yes
Puma, Beatle, Alex and Ibis XP Power Wheelchairs	Handicare	Advice regarding a device modification	15 November 2011	Yes
Acheeva Learning Station	Helping Hand	Advice regarding changes/updates made to instructions for use	25 October 2011	Yes
Galileo Echo Blood Bank Analyzer	Immucor Gamma	Advice regarding the use of the device	12 September 2011	Yes
CUSA Excel ® and CUSA Excel ® +	Integra LifeSciences Ltd	Advice regarding the use of the device	29 July 2011	Yes

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da Vinci Tip Cover Accessory	Intuitive Surgical	Advice regarding the use of the device	10 October 2011	Yes
da Vinci Surgeon Console, da Vinci EndoWrist Instruments, da Vinci Cannula, 8mm, Regular	Intuitive Surgical	Advice regarding the use of the device	10 October 2011	Yes
Posture Belt (Lapbelt) with REA Assist Wheelchairs	Invacare	Advice regarding the use of the device	10 November 2011	Yes
FLOW-i	Maquet Critical Care AB	Advice regarding a software upgrade	25 November 2011	Yes
Data-Cyte Plus 3% & Data-Cyte Plus 0.8%	Medion Grifols Diagnostics AG	Advice regarding the use of the device	21 October 2011	Yes
Medtronic Self-Tapping Screw module, Ref. 176-513, used with the ATLANTIS® Anterior Cervical Plate System	Medtronic	Advice regarding a device removal	06 July 2011	Yes
Mercia Syphilis M	Microgen Bioproducts Limited	Advice regarding a device removal	28 October 2011	Yes
Multigent Vancomycin Calibrators	Microgenics Corporation	Advice regarding a device removal	26 October 2011	Yes
Olympus ESG-100 Electrosurgical Generator	Olympus Surgical Technologies Europe	Advice regarding the use of the device	18 November 2011	Yes
GB Primary Adapter for Power Supply 757S1=GB-1	Otto Bock	Advice regarding a device removal	18 October 2011	Yes
Pinnacle 3 Radiation Therapy Planning System, software version 9.0	Philips Healthcare	Advice regarding a software upgrade	16 November 2011	Yes
MammoDiagnost DR	Philips Healthcare	Advice regarding a device modification	15 November 2011	Yes
Dimension Flex reagent cartridge, Creatinine CREA	Siemens Healthcare Diagnostics	Advice regarding a device removal	24 November 2011	Yes
5.5mm DYONICS ELECTROBLADE Resector	Smith & Nephew	Advice regarding a device removal	17 November 2011	Yes
Bivona® Neonatal, Pediatric and Flexend Tracheostomy Tubes	Smiths Medical	Advice regarding a device removal	15 November 2011	Yes
Riata and Riata ST silicone endocardial leads	St Jude Medical	Advice regarding the use of the device	28 November 2011	Yes
Visum LED Surgical Light	Stryker Communications	Advice regarding a device modification	24 November 2011	Yes
Triathlon® Tibial Alignment Handle and Nav Tibial Alignment Handle	Stryker Orthopaedics	Advice regarding a device removal	16 November 2011	Yes
Sunquest Laboratory versions 6.4.0 and later using Online Entry (OEM)	Sunquest Information Systems	Advice regarding a software upgrade	15 November 2011	Yes
G8 Hemoglobin F&A2 Calibrator and Control	Tosoh Corporation	Advice regarding the use of the device	07 September 2011	Yes
Clinac®, Trilogy®, Trilogy Tx™ and Novalis Tx™	Varian Medical Systems	Advice regarding the use of the device	02 November 2011	Yes
On-Board Imager (OBI) / TrueBeam	Varian Medical Systems	Advice regarding a software upgrade	11 November 2011	Yes
High Definition 120 Multi-Leaf Collimator (HD120 MLC)	Varian Medical Systems	Advice regarding the use of the device	18 November 2011	Yes
VitreaCore PET/CT feature for the Vitrea Enterprise Suite	Vital Images Inc.	Advice regarding a software upgrade	18 November 2011	Yes