

	IRISH MEDICINES BOARD FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- FEBRUARY 2011			
Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Is the Irish market affected?
Abbott PRISM Reaction Trays	Abbott Diagnostics	Advice regarding the use of the device	21 December 2010	Yes
Amplatzer® Cardiac Plug	AGA Medical Corporation	Advice regarding changes/updates made to instructions for use	28 January 2011	Yes
Visitec High Viscosity Injectors	Beaver Visitec	Advice regarding a device removal	07 January 2011	Yes
Access Free T4 Calibrators	Beckman Coulter Inc	Advice regarding the use of the device	01 November 2010	Yes
COULTER® LH750 Analyzer, COULTER® LH780 Analyzer, COULTER® LH 500 Series System, COULTER® GEN*S UniCel Dxl 800 Access Immunoassay Systems, UniCel Dxl 600 Access Immunoassay Systems, UniCel DxC 660i, 680i, 860i, 880i SYNCHRON Access Clinical Systems	Beckman Coulter Inc	Advice regarding a software upgrade	31 January 2011	Yes
BD Microlance 30G x 1/2" Needle - Sterile	Becton Dickenson	Advice regarding a device removal	27 January 2011	Yes
BacT/ALERT	BioMerieux Inc	Advice regarding the use of the device	15 February 2011	Yes
NEX510, NEX512, NEX610, NEX612, NEX710, NEX712, NEX56A, NEX66A, NEX76A	Cardinal Health	Advice regarding a device removal	01 December 2011	Yes
PleurX™ Drainage Kits	CareFusion	Advice regarding a device removal	15 September 2010	Yes
VCARE® Vaginal-Cervical Ahluwalia's Retractor-Elevator	ConMed Corporation	Advice regarding the use of the device	23 February 2011	Yes
Gryphon™ BR Anchors – Suture Anchors	ConMed Corporation	Advice regarding changes/updates made to instructions for use	15 February 2011	Yes
Gryphon™ BR Anchors – Suture Anchors	DePuy Mitek	Advice regarding a device removal	23 February 2011	Yes
Desktop Pro™	Elekta Limited	Advice regarding a device removal	26 January 2011	Yes
DERMABOND® Topical Skin Adhesive and DERMABOND™ Mini Topical Skin Adhesive	Ethicon	Advice regarding a software upgrade	26 January 2011	Yes
Galileo Echo	Ethicon	Advice regarding a device removal	10 February 2011	Yes
Galileo Echo	Immucor Medizinische Diagnostik GmbH	Advice regarding the use of the device	21 February 2011	Yes
ACL 8000, ACL 9000, ACL 10000, ACL Elite, ACL Elitepro	Instrumentation Laboratory	Advice regarding a software upgrade	01 January 2011	Yes
Oxford Voyager Fixed Overhead Ceiling Hoists	Joerns Healthcare Ltd.	Advice regarding a device modification	06 January 2011	Unknown
LUCAS 2 Chest Compression System	Jolife	Advice regarding the use of the device	24 February 2011	Yes
UnBalloon Non-Occlusive Modeling Catheter	LeMaitre	Advice regarding a device removal	15 June 2010	Yes
Screen-cyte 3%	Medion Grifols Diagnostics AG	Advice regarding a device removal	22 February 2011	Yes
PANTA® Nail Support Device	Newdeal SAS	Advice regarding a device removal	09 February 2011	Yes
Mobility Care Heavy Duty Rollator - Titanium L97986	Nottingham Rehab Supplies	Advice regarding the use of the device	09 February 2011	Yes
Total Knee® 2100	Nottingham Rehab Supplies	Advice regarding a device modification	31 January 2011	Yes
HeartStart MRx	Össur	Advice regarding a device removal	15 February 2011	Yes
HeartStart MRx	Philips	Advice regarding a software upgrade	11 February 2011	Yes
Philips Brilliance 6, 10, 16, 16P, 40, 64, Big Bore, iCT, iCT SP	Philips	Advice regarding a device modification	14 January 2011	Yes

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Airtraq Optical Laryngoscope	Prodol Meditec S.A.	Advice regarding a device removal	15 February 2011	Yes
Accu-Chek Inform II	Roche Diagnostics	Advice regarding a software upgrade	09 February 2011	Yes
ACUSON SC2000 Ultrasound system	Siemens	Advice regarding a software upgrade	16 February 2011	Yes
CADD®-Solis Ambulatory Infusion Pumps	Smiths Medical	Advice regarding a device modification	25 January 2011	Yes
Triathlon® PKR Instruments, Peg Drill	Stryker Orthopaedics	Advice regarding a device removal	10 February 2011	Yes
Quickie Neon Swing-Away	Sunrise Medical	Advice regarding a device modification	10 February 2011	Yes
THERAKOS™ UVAR XTS™ Procedural Kits	Therakos Photopheresis	Advice regarding a device removal	01 February 2011	Yes
Oxoid XLD Medium, CM0469	ThermoFisher Scientific	Advice regarding a device removal	16 February 2011	Yes
Toshiba Diagnostic Ultrasound Systems Aplio (XG and MX) and Xario XG	Toshiba Medical Systems Corporation	Advice regarding a software upgrade	31 January 2011	Yes
RT Chart, a function of ARIATM versions 8.0 and 8.1	Varian	Advice regarding a software upgrade	18 February 2011	Yes