



IRISH MEDICINES BOARD

FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- February 2013

Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Link to FSN on IMB website	Is the Irish market affected?
MitraClip Mitral Valve Repair System	Abbott Vascular	Advice regarding a device modification	27 January 2013	Manufacturer's FSN	Yes
Access Immunoassay System	Beckman Coulter Inc	Advice regarding the use of the device	26 February 2013	Manufacturer's FSN	Yes
RHK Axle, RHK Short Hinge and RHK Long Hinge Assembly	Biomet Orthopedics Switzerland GmbH	Advice regarding a device removal	19 December 2012	Manufacturer's FSN	Yes
Pharos Vitesse	Biotronik	Advice regarding the use of the device	06 February 2013	Manufacturer's FSN	Yes
ExacTrac 6.0	BrainLAB AG	Advice regarding a software upgrade	22 February 2013	Manufacturer's FSN	Yes
Carestream DRX	Carestream Health	Advice regarding the use of the device	01 February 2013	Manufacturer's FSN	Yes
CT ASPHINA 409MP Intraocular lenses	Carl Zeiss Meditec SAS	Advice regarding a device removal	01 February 2013	Manufacturer's FSN	Yes
Combined use of the Reagent STA [®] - LIATEST [®] VVVWF:AG (REF. 00518) with STA-R [®] / STA-R EVOLUTION [®]	Diagnostica Stago	Advice regarding the use of the device	18 January 2013	Manufacturer's FSN	Yes
Multi-X 10 cm x 7.5 cm 32 ply X-ray detectable gauze swabs	Frontier Multigate	Advice regarding a device removal	23 October 2012	Manufacturer's FSN	Yes
Restylane Sub Q Lidocaine	Galderma	Advice regarding a device removal	27 February 2013	Manufacturer's FSN	Yes
Gambro Conventional Bloodlines	Gambro	Advice regarding the use of the device	15 February 2013	Manufacturer's FSN	Yes
Ondal Acrobat [®] Swing spring arms	Gebrüder Martin GmbH & Co. KG	Advice regarding a device removal	31 January 2013	Manufacturer's FSN	Yes
PLUM A+ Infusion System Family	Hospira Inc	Advice regarding the use of the device	25 January 2013	Manufacturer's FSN	Yes
PLUM A+ Infusion System Family	Hospira Inc	Advice regarding the use of the device	19 February 2013	Manufacturer's FSN	Yes
PLUM A+ Infusion System Family	Hospira Inc	Advice regarding the use of the device	25 January 2013	Manufacturer's FSN	Yes
PLUM A+ Infusion System Family	Hospira Inc	Advice regarding the use of the device	25 January 2013	Manufacturer's FSN	Yes
PLUM A+ Infusion System Family	Hospira Inc	Advice regarding the use of the device	25 January 2013	Manufacturer's FSN	Yes
EXcel 23 kHz Standard Tip & Flue	Integra Lifesciences	Advice regarding changes/updates made to instructions for use	07 February 2013	Manufacturer's FSN	Yes
Oxford Advance Hoists	Joerns Healthcare Limited	Advice regarding a device modification	11 February 2013	Manufacturer's FSN	Yes
Spacers for Delta Liners in Delta Acetabular System	Lima Corporate	Advice regarding changes/updates made to instructions for use	06 February 2013	Manufacturer's FSN	Yes
VersaCut Morcellator	Lumenis	Advice regarding changes/updates made to instructions for use	18 January 2013	Manufacturer's FSN	Yes
HbA1c Calibrator	MCA Laboratory	Advice regarding the use of the device	07 February 2013	Manufacturer's FSN	Yes

Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Link to FSN on IMB website	Is the Irish market affected?
Data-Cyte Plus 0.8%, Plus P 0.8%, Plus Di ^a 0.8%, Plus Di ^b 3%, Plus 3%	Medion Grifols Diagnostics AG	Advice regarding the use of the device	01 February 2013	Manufacturer's FSN	Yes
Deep Brain Stimulation (DBS) Lead Kits	Medtronic	Advice regarding the use of the device	08 February 2013	Manufacturer's FSN	Yes
O-arm Imaging System	Medtronic	Advice regarding a device modification	28 January 2013	Manufacturer's FSN	Yes
DLP Single Stage Venous Cannula with Metal Tip	Medtronic Inc.	Advice regarding a device removal	20 February 2013	Manufacturer's FSN	Yes
Cannulated screwdriver, ref. 129733 and screwdriver tip ref. 129735	Newdeal SAS	Advice regarding a device removal	08 February 2013	Manufacturer's FSN	Yes
AQUARIUS Regular Haemofiltration Device	Nikkiso Europe GmbH	Advice regarding a software upgrade	15 February 2013	Manufacturer's FSN	Yes
Damon 3MX Bicuspid Brackets	Ormco Corporation	Advice regarding a device removal	22 May 2012	Manufacturer's FSN	Yes
LifeCycle for Prenatal Screening	Perkin Elmer	Advice regarding a software upgrade	11 February 2013	Manufacturer's FSN	Yes
HeartStart XL+	Philips Healthcare	Advice regarding a software upgrade	18 February 2013	Manufacturer's FSN	Yes
Sure Sign Patient Monitor	Philips Healthcare	Advice regarding a device modification	01 January 2013	Manufacturer's FSN	Yes
TCM4 series Base Unit	Radiometer Medical Aps	Advice regarding a device modification	14 December 2012	Manufacturer's FSN	Yes
Reflotron Hemoglobin / Reflotron PST Hemoglobin / RT-HB-III 6 mm	Roche Diagnostics GmbH	Advice regarding the use of the device	01 February 2013	Manufacturer's FSN	Yes
Accutrend BM-Lactate	Roche Diagnostics GmbH	Advice regarding a device removal	07 January 2013	Manufacturer's FSN	Yes
Level 1® Fast Flow and NORMOFLO® Irrigation Fluid Warmers	Smiths Medical	Advice regarding a device modification	28 January 2013	Manufacturer's FSN	Yes
Isoline	Sorin	Advice regarding a device removal	28 January 2013	Manufacturer's FSN	Yes
Terumo 50ML Luer Lock Syringe	Terumo Europe NV	Advice regarding a device removal	25 February 2013	Manufacturer's FSN	Yes
Oxoid Antimicrobial Susceptibility Testing Discs CPD10 (Cefpodoxime)	Thermofisher Scientific	Advice regarding a device removal	05 February 2013	Manufacturer's FSN	Yes
Vitreia Enterprise Suite, Vitrea, VitreaAdvanced, VitreaCore (VitalConnect) and Vitrea fX	Vital Images Inc.	Advice regarding a software upgrade	05 February 2013	Manufacturer's FSN	Yes