



## IRISH MEDICINES BOARD

## FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- JANUARY 2013

Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Link to FSN on IMB website	Is the Irish market affected?
ARCHITECT Testosterone	Abbott Diagnostics Division	Advice regarding the use of the device	31 December 2012	<a href="#">Manufacturer's FSN</a>	Yes
Active Knee – Patella component	Advanced Surgical Design & Manufacture (ASDM)	Advice regarding a device removal	28 November 2012	<a href="#">Manufacturer's FSN</a>	Unknown
Alere Cholestech LDX Multianalyte Control	Alere	Advice regarding a device removal	30 January 2013	<a href="#">Manufacturer's FSN</a>	Yes
Animas 2020 Insulin Pump	Animas	Advice regarding a device removal	01 January 2013	<a href="#">Manufacturer's FSN</a>	Yes
Animas 2020 Insulin Pump	Animas	Advice regarding a device removal	01 January 2013	<a href="#">Manufacturer's FSN</a>	Yes
NIPPY 3 ventilator, NIPPY JUNIOR ventilator, NIPPY ST ventilator, NIPPY S ventilator	B&D Electromedical	Advice regarding the use of the device	16 January 2013	<a href="#">Manufacturer's FSN</a>	Yes
HomeChoice Automated PD System and HomeChoice PRO Automated PD System	Baxter Healthcare	Advice regarding the use of the device	21 January 2013	<a href="#">Manufacturer's FSN</a>	Yes
NAVIOS 10 Colors/3 Lasers, 8 Colors/2 Lasers, 6 Colors/2 Lasers	Beckman Coulter	Advice regarding the use of the device	08 January 2013	<a href="#">Manufacturer's FSN</a>	Yes
SYNCHRON Systems Glucose	Beckman Coulter	Advice regarding the use of the device	10 December 2012	<a href="#">Manufacturer's FSN</a>	Yes
Disposable Active Electrodes and Accessories	ConMed Corporation	Advice regarding a device removal	07 January 2013	<a href="#">Manufacturer's FSN</a>	Yes
Zilver PTX Drug-Eluting Peripheral Stent	Cook Ireland Ltd	Advice regarding the use of the device	18 December 2012	<a href="#">Manufacturer's FSN</a>	Yes
CONFIDENCE SPINAL CEMENT SYSTEM® KIT	DePuy Synthes	Advice regarding a device removal	18 January 2013	<a href="#">Manufacturer's FSN</a>	Yes
INDIGO CARMINE	Derm Tech France	Advice regarding a device removal	14 October 2012	<a href="#">Manufacturer's FSN</a>	Yes
IsoCord I25.S06 (ceramic core with gold marker)	Eckert & Ziegler	Advice regarding the use of the device	14 December 2012	<a href="#">Manufacturer's FSN</a>	Yes
XVI R3.5.3, R4.2.2, R4.5.1	Elekta	Advice regarding a software upgrade	01 December 2012	<a href="#">Manufacturer's FSN</a>	Yes
XVI R4.6	Elekta	Advice regarding a software upgrade	01 December 2012	<a href="#">Manufacturer's FSN</a>	Yes
XVI R3.5, R4.0, R4.3, R4.	Elekta	Advice regarding a software upgrade	01 December 2012	<a href="#">Manufacturer's FSN</a>	Yes
Gambro bloodlines	Gambro	Advice regarding the use of the device	17 January 2013	<a href="#">Manufacturer's FSN</a>	Yes
Giraffe Incubator and Giraffe OmniBed	GE Healthcare	Advice regarding a device modification	17 January 2013	<a href="#">Manufacturer's FSN</a>	Yes
HAMILTON-T1	Hamilton Medical AG	Advice regarding a software upgrade	19 December 2012	<a href="#">Manufacturer's FSN</a>	Yes
Plum A+ Family of Infusers	Hospira Inc	Advice regarding a software upgrade	21 September 2012	<a href="#">Manufacturer's FSN</a>	Yes
1-DAY ACUVUE® MOIST® (etafilcon A) Brand Contact Lenses	Johnson & Johnson Vision Care	Advice regarding a device removal	09 January 2013	<a href="#">Manufacturer's FSN</a>	Yes

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VersaCut Morcellator	Lumenix	Advice regarding changes/updates made to instructions for use	18 January 2013	<a href="#">Manufacturer's FSN</a>	Yes
VITROS Chemistry Products Vapor Adsorption Cartridge	Ortho-Clinical Diagnostics	Advice regarding a device removal	02 January 2013	<a href="#">Manufacturer's FSN</a>	Yes
Powered Wheelchair B400 ISO Transportation Kits - Rear Seat Mounting Bolts	Otto Bock Mobility Solutions GmbH	Advice regarding a device modification	04 December 2012	<a href="#">Manufacturer's FSN</a>	Yes
Brilliance CT series, iCT, iCT SP, Ingenuity Core, Ingenuity CT and MX8000 Dual v. EXP	Philips Healthcare	Advice regarding a device modification	20 December 2012	<a href="#">Manufacturer's FSN</a>	Yes
MX 16-slice	Philips Healthcare	Advice regarding a device modification	14 December 2012	<a href="#">Manufacturer's FSN</a>	Yes
Oncor/Primus/Artiste Impression Plus Linear Accelerator	Siemens AG Healthcare	Advice regarding a device modification	01 January 2013	<a href="#">Manufacturer's FSN</a>	Yes
syngo Workflow MLR	Siemens AG Healthcare	Advice regarding a software upgrade	17 January 2013	<a href="#">Manufacturer's FSN</a>	Yes
ADVIA Centaur HBc Total Assay	Siemens Healthcare Diagnostics	Advice regarding the use of the device	01 November 2012	<a href="#">Manufacturer's FSN</a>	Yes
Dimension IRON Calibrator (DC85)	Siemens Healthcare Diagnostics	Advice regarding the use of the device	02 January 2013	<a href="#">Manufacturer's FSN</a>	Yes
Dimension TACR Flex Reagent Cartridge	Siemens Healthcare Diagnostics	Advice regarding the use of the device	01 January 2013	<a href="#">Manufacturer's FSN</a>	Yes
IMMULITE ACTH Control Module	Siemens Healthcare Diagnostics	Advice regarding the use of the device	01 October 2012	<a href="#">Manufacturer's FSN</a>	Yes
Dimension Clinical Chemistry Systems	Siemens Healthcare Diagnostics	Advice regarding the use of the device	01 January 2013	<a href="#">Manufacturer's FSN</a>	Yes
Gliding Nail GN™ Blade handle	Smith&Nephew Orthopaedics AG	Advice regarding a device removal	22 October 2012	<a href="#">Manufacturer's FSN</a>	Unknown
Coopers Walking Frames	Sunrise Medical	Advice regarding a device modification	12 November 2012	<a href="#">Manufacturer's FSN</a>	Yes
Hand Switch for Electric Pen Drive	Synthes	Advice regarding a device removal	17 January 2013	<a href="#">Manufacturer's FSN</a>	Yes
Berman Angiographic Balloon Catheters	Teleflex Medical	Advice regarding changes/updates made to instructions for use	08 January 2013	<a href="#">Manufacturer's FSN</a>	Yes
Oxoid Ready Poured Plate Brilliance VRE Agar	Thermofisher Scientific	Advice regarding a device removal	23 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
Versys® and Slotted Provisional Femoral Heads	Zimmer	Advice regarding the use of the device	16 November 2012	<a href="#">Manufacturer's FSN</a>	Yes