



IRISH MEDICINES BOARD

FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- MARCH 2012

Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Is the Irish market affected?
Bar Code Scanner	Abbott Molecular	Advice regarding changes/updates made to instructions for use	31 January 2012	Unknown
i-STAT cTnl cartridge	Abbott Point of Care	Advice regarding the use of the device	13 March 2012	Yes
Baxter Transfer Sets	Baxter Healthcare Corporation	Advice regarding changes/updates made to instructions for use	17 February 2012	Yes
BacT/ALERT Blood Collection Adapter Cap	BioMerieux	Advice regarding the use of the device	09 March 2012	Yes
IMAGER™ II Angiographic Catheter	Boston Scientific Corporation	Advice regarding a device removal	21 March 2012	Yes
IMAGER™ II Urology Catheter	Boston Scientific Corporation	Advice regarding a device removal	21 March 2012	Yes
BrainSCAN and iPlan RT Dose and iPlan RT treatment planning software	BrainLab AG	Advice regarding changes/updates made to instructions for use	09 March 2012	Yes
Alaris® IVAC® 590 Series Blood Set	CareFusion	Advice regarding a device removal	16 March 2012	Yes
Etac Avant, Avant LW and Salsa Walkers	Etac	Advice regarding a device modification	22 February 2012	Yes
Revolution XRD X-ray Systems:	GE Healthcare	Advice regarding a device modification	01 December 2011	Yes
Infinia Systems	GE Healthcare	Advice regarding a device modification	28 February 2012	Yes
PO Interconnect-Cable - Compact 7700 Plus Mobile C-Arm	GE OEC Medical Systems Inc	Advice regarding the use of the device	20 February 2012	Unknown
Lifecare 5000 IV Pump Set	Hospira Inc.	Advice regarding the use of the device	15 March 2012	Yes
Galileo Echo Blood Bank Analyser	Immucor Inc.	Advice regarding the use of the device	09 March 2012	Yes
MAGNUS 1180.16Ax, 1180.16Fx and T285.7000 carbon-fibre table tops	Maquet	Advice regarding a device modification	28 March 2012	Yes
EnTrust	Medtronic	Advice regarding the use of the device	05 March 2012	Yes
ATLANTIS™ / PREMIER® / VERTEX © 876-460, 6860460 and 6905712	Medtronic Sofamor Danek Inc.	Advice regarding a device removal	01 March 2012	Yes
Brilliance Workspace Portal with software versions 2.5.2 or 2.6.0	Philips Healthcare	Advice regarding a software upgrade	08 February 2012	Yes
MultiDiagnost Eleva FD	Philips Healthcare	Advice regarding a software upgrade	21 February 2012	Yes
Freeway Mobile Hoists	Prism Medical UK	Advice regarding a device modification	29 February 2012	Yes
Syngo.Plaza	Siemens AG Healthcare Sector	Advice regarding a software upgrade	20 January 2012	Yes
Syngo.Plaza	Siemens AG Healthcare Sector	Advice regarding a software upgrade	24 February 2012	Yes
ADVIA Centaur Systems Cortisol Reagent	Siemens Healthcare Diagnostics	Advice regarding the use of the device	07 March 2012	Yes
Acuson SC2000	Siemens Ltd.	Advice regarding a software upgrade	23 January 2012	Yes

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12Fr SLS II Laser Sheath, Model No. 500-001	Spectranetics	Advice regarding a device removal	14 March 2012	Yes
Sarns™ Soft-Flow™ Aortic Cannula with angled tip	Terumo CVS	Advice regarding a device removal	13 March 2012	Yes
Oxoid Antimicrobial Susceptibility Testing Disc CN30 Gentamicin, CT0072B	Thermofisher Scientific	Advice regarding a device removal	08 March 2012	Yes
Portal Vision	Varian Medical Systems Inc.	Advice regarding the use of the device	29 February 2012	Yes
4D Integrated Treatment Console (4DITC) and TrueBeam	Varian Medical Systems Inc.	Varian Medical Systems Inc.	01 March 2012	Yes
FastPlan Treatment Planning System	Varian Medical Systems Inc.	Advice regarding a software upgrade	08 March 2012	Yes
Eclipse Treatment Planning System	Varian Medical Systems Inc.	Advice regarding the use of the device	13 March 2012	Yes
ARIA Radiation Oncology System	Varian Medical Systems Inc.	Advice regarding the use of the device	12 March 2012	Yes
52-leaf MLCs	Varian Medical Systems Inc.	Advice regarding the use of the device	23 March 2012	Yes
4D Integrated Treatment Console (4DITC)	Varian Medical Systems Inc.	Advice regarding the use of the device	29 March 2012	Yes