



IRISH MEDICINES BOARD

FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- DECEMBER 2010

Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Link to FSN on IMB website	Is the Irish market affected?
AMO WaveScan WaveFront Systems	Abbott Medical Optics	Advice regarding a software upgrade	25 June 2010	Manufacturer's FSN	Yes
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i-STAT Celite ACT Cartridges	Abbott Point of Care	Advice regarding the use of the device	01 December 2010	Manufacturer's FSN	Yes
Copper and Zinc Reagent Kits	Audit Diagnostics	Advice regarding a device removal	30 November 2010	Manufacturer's FSN	Yes
Bausch + Lomb Renu® Multi-Purpose Solution	Bausch & Lomb	Advice regarding a device removal	10 December 2010	Manufacturer's FSN	Yes
Access Free T4 Calibrators	Beckman Coulter	Advice regarding a device removal	29 November 2010	Manufacturer's FSN	Yes
DHEA RIA Kit	Beckman Coulter	Advice regarding a device removal	15 November 2010	Manufacturer's FSN	Yes
UniCel® DxC Clinical Systems	Beckman Coulter	Advice regarding the use of the device	16 November 2010	Manufacturer's FSN	Yes
SYNCHRON® System(s) Immunoglobulin A (Ig-A) Reagent	Beckman Coulter	Advice regarding a device removal	01 November 2010	Manufacturer's FSN	Yes
Precision™ Implantable Pulse Generator	Boston Scientific	Advice regarding a software upgrade	23 November 2010	Manufacturer's FSN	Yes
Alaris® Syringe Pumps	CareFusion	Advice regarding the use of the device	16 December 2010	Manufacturer's FSN	Yes
Spectra Optia Apheresis System	Caridian BCT	Advice regarding a device modification	09 December 2010	Manufacturer's FSN	Yes
Zilver Flex 35 Vascular Self-Expanding stent	Cook Medical	Advice regarding a device removal	22 December 2010	Manufacturer's FSN	Yes
LigaSure Blunt Tip Laparoscopic Sealer/Divider	Covidien	Advice regarding a device removal	01 December 2010	Manufacturer's FSN	Yes
Micro Balance Scooters - MB 170	Electric Mobility Euro Ltd.	Advice regarding a device modification	30 November 2010	Manufacturer's FSN	Yes
All GE MR Cylindrical systems with field strengths greater than or equal to 1.0 Tesla except MR450, MR450W, and MR750	GE Healthcare	Advice regarding a device modification	02 December 2010	Manufacturer's FSN	Yes
1.5T Infinity Twinspeed system, Signa Infinity MR System With Excite Technology, 3.0T Signa Infinity Twinspeed With Excite, Signa Excite 1.5T, Signa Excite 3.0T, 1.5T Signa HDx, 3.0T Signa HDx, Signa HDxt 1.5T & 3.0T, Signa 3.0T with Excite, 1.0T and 1.5T Signa Horizon LX, Signa Horizon, Signa Advantage SP, 0.7T Signa Openspeed, Signa HDe 1.5T, Optima MR360 and Brivo MR355 MR systems MR Systems	GE Healthcare	Advice regarding a device modification	03 December 2010	Manufacturer's FSN	Yes
All GE Healthcare MR systems	GE Healthcare	Advice regarding changes/updates made to instructions for use	02 December 2010	Manufacturer's FSN	Yes
Advantage Sim MD CT/X-ray system	GE Healthcare	Advice regarding a software upgrade	09 December 2010	Manufacturer's FSN	Yes
eNTEGRA and Xeleris workstation 1.0, 1.1, 2.0, 2.1:	GE Healthcare	Advice regarding changes/updates made to instructions for use	10 December 2010	Manufacturer's FSN	Yes

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SEQUENCER	IMPAC Medical Systems, Inc.	Advice regarding the use of the device	18 November 2010	Manufacturer's FSN	Yes
Vision Alpha High Frequency Oscillator Ventilators	Inspiration Healthcare Limited	Advice regarding a device modification	22 September 2010	Manufacturer's FSN	Yes
ACL ELITE, ACL ELITE PRO, ACL 8000, ACL 9000 and ACL 10000 Coagulation Analyzers	Instrumentation Laboratory	Advice regarding the use of the device	02 December 2010	Manufacturer's FSN	Yes
Action 3 Junior push bar handle	Invacare	Advice regarding a device modification	17 November 2010	Manufacturer's FSN	Yes
Determine HIV-1/2 Ag/Ab Combo	Inverness Medical	Advice regarding a device removal	09 December 2010	Manufacturer's FSN	Yes
RELI SSO HLA-B Typing kit	Invitrogen	Advice regarding the use of the device	06 December 2010	Manufacturer's FSN	Yes
ViaMetrics-E Embryo Assesment System	Molecular Biometrics, Inc.	Advice regarding a device removal	13 December 2010	Manufacturer's FSN	Yes
Vitros Chemistry Products mALB Reagent/ Vitros 5, 1FS Chemistry Systems/Vitros 5600 Integrated System	Ortho-Clinical Diagnostics	Advice regarding the use of the device	29 August 2010	Manufacturer's FSN	Yes
COBAS® AmpliPrep / COBAS® TaqMan® HBV v 2.0 CE-IVD	Roche Diagnostics	Advice regarding the use of the device	17 December 2010	Manufacturer's FSN	Yes
Fluido® Junior Disposable Set (630000)	Sewoon Medical Co. Limited	Advice regarding a device removal	24 December 2010	Manufacturer's FSN	Yes
ACUSON SC2000	Siemens	Advice regarding a software upgrade	10 December 2010	Manufacturer's FSN	Yes
Magnetom Systems	Siemens AG	Advice regarding a device modification	24 November 2010	Manufacturer's FSN	Yes
ADVIA Centaur Ag/Ab Combo (CHIV) Quality Control Kit	Siemens Healthcare Diagnostics Inc	Advice regarding a device modification	01 December 2010	Manufacturer's FSN	Yes
Renasys Port	Smith & Nephew	Advice regarding a device removal	17 December 2010	Manufacturer's FSN	Yes
Riata and Riata ST	St. Jude Medical	Advice regarding a device removal	15 December 2010	Manufacturer's FSN	Yes
Crossfire Console	Stryker Endoscopy	Advice regarding a software upgrade	02 August 2010	Manufacturer's FSN	Yes
Scorpio T72 Tibial Insert Trial	Stryker Orthopaedics	Advice regarding a device removal	23 August 2010	Manufacturer's FSN	Yes
CDI™ 500 Blood Parameter Monitoring System	Terumo	Advice regarding the use of the device	10 December 2010	Manufacturer's FSN	Yes
HM550 Cryostat	ThermoFisher Scientific	Advice regarding the use of the device	22 September 2010	Manufacturer's FSN	Yes
Automated Enzyme Immunoassay Analyzer AIA-2000 ST/LA, Automated Enzyme Immunoassay Analyzer AIA-1800 ST/LA	Tosoh Corporation	Advice regarding the use of the device	23 November 2010	Manufacturer's FSN	Yes
Ondal Acrobat 2000 Sprung Arm used to carry HELION and XENION surgical lights and monitors	TRUMPF Medizin Systeme GmbH	Advice regarding a device modification	21 July 2010	Manufacturer's FSN	Yes