



IRISH MEDICINES BOARD

FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- NOVEMBER 2012

Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Is the Irish market affected?
Clinical Chemistry Phenobarbital	Abbott Laboratories	Advice regarding a device removal	16 November 2012	Yes
Sterrad® Cyclesure® 24 BI	ASP	Advice regarding a device removal	06 November 2012	Yes
BD BBL™ Taxo™ XV Factor Strips	BD Diagnostic Systems	Advice regarding a device removal	05 November 2012	Yes
INSTI HIV-1/HIV-2 Antibody Test Kits	BioLytical Laboratories	Advice regarding the use of the device	22 November 2012	Yes
Cuticell Classic Paraffin Gauze	BSN Medical Limited UK	Advice regarding a device removal	15 August 2012	Yes
Standard Rigid Tip Suction Wand	California Medical Laboratories Inc.	Advice regarding a device removal	02 November 2012	Yes
Carestream DRX-1 System Console	Carestream Health	Advice regarding a device modification	12 November 2012	Yes
EkoSonic Endovascular Device	Ekos Corporation	Advice regarding changes/updates made to instructions for use	20 August 2012	Yes
Swift Mobil Shower Chair	Etac Supply Centre AB	Advice regarding a device modification	31 October 2012	Yes
ENSEAL® G2 Curved and Straight Tissue Sealer devices	Ethicon Endo-Surgery LLC	Advice regarding a device removal	27 November 2012	Yes
MobiCath Bi-Directional Guiding Sheath	Greatbatch Limited	Advice regarding a device removal	12 November 2012	Yes
Action 3 Junior Wheelchairs	Invacare	Advice regarding a device modification	08 October 2012	Yes
REA Azalea Base	Invacare	Advice regarding the use of the device	22 October 2012	Yes
FDX Electrical Power Wheelchair	Invacare	Advice regarding a device modification	22 November 2012	Yes
KAPS Ceiling Mounted Microscope SOM32	Karl Kaps GmbH & Co. KG	Advice regarding the use of the device	02 November 2012	Yes
RTU-TdT-339	Leica Biosystems	Advice regarding a device removal	14 November 2012	Yes
SynchroMed® Implantable Infusion Pump	Medtronic	Advice regarding the use of the device	08 November 2012	Yes
cardiolife TEC-5500K series	Nihon Kohden Corp	Advice regarding a software upgrade	07 November 2012	Yes
Oxoid Antimicrobial Susceptibility Testing Disc VA5 (Vancomycin), CT0188B	Oxoid Limited	Advice regarding a device removal	02 November 2012	Yes
Oxoid Staphylect Plus DR0850M and DR0850B	Oxoid Limited	Advice regarding a device removal	15 November 2012	Yes
Digital Diagnost X-ray System	Philips Healthcare	Advice regarding a software upgrade	25 October 2012	Yes
cobas b 123 Fluidpack COOX , 200/400/700	Roche Diagnostics	Advice regarding a device removal	05 November 2012	Yes
ADVIA Centaur BNP / BR / CA 19-9 / DHEA-S04 / Digitoxin / Folate / Procalcitonin / Theophylline	Siemens Healthcare Diagnostics	Advice regarding the use of the device	06 November 2012	Yes
ADVIA Centaur and ADVIA Centaur XP	Siemens Healthcare Diagnostics	Advice regarding the use of the device	09 November 2012	Yes
Dimension® Tacrolimus (TACR)FleX® reagent cartridge	Siemens Healthcare Diagnostics	Advice regarding a device removal	15 November 2012	Yes

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RAPIDLab® 1200 Series, RAPIDPoint® 400 Series, and RAPIDPoint® 500 Analyzers	Siemens Healthcare Diagnostics	Advice regarding the use of the device	15 November 2012	Yes
IMMULITE IGF-1, IMMULITE 2000 IGF-1	Siemens Healthcare Diagnostics	Advice regarding the use of the device	15 November 2012	Yes
Pedicular screw ROMEO Diameter 7mm; Ref. ELL-PS 07 XX-S	Spineart	Advice regarding a device removal	29 October 2012	Yes
BRAHMS Free βhCG KRYPTOR	Thermofisher Scientific	Advice regarding a device removal	01 November 2012	Yes
Oxoid Antimicrobial Susceptibility Testing Disc CIP5 CT0425B (Ciprofloxacin)	Thermofisher Scientific Microbiology	Advice regarding the use of the device	13 November 2012	Yes
WD440 & WD440 PT Endoscope Washer Disinfectors	Wassenburg	Advice regarding the use of the device	06 October 2012	Yes