



IRISH MEDICINES BOARD

FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- FEBRUARY 2012

Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Is the Irish market affected?
AxSYM Free T4 Standard Calibrator & Controls	Abbott Ireland Diagnostics Division	Advice regarding the review of patient results/patient recall/sample retesting is required	05 January 2012	Yes
AxSYM Free T4 Standard Calibrator & Controls	Abbott Ireland Diagnostics Division	Advice regarding the review of patient results/patient recall/sample retesting is required	17 February 2012	Yes
BC110SU Delicate Scissors Str.SP/SP 110mm; BC324SU Single Use Scissors; BD047SU Dissect. Forceps w/o Teeth 145mm; BD222SU Adson Dissect. Forceps w/o T.120mm; BD239SU Cushing Dissecting Forceps 1x2 Teeth 200mm; BF059SU Single use Maier Sponge Forceps w/ratchet, curved, 265mm; FK850SU Curette Sharp DBend 215mm	Aesculap AG	Advice regarding a device removal	08 February 2012	Yes
ACRYSOFF® CACHET™ Phakic Lens	Alcon	Advice regarding changes/updates made to instructions for use	06 February 2012	Yes
Animas 2020 Insulin Pump	Animas	Advice regarding a device removal	15 August 2011	Yes
Afinion CRP	Axis-Shield POC AS	Advice regarding the use of the device	01 January 2012	Yes
Baltacci Infusion Catheters	BALT Extrusion	Advice regarding changes/updates made to instructions for use	02 February 2012	Yes
CARTO 3 System and CARTO 3 RMT System	Biosense Webster Limited	Advice regarding a device modification	09 February 2012	Yes
Powerheart 9300A, 9300E, 9300P, 9390A, and 9390E and CardioVive 92532 and 92533 models	Cardiac Science	Advice regarding a device removal	17 January 2012	Yes
CaridianBCT Trima Accel® Disposable Tubing Sets	Caridian BCT	Advice regarding the use of the device	06 February 2012	Yes
Walker Etac ONO	Etac	Advice regarding a device modification	08 February 2012	Yes
PT100 myAIRVO & PT101 AIRVO Humidifier	Fisher &Paykel Healthcare Limited	Advice regarding a device removal	11 January 2012	Yes
OEC® 9800, OEC® FluororTrak 9800 Plus, OEC® 9800 Plus, OEC® 9800MD Motorized C-arm System	GE Healthcare	Advice regarding a device modification	03 February 2012	Yes
GE LOGIQ P6 system	GE Healthcare	Advice regarding a software upgrade	03 February 2012	Yes
GE LOGIQ S8 system	GE Healthcare	Advice regarding a software upgrade	07 February 2012	Yes
Hill-Rom NP150 Viscoelastic Mattress	Hill-Rom	Advice regarding changes/updates made to instructions for use	15 December 2011	Yes
Hexagon HIV	Human Diagnostics	Advice regarding the use of the device	12 January 2012	Yes
INTELEPACS Versions 3.2.1 and up	Intelerad	Advice regarding the use of the device	24 February 2012	Yes
da Vinci S Surgical System, da Vinci Si Surgical System, and da Vinci Sie Surgical System	Intuitive Surgical Inc.	Advice regarding the use of the device	03 February 2012	Yes
ACUVUE® OASYS® (senofilcon A) Brand Contact Lenses	Johnson & Johnson Vision Care	Advice regarding a software upgrade	28 December 2011	Yes
AlgiNot FS Volume Intro Kit, AlgiNot FS Volume Volume Refills	Kerr Corporation	Advice regarding a device removal	24 February 2012	Yes

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Brilliance CT Big Bore, EBW, GEMINI GXL 16, GEMINI TF 16, GEMINI TF 64, and GEMINI TF Big Bore	Philips Healthcare	Advice regarding the use of the device	26 January 2012	Yes
IntelliVue Patient Monitors	Philips Healthcare	Advice regarding a software upgrade	07 February 2012	Yes
COBAS INTEGRA 400 / 400 Plus / 800 analyzer Cobas c 311 / 501 / 502 analyzer	Roche Diagnostics	Advice regarding the use of the device	15 February 2012	Yes
Fluido Junior Disposable Sets(630000)	Sewoon Medical Co. Limited	Advice regarding the use of the device	30 January 2012	Yes
Smith & Nephew Endoscopy Dyonics Power II Control Unit (Product Code 72200873)	Smith & Nephew	Advice regarding a device modification	05 January 2012	Yes
SpatialFrame.com Software Version 4.1.1	Smith & Nephew	Advice regarding a software upgrade	31 January 2012	Yes
SonRtip	Sorin CRM	Advice regarding the use of the device	22 February 2012	Yes
Wingspan Stent System and Gateway PTA Balloon Catheter	Stryker Neurovascular	Advice regarding changes/updates made to instructions for use	01 February 2012	Yes
Accolade Rasp Handle Assembly	Stryker® Orthopaedics	Advice regarding a device removal	31 January 2012	Yes
Vector TAS Modular Driver and Vector TAS Kit	Sybron Dental Specialties Inc. / Ormco Europe B.V.	Advice regarding the use of the device	03 January 2012	Yes
HeartMate II Sealed Outflow Graft / HeartMate II Sealed Outflow Short Bend Relief / HeartMate II LVAS Implant Kit (with Sealed Grafts)	Thoratec Corporation	Advice regarding the use of the device	23 February 2012	Yes
VariSeed	Varian	Advice regarding the use of the device	19 January 2012	Yes
C-Series Clinac models	Varian Medical Systems	Advice regarding the use of the device	07 February 2012	Yes
Millennium or Mark MLC (Multi-Leaf Collimator)	Varian Medical Systems	Advice regarding a software upgrade	16 February 2012	Yes
Eclipse Treatment Planning System	Varian Medical Systems	Advice regarding the use of the device	27 February 2012	Yes
Anaconda and Anaconda ONE-LOKTM Stent Graft Systems	Vascutek Ltd	Advice regarding the use of the device	17 February 2012	Yes
Waters MassTrak Immunosuppressants XE Research Use Only Kit	Waters Corporation	Advice regarding a device removal	07 February 2012	Yes