



IRISH MEDICINES BOARD

FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- JANUARY 2012

Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Is the Irish market affected?
Baxa EVA & Multilayer Bags for Total Parenteral Nutrition (TPN) - All Sizes	Baxa Limited	Advice regarding the use of the device	11 September 2011	Yes
IV Start Kit, Povidone Iodine Prep Pads (H&P Industries)	Busse Hospital Disposables	Advice regarding a device removal	30 November 2011	Yes
SYNCHRON® System(s) Multi Calibrator Diskette	Beckman Coulter Inc	Advice regarding a device removal	15 December 2011	Yes
IMMAGE Immunochemistry Systems Rheumatoid Factor Reagent	Beckman Coulter Inc	Advice regarding a device removal	27 January 2012	Yes
AU2700/AU2700 Plus & AU5400 Clinical Chemistry Analyzers	Beckman Coulter Inc	Advice regarding the use of the device	11 January 2012	Yes
Cirrus HD-OCT Models 4000 and 400 with Instrument and Review Software Versions 5.0.0 and 5.1.0	Carl Zeiss Meditech, Inc.	Advice regarding a software upgrade	11 March 2011	Yes
Wispa Spreader Bar	Chiltern Invadex (UK) Limited	Advice regarding a device removal	12 January 2012	Yes
Cordis SMART Control Nitinol System	Cordis	Advice regarding a device removal	31 January 2012	Yes
Duet TRS Universal Straight and Articulating Single Use Loading Units	Covidien	Advice regarding the use of the device	13 January 2012	Yes
BIS Bilateral Sensors	Covidien	Advice regarding a device removal	08 November 2011	Yes
Lupine Suture Anchors (Various)	DePuy	Advice regarding a device removal	27 January 2012	Yes
Walker Etac ONO	Etac	Advice regarding a device modification	19 October 2011	Yes
Vital Signs enFlow IV Fluid Warmer Model 100	GE Healthcare	Advice regarding the use of the device	29 December 2011	Yes
GE OEC Fluorostar 7900	GE Healthcare	Advice regarding a software upgrade	13 December 2011	Yes
HemosIL® Calibration Plasma / HemosIL Normal Assayed Control / HemosIL Low Abnormal Assayed Control / HemosIL High Abnormal Assayed Control / HemosIL Special Test Control Level 1 / HemosIL Special Test Control Level 2	Instrumentation Laboratory	Advice regarding the use of the device	14 December 2011	Yes
1 Day ACUVUE MOIST (etafilcon A) Brand Contact Lenses for ASTIGMATISM	Johnson & Johnson Vision Care	Advice regarding a device removal	30 November 2011	Yes
NCL-CD4-1F6, NCL-L-CD4-1F6, RTU-CD4-1F6, ORG-8756, NCL-L-CD7-580, NCL-ER-6F11, NCL-ER-6F11, RTU-ER-6F11	Leica Biosystems	Advice regarding the use of the device	15 December 2011	Yes
Adapta, Versa, Sensia, EnPulse, Kappa 600, 700, 800, 900, Relia, and Vitatron Models E50A1, E60A1, and G70A1 series (only Dual Chamber pacemakers are affected).	Medtronic	Advice regarding a software upgrade	17 January 2012	Yes
Adapta, Versa, Sensia, EnPulse, Kappa 600, 700, 800, 900, Relia, and Vitatron Models E50A1, E60A1, and G70A1 series (only Dual Chamber pacemakers are affected).	Medtronic	Advice regarding a software upgrade	17 January 2012	Yes
Single-Use Gas Filter 031122-25	mtp - medical technical promotion gmbh	Advice regarding a device removal	10 November 2011	Yes

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MultiDiagnost Eleva FD	Philips Healthcare	Advice regarding a software upgrade	31 January 2012	Yes
Humidification Chamber 1035609	Philips Respironics UK	Advice regarding changes/updates made to instructions for use	01 November 2011	Yes
COBAS® TaqMan® HIV-1 Test, version 2.0 for use with the High Pure System, CE-IVD	Roche Diagnostics	Advice regarding the use of the device	01 December 2011	Yes
AXIOM Artis/Artis Zee	Siemens	Advice regarding a device modification	22 December 2011	Yes
Dade® Actin® FSL Activated PTT Reagent	Siemens Healthcare Diagnostics	Advice regarding the use of the device	20 December 2011	Yes
IMMULITE CK-MB	Siemens Healthcare Diagnostics	Advice regarding the use of the device	01 January 2012	Yes
Syringes for BEP III	Siemens Healthcare Diagnostics	Advice regarding the use of the device	01 January 2012	Yes
Level 1® D/DI-60HL Normothermic IV Fluid Administration Sets	Smiths Medical	Advice regarding a device removal	28 November 2012	Yes
HOTLINE® Blood and IV Fluid Administration Sets (L-70, L-70NI, L-80, L-270 and L-370)	Smiths Medical	Advice regarding a device removal	28 November 2012	Yes
Oxygenator, External Bubble	Sorin Group Italia S.r.l.	Advice regarding changes/updates made to instructions for use	29 November 2011	Yes
Acetabular Reamer 44mm	Stryker Orthopaedics	Advice regarding a device removal	10 January 2012	Yes
Pressure Area Care Mattresses and Cushions, 50-02-07-200	Talley Group	Advice regarding changes/updates made to instructions for use	04 July 2011	Yes
ImmunoCAP Allergen f14, Soybean Art. No. 14-4115-01	Thermofisher Scientific	Advice regarding the use of the device	25 November 2011	Yes
Oxoid Diagnostic Discs Fox10 Cefoxitin DD0026B	Thermofisher Scientific	Advice regarding a device removal	14 December 2011	Yes
AMC30 Amoxicillin/Clavulanic Acid CT0223B	Thermofisher Scientific	Advice regarding a device removal	15 December 2011	Yes
Sterilisable Handle ALC, Surgical Lighting System iLED and TruLight in use with ALC+ function	TRUMPF Medizin Systeme GmbH + Co. KG	Advice regarding a device modification	13 December 2011	Yes
Eclipse Treatment Planning System with ARIA Radiation Oncology (RT Chart module)	Varian Medical Systems	Advice regarding a software upgrade	16 January 2012	Yes
Gammamed 12i Accessory: Clamping adapters for bronchial catheters, 1.8mm diameter, Model 1 and 2	Varian Medical Systems	Advice regarding a device removal	20 December 2011	Yes
C-Series Clinac or Trilogy	Varian Medical Systems	Advice regarding the use of the device	24 January 2012	Yes