



IRISH MEDICINES BOARD

FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- DECEMBER 2012

Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Is the Irish market affected?
ARCHITECT 25-OH Vitamin D	Abbott	Advice regarding a device removal	12 December 2012	Yes
m2000sp Instrument	Abbott Molecular	Advice regarding a software upgrade	04 December 2012	Yes
STERRAS NX Cassette REF 10133	Advanced Sterilization Products (ASP)	Advice regarding a device removal	06 December 2012	Yes
aks-foldy patient lift and aks-torneo patient lift	Aks Aktuelle Krankenpflege Systeme GmbH	Advice regarding a device modification	16 November 2012	Unknown
ALLEGRO Topolyzer VARIO, Wavelight Oculyzer II	Alcon Laboratories	Advice regarding the use of the device	17 December 2012	Yes
Animas Insulin Pumps	Animas Corporation	Advice regarding the use of the device	20 December 2012	Yes
Custom Procedure Tray (containing Terumo Soft Flow Aortic Cannula)	ArcRoyal	Advice regarding a device removal	21 March 2012	Yes
Amvisc & Amvisc Plus	Bausch & Lomb	Advice regarding a device removal	30 November 2012	Yes
AU5800 Clinical Chemistry Analyzer	Beckman Coulter Inc.	Advice regarding the use of the device	12 December 2012	Yes
AMH Gen II ELISA	Beckman Coulter Inc.	Advice regarding the use of the device	27 November 2012	Yes
Alaris GP Infusion System	CareFusion	Advice regarding the use of the device	01 November 2012	Yes
Snowden-Pencer Tebbetts Fiber Optic Retractors	CareFusion	Advice regarding the use of the device	16 October 2012	Yes
Zilver PTX Drug Eluting Peripheral Stent	Cook Ireland Limited	Advice regarding the use of the device	19 December 2012	Yes
Pipeline Embolization Device	Covidien	Advice regarding the use of the device	05 December 2012	Yes
LIAISON Biotrin Parvovirus B19 IgM	DiaSorin SpA	Advice regarding the review of patient results/patient recall/sample retesting is required	11 December 2012	Yes
LIP W11050 Columbia Blood Agar	Fannin LIP Limited	Advice regarding the use of the device	12 December 2012	Yes
Harefield Pectoral Bar range	Fannin UK	Advice regarding a device removal	05 December 2012	Yes
Mediline O2/N20 Demand Valves	GCE Ltd.	Advice regarding changes/updates made to instructions for use	08 October 2012	Yes
Blood collection sets	Haemonetics	Advice regarding the use of the device	12 December 2012	Yes
Samaritan PAD 300/PAD 300P AED	Heartsine	Advice regarding a device modification	18 September 2012	Yes
Plum A+	Hospira Inc.	Advice regarding the use of the device	12 December 2012	Yes
R100/Vision α Diaphragm Chamber	Metran	Advice regarding the use of the device	26 November 2012	Yes
Philips IntelliVue Information Centre / Philips IntelliVue Information Centre iX	Philips	Advice regarding a device modification	09 November 2012	Yes
MobileDiagnost wDR	Philips	Advice regarding the use of the device	07 November 2012	Yes

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Mobile Diagnost wDR	Philips	Advice regarding a device modification	05 December 2012	Yes
MX 16-slice, MX4000, MX4000 Dual, MX 6000 Dual	Philips	Advice regarding the use of the device	14 December 2012	Yes
Freeway Ceiling Track Hoists	Prism Medical UK	Advice regarding a device modification	26 November 2012	Yes
SOMATOM CTs equipped with software syngo CT2010A, syngo CT2010B, syngo CT2011A and syngo CT2012B	Siemens	Advice regarding the use of the device	27 November 2012	Yes
IMMULITE/IMMULITE 1000 Folic Acid	Siemens Healthcare Diagnostics	Advice regarding the use of the device	01 November 2012	Yes
CLINITEK Atlas and Chek-Stix Positive Urinalysis Control Solutions	Siemens Healthcare Diagnostics	Advice regarding the use of the device	01 December 2012	Yes
Syva Emit tox Serum Calibrators	Siemens Healthcare Diagnostics	Advice regarding the use of the device	03 December 2012	Yes
IMMULITE IGF-1 Control Module	Siemens Healthcare Diagnostics	Advice regarding the use of the device	01 October 2012	Yes
ADVIA Centaur / Centaur XP / Centaur CP HBc Total Assay	Siemens Healthcare Diagnostics	Advice regarding the use of the device	16 November 2012	Yes
Dimension Total Iron Binding Capacity Flex reagent cartridges.	Siemens Healthcare Diagnostics	Advice regarding a device modification	19 December 2012	Yes
ADVIA Centaur HBsAg II kit	Siemens Healthcare Diagnostics	Advice regarding the use of the device	19 December 2012	Yes
ACUSON X150 and SONOLINE G40 Ultrasound Systems	Siemens Medical Solutions USA Inc.	Advice regarding the use of the device	12 October 2012	Yes
Restoration Modular Cone Body Trials	Stryker	Advice regarding the use of the device	05 April 2012	Yes
Oxoid Antimicrobial Susceptibility Testing Disc CIP5 CT0425B (Ciprofloxacin)	Thermofisher Scientific	Advice regarding the use of the device	13 November 2012	Unknown
B.R.A.H.M.S Osteocalcin Kryptor	Thermofisher Scientific	Advice regarding the use of the device	19 October 2012	Unknown
Biplex Vascular Grafts; Biplex Biovalsalva Conduit	Vascutek Ltd	Advice regarding the use of the device	20 December 2012	Yes
Narrow Bore Extension Line with Clamp	Vygon	Advice regarding the use of the device	11 December 2012	Yes
Line Cord / power transformers used in conjunction with British Standard Safety Plug (BS 1363 / IS 401 only)	Welch Allyn Inc	Advice regarding a device modification	07 December 2012	Yes