



IRISH MEDICINES BOARD

## FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET - FEBRUARY 2014

Case ID	Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Link to FSN on IMB website	Is the Irish market affected?
V20030	FreeStyle Mini® and FreeStyle® Blood Glucose Monitoring System	Abbott Diabetes Care	Advice regarding a device removal	19 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20026	ARCHITECT Intact PTH Assay, Reagents (8K25-20, 8K25-25, 8K25-27), Calibrators (8K25-01) and Controls (8K25-10)	Abbott Laboratories	Advice regarding a device removal	12 February 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19965	KAMRA Corneal Inlay	Acufocus Inc.	Advice regarding changes/updates made to instructions for use	05 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19980	Impax RIS	Agfa Helthcare N.V.	Advice regarding a software upgrade	07 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19973	Alere Triage® TOX Drug Screen	Alere	Advice regarding a device removal	03 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19946	Custom procedural trays containing BD Plastipak 50ml Luer Lok Syringe	ArcRoyal	Advice regarding the use of the device	29 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19893	Arrow® Edge® Hemodialysis Catherization Set Long-Term Access. Arrow® NextStep® Antegrade Hemodialysis Catheterization Set, Long-Term Access	Arrow International	Advice regarding a device removal	31 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20019	Aycan OsiriX	Aycan	Advice regarding a software upgrade	30 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V18947	UniCel Dxl Dxl 600 or 800 Access Immunoassay System, software versions 4.6 and 4.6.1	Beckman Coulter	Advice regarding a software upgrade	30 October 2013	<a href="#">Manufacturer's FSN</a>	Yes
V20031	Etest Ertapenem	BioMérieux Inc.	Advice regarding a device removal	10 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20074	PENTARAY® NAV CATHETER	Biosense Webster	Advice regarding a device removal	18 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20074	PENTARAY® NAV CATHETER	Biosense Webster	Advice regarding a device removal	18 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20135	nMARQTM Circular and Crescent Irrigated CATHETERS	BioSense Webster	Advice regarding the use of the device	26 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20099	RetCam3, RetCam Shuttle, RetCam Portable with Software Versions 6.0.x, 6.1.x, and 6.2.x	Clarity Medical Systems Inc.	Advice regarding a software upgrade	24 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V15605	Puritan Bennett 840 Ventilator	Covidien	Advice regarding the use of the device	28 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20053	Oxylog 3000plus, Oxylog 2000plus	Draeger	Advice regarding a device modification	18 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20062	Evita Infinity V500, Babylog VN500, Evita V300	Draeger	Advice regarding the use of the device	18 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V18122	Precise Digital Accelerator, Synergy Platform, Synergy, Synergy S, Infinity, Axesse	Elekta	Advice regarding a software upgrade	21 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V18122	Precise Digital Accelerator, Synergy Platform, Synergy, Synergy S, Infinity, Axesse	Elekta	Advice regarding a software upgrade	21 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V18122	Precise Digital Accelerator, Synergy Platform, Synergy, Synergy S, Infinity, Axesse	Elekta	Advice regarding a software upgrade	21 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V18122	Precise Digital Accelerator, Synergy Platform, Synergy, Synergy S, Infinity, Axesse	Elekta	Advice regarding a software upgrade	21 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V20033	XiO RTP System	Elekta	Advice regarding a software upgrade	14 February 2014	<a href="#">Manufacturer's FSN</a>	Yes

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V19955	Precision 500D and Proteus XR/a equipped with Wireless Digital Radiography Option (WDR1)	GE Healthcare	Advice regarding a software upgrade	03 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19967	Carescape Monitor B850	GE Healthcare	Advice regarding a device modification	04 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20091	Infinia and Infinia Hawkeye Nuclear Medicine systems Millennium VG, VG Hawkeye and VariCam Nuclear Medicine systems Helix Nuclear Medicine systems	GE Healthcare	Advice regarding a software upgrade	21 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20017	Standard Offset Cup Impactor	GreatBatch Medical	Advice regarding changes/updates made to instructions for use	17 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20097	samaritan PAD	HeartSine	Advice regarding a software upgrade	27 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19424	Flexible Bronchoscopes and Intubation Fiberscopes	Karl Storz	Advice regarding changes/updates made to instructions for use	29 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17166	Maxcem Elite	KerrHawe	Advice regarding a device removal	20 February 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19966	NOVO X 550 Bed - Central Arrest	Likamed GmbH	Advice regarding a device modification	05 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20014	Edi catheter	Maquet Critical Care AB	Advice regarding changes/updates made to instructions for use	11 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20090	Accutron MR	Medtronic AG	Advice regarding changes/updates made to instructions for use	07 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20035	Leads used for Medtronic Spinal Cord Stimulation (SCS) Therapy	Medtronic	Advice regarding the use of the device	17 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19999	Giraffe Stand Alone Infant Resuscitation System (StAR)	Ohmeda Medical	Advice regarding a device modification	10 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20108	Pinnacle Radiation Treatment Planning System	Philips	Advice regarding a software upgrade	10 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20007	Kryo range of freezers	Planer PLV	Advice regarding a software upgrade	30 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20049	Pride Elite Sport battery - S74 scooters	Pride Mobiltiy	Advice regarding a device removal	21 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19983	Rayner Hydrophilic Acrylic Single use Intraocular Lens	Rayner Intraocular Lenses Limited	Advice regarding a device removal	07 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19993	Sulcoflex 620H IOL	Rayner Intraocular Lenses Limited	Advice regarding a device removal	07 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20044	RIWOmobil Equipment Carts	Richard Wolf GmbH	Advice regarding a device modification	17 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19952	Reference Electrode - OMNI S and cobas b 221 systems	Roche Diagnostics	Advice regarding the use of the device	03 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19954	Luer Lock Caps, TP-MF-TP-MF-A	Sendal S.L.	Advice regarding a device removal	03 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20024	IMMULITE 2000, IMMULITE 2000XPi, VersaCell	Siemens Healthcare Diagnostics	Advice regarding the use of the device	13 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20087	ADVIA Centaur HIV Ag/Ab Combo (CHIV) Assay	Siemens Healthcare Diagnostics	Advice regarding changes/updates made to instructions for use	16 September 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19984	DYONICS™ 25 Patient Tube Set	Smith&Nephew	Advice regarding a device removal	06 February 2014	<a href="#">Manufacturer's FSN</a>	Yes

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V19462	Excelsior Microcatheters, GDC Coils, Neuroform EZ Stents, Transform Balloons	Stryker Neurovascular	Advice regarding a device removal	09 December 2014	<a href="#">Manufacturer's FSN</a>	Unknown
V20008	Teleflex ISIS Tracheal Tube with Subglottic Secretion Suction Port	Teleflex	Advice regarding a device removal	12 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19591	Oxoid Legionella BCYE Growth Supplement, SR0110C	Thermofisher Scientific	Advice regarding a device removal	11 December 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19985	REMEL <i>Shigella sonnei</i> (Phases 1&2) Agglutinating Serum	Thermofisher Scientific	Advice regarding a device removal	06 February 2014	<a href="#">Manufacturer's FSN</a>	Yes
V18975	Heyinovo biopsy forceps	Wilson Instruments	Advice regarding a device removal	11 December 2013	<a href="#">Manufacturer's FSN</a>	Yes