



IRISH MEDICINES BOARD

## FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET - January 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?
V19854	CyberKnife Robotic Radiosurgery System	Accuray Incorporated	Advice regarding a device modification	14 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19299	Multi-X X-ray Detectable Swabs	Aquilant Medical	Advice regarding the use of the device	17 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19863	Multi-X X-ray Detectable Swabs	Aquilant Medical	Advice regarding the use of the device	30 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19630	15L Cyclor Drainage Bag	Baxter	Advice regarding the use of the device	15 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19761	Bladder Irrigation Connector	Baxter	Advice regarding a device removal	16 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19781	Cyto-Set Infusomat Space	BBraun Medical Melsungen AG	Advice regarding the use of the device	17 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V17952	BD Vacutainer® Multiple Sample Luer Adaptor	BD	Advice regarding the use of the device	30 August 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19737	BD Plastipak™ 50ml Luer Lok Syringe	BD Medical	Advice regarding the use of the device	13 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19772	bioNexia FOBplus 410594	BioMerieux SA France	Advice regarding a device removal	02 December 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19835	Powerheart G5 AED	Cardiac Science Corporation	Advice regarding a device modification	01 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19736	Kodak 2100 and Kodak 2200 Intraoral X-Ray Systems	Carestream Health Inc.	Advice regarding a device modification	10 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19743	Duowire Guidewire	Coloplast A/S	Advice regarding a device removal	07 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19752	Peristeen Anal Irrigation System	Coloplast A/S	Advice regarding changes/updates made to instructions for use	15 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V15174	Onyx Liquid Embolic System	Covidien	Advice regarding changes/updates made to instructions for use	14 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V15605	Puritan Bennett 840 Ventilator	Covidien	Advice regarding a software upgrade	04 December 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
V19636	Instrument Manager 8.12.	Data Innovations	Advice regarding a software upgrade	13 December 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19770	Aisys anaesthesia system	Datex Ohmeda	Advice regarding changes/updates made to instructions for use	17 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19776	Anspatch® Short Carbide Cutting Burrs	DePuy Synthes	Advice regarding a device removal	16 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19306	Infinity® Acute Care System (IACS) in Neonatal Mode	Drager Medical	Advice regarding a software upgrade	18 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19625	Peripheral Access Arterial / Femoral Arterial Cannulas	Edwards Lifesciences LLC	Advice regarding the use of the device	06 January 2014	<a href="#">Manufacturer's FSN</a>	Yes

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V19627	XiO RTP System	Elekta	Advice regarding a software upgrade	19 December 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19629	Synergy XVI	Elekta	Advice regarding a software upgrade	27 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19717	Procure B20, B30 and B40 Patient Monitor	GE Healthcare	Advice regarding a software upgrade	13 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19749	Precision 500D, MPI RXI X-ray imaging systems	GE Healthcare	Advice regarding a device modification	16 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19817	CARESCAPE Monitor B650 and CARESCAPE Monitor B850	GE Healthcare Finland Oy	Advice regarding a device modification	22 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19806	Innova 2100IQ, 3100, 3100IQ, 4100,4100IQ, 2121IQ, and 3131IQ cardiovascular X-ray imaging systems	GE Medical Systems SCS	Advice regarding a device modification	22 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19593	CEM™ Nosecones for use with CUSA® Excel/Excel+ Ultrasonic Aspirator	Integra LifeSciences Corporation	Advice regarding the use of the device	17 December 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19383	Large and Mega Needle Drivers / Endowrist® Instruments	Intuitive Surgical	Advice regarding a device removal	18 December 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19783	Compoglass F	Ivoclar Vivadent AG	Advice regarding a device removal	19 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19645	AllSet+ and UniTray+	Life Technologies	Advice regarding the use of the device	31 October 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19718	OneTouch Ultra Test Strips	LifeScan	Advice regarding a device removal	10 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19866	PLEGIOX Cardioplegia Heat Exchanger	Maquet Cardiopulmonary AG	Advice regarding a device modification	27 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19907	Medtronic® Select 3D™ and Select CAP™ Arterial Cannula	Medtronic	Advice regarding a device removal	31 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19721	Mosaic Aortic Bioprosthesis	Medtronic Inc	Advice regarding the use of the device	09 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19879	Spike Biopsy Forceps	Micro-Tech Nanjing Co. Limited	Advice regarding a device removal	15 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19758	Lifescop J BSM9101K using s/w 13-05	Nihon Kohden	Advice regarding a software upgrade	20 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19659	ProLift S 222 Standsupport Slings.	Novacare	Advice regarding a device removal	26 September 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19808	Lambda Cell Trays	One Lambda Inc	Advice regarding changes/updates made to instructions for use	12 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19449	ORTHO BioVue System Cassettes	Ortho-Clinical Diagnostics	Advice regarding the use of the device	30 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19916	Oxoid Legionella pneumophila serogroup 2-14 Test Reagent (DR0802M)	Oxoid Limited	Advice regarding a device removal	30 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19773	BrightView SPECT, BrightView X, BrightView XCT	Phillips Medical Systems	Advice regarding a software upgrade	01 December 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19741	Freeway Mobile Hoists FGE150, FSE175, FME200, FGH150, FSH175 & FMH200	Prism Medical	Advice regarding the use of the device	02 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19092	Accu-Chek Aviva Combo Handset	Roche Diagnostics	Advice regarding the use of the device	28 October 2013	<a href="#">Manufacturer's FSN</a>	Yes

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V19092	Accu-Chek Aviva Combo Handset	Roche Diagnostics	Advice regarding the use of the device	30 October 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19518	cobas® PCR media 4.3 mL IVD	Roche Diagnostics	Advice regarding a device removal	18 December 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19774	HIV combi PT	Roche Diagnostics	Advice regarding a device removal	17 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19049	RAPIDPoint® 400 Series, RAPIDPoint® 500, and RAPIDLab® 1200 Series Analyzers	Siemens	Advice regarding a software upgrade	17 September 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19689	IMMULITE/IMMULITE 1000/IMMULITE 2000/2000 XPi IgE	Siemens	Advice regarding the use of the device	03 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19909	ACUSON SC2000™ ultrasound systems	Siemens	Advice regarding a device modification	29 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V18835	Torque Wrench: Xia, Xia 3, Xia Elegance Short, Mantis Redux	Stryker Spine	Advice regarding a device removal	22 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19638	Navigation Compatible Accolade Broach Handle	Stryker® Orthopaedics	Advice regarding a device removal	23 December 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19729	Oxoid Antimicrobial Susceptibility Testing Disc VA30 Vancomycin, CT0058B	Thermofisher Scientific	Advice regarding a device removal	10 January 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19853	MAS Omni IMMUNE and Omni IMMUNE PRO controls OIM-101, OIM-202, OIM-303, OIM-SP, OPR0-101, OPR0-202, OPR0-303, OPRO-SP	Thermofisher Scientific	Advice regarding a device removal	22 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19869	Radial head Prosthesis MoPyC - Head	Tornier	Advice regarding a device removal	31 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19801	ACE Normal Control	Trinity Biotech	Advice regarding a device modification	21 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19603	Ventilogic LS	Weinmann Geräte für Medizin GmbH + Co. KG	Advice regarding a device modification	18 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19804	Zimmer Trabecular Metal™ Reverse Shoulder System Glenosphere & Base Plate	Zimmer	Advice regarding the use of the device	31 December 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19652	Manual Orthopaedic Surgical Instruments	Zimmer GmbH	Advice regarding changes/updates made to instructions for use	30 December 2013	<a href="#">Manufacturer's FSN</a>	Yes