

		IRISH MEDICINES BOARD				
		FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET - MAY 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?
V20709	Hemoglobin A1c Calibrators	Abbott Laboratories	Advice regarding the use of the device	30 April 2014	Manufacturer's FSN	Yes
V20768	Pressure Injectable Central Venous Catheter Product, Multiple-Lumen Central Venous Catheterization Product, Multiple-Lumen Central Venous Catheterization Product with ARROWgard® Antimicrobial Surface	Arrow International Inc.	Advice regarding a device removal	15 May 2014	Manufacturer's FSN	Yes
V13398	Baxter Transfer Sets	Baxter Healthcare	Advice regarding changes/updates made to instructions for use	03 October 2013	Manufacturer's FSN	Yes
V20736	Xenium Ultra High Flux Dialyzer	Baxter Healthcare	Advice regarding the use of the device	15 May 2014	Manufacturer's FSN	Yes
V20674	Medrad Continuum MR Infusion System	Bayer Medical Care Inc.	Advice regarding the use of the device		Manufacturer's FSN	Yes
V20741	NOxBOXi Inhaled Nitric Oxide Delivery and Monitoring Device	Bedfont Scientific Limited	Advice regarding the use of the device	24 April 2014	Manufacturer's FSN	Yes
V20734	PentaRay NAV Catheter and PentaRay NAV ECO Catheter	Biosense Webster	Advice regarding a device removal	01 May 2014	Manufacturer's FSN	Yes
V20684	Flexi-Seal™ CONTROL™ Fecal Management System	ConvaTec Limited	Advice regarding a device removal	07 May 2014	Manufacturer's FSN	Yes
V20684	Flexi-Seal™ CONTROL™ Fecal Management System	ConvaTec Limited	Advice regarding a device removal	07 May 2014	Manufacturer's FSN	Yes
V20696	VentraLight ST Mesh with Echo PS Positioning System & Composix L/P Mesh with Echo PS Positioning System	Davol Inc.	Advice regarding a device removal	02 May 2014	Manufacturer's FSN	Yes
V20983	Zeus IE Anesthesia Unit	Dräger Medical AG & Co. KG	Advice regarding a software upgrade	28 May 2014	Manufacturer's FSN	Yes
V20846	Disposable ventilation hoses Ventstar for the Dräger emergency breathing device Oxylog 2000	Dräger Medical GmbH	Advice regarding the use of the device	22 May 2014	Manufacturer's FSN	Yes
V20981	Drive Medical Walking Frames	Drive Medical	Advice regarding a device removal	30 May 2014	Manufacturer's FSN	Yes
V20771	Synergy XVI	Elekta	Advice regarding a software upgrade	20 May 2014	Manufacturer's FSN	Yes
V20771	Synergy XVI	Elekta	Advice regarding a software upgrade	09 May 2014	Manufacturer's FSN	Yes
V20805	MOSAIQ Radiation Treatment Planning System Software	Elekta	Advice regarding a software upgrade	23 May 2014	Manufacturer's FSN	Yes
V19629	Synergy XVI	Elekta Limited	Advice regarding a software upgrade	13 May 2014	Manufacturer's FSN	Yes
V20707	Triple Sugar Iron Agar	Fannin Limited (LIP)	Advice regarding a device removal	02 May 2014	Manufacturer's FSN	Yes
V20706	Vivid E9	GE Healthcare	Advice regarding a software upgrade	02 May 2014	Manufacturer's FSN	Yes
V20746	Discovery MR450, Discovery MR750, Optima MR450w, Optima MR450w equipped with the GEM option, Discovery MR750w, and Discovery MR750w equipped with the GEM option products	GE Healthcare	Advice regarding a device modification	07 May 2014	Manufacturer's FSN	Yes
V20775	Kenex ceiling suspended radiation shield and surgical lamp	GE Healthcare	Advice regarding a device modification	08 May 2014	Manufacturer's FSN	Yes

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V20885	Centricity PACS RA1000 Workstation versions 3.2 and higher	GE Healthcare	Advice regarding a device modification	23 May 2014	Manufacturer's FSN	Yes
V20750	MGuard Prime Coronary Stent System Embolic Protective Stent	InspireMD	Advice regarding a device removal	02 May 2014	Manufacturer's FSN	Yes
V20791	Aquatec® Ocean VIP	InvaCare	Advice regarding a device modification	14 May 2014	Manufacturer's FSN	Yes
V20817	McKesson Horizon Medical Imaging (HMI) releases 4.5 up to 11.9 and McKesson Radiology 12.0	McKesson Medical Imaging Company	Advice regarding a software upgrade	05 May 2014	Manufacturer's FSN	Yes
V20806	Medtronic Navigation Sterile Devices	Medtronic Navigation Inc.	Advice regarding a device removal	16 May 2014	Manufacturer's FSN	Yes
V20596	pH Indicator Strips non-bleeding	Merck Serono	Advice regarding the use of the device	02 May 2014	Manufacturer's FSN	Yes
V20908	ReNew Fenestrated Grasper Forceps Tips	Microline Surgical	Advice regarding a device removal	20 May 2014	Manufacturer's FSN	Yes
V20710	IntelliVue Patient Monitor MP2, X, MP5, MP5T, MP20, MP30, MP40 and MP50	Philips Healthcare	Advice regarding changes/updates made to instructions for use	06 May 2014	Manufacturer's FSN	Yes
V20883	Ingenia, Intera, Achieva and Multiva MR Systems on R5.1.1 and R5.1.2	Philips Healthcare UK	Advice regarding a software upgrade	23 May 2014	Manufacturer's FSN	Yes
V20683	MODULAR ANALYTICS E 170 / EVO E 170, cobas e 601 module & cobas e 602 module	Roche Diagnostics	Advice regarding the use of the device	08 May 2014	Manufacturer's FSN	Yes
V20837	LANTIS OIS system	Siemens AG Healthcare	Advice regarding the use of the device	21 May 2014	Manufacturer's FSN	Yes
V20544	AXIOM Artis, Artis Zee or Artis Q systems	Siemens Healthcare	Advice regarding a device modification	07 May 2014	Manufacturer's FSN	Yes
V20726	Acuson SC2000	Siemens Healthcare	Advice regarding a software upgrade	07 May 2014	Manufacturer's FSN	Yes
V20764	Siemens Ysio Systems	Siemens Healthcare	Advice regarding changes/updates made to instructions for use	14 May 2014	Manufacturer's FSN	Yes
V20945	RAPIDPoint® 500 System Measurement Cartridge Lactate	Siemens Healthcare	Advice regarding the use of the device	28 May 2014	Manufacturer's FSN	Yes
V19049	RAPIDPoint® 400 Series, RAPIDPoint® 500, and RAPIDLab® 1200 Series Analyzers	Siemens Healthcare Diagnostics	Advice regarding a software upgrade	20 November 2013	Manufacturer's FSN	Yes
V20927	AutoFIX™ 3.0/4.0 non sterile range	Small Bone Innovations International	Advice regarding a device removal	27 May 2014	Manufacturer's FSN	Yes
V20173	Mio, Vector, Tilty (II, Vario), Siro (II) Wheelchairs	SORG Rollstuhltechnik GmbH & Co.KG	Advice regarding a device modification	06 March 2014	Manufacturer's FSN	Yes
V20755	Axium Implantable Lead Kit	Spinal Modulation Inc	Advice regarding the use of the device	15 May 2014	Manufacturer's FSN	Yes
V20802	DETEX X-ray Detectable Swabs	Synergy Health UK	Advice regarding a device removal	13 May 2014	Manufacturer's FSN	Yes
V20858	BONDEK/TEVDEK suture	Teleflex	Advice regarding a device removal	22 May 2014	Manufacturer's FSN	Yes
V20702	Oxoid Antimicrobial Susceptibility Disc P1 Penicillin G CT0152B	Thermofisher Scientific	Advice regarding a device removal	02 May 2014	Manufacturer's FSN	Yes
V20704	Oxoid Cycloheximide 0.1% Solution SR0222C	Thermofisher Scientific	Advice regarding a device removal	02 May 2014	Manufacturer's FSN	Yes
V20857	Oxoid Beta Lactamase Identification Sticks BR0066A	Thermofisher Scientific	Advice regarding a device removal	21 May 2014	Manufacturer's FSN	Yes

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V20220	Embryoscope ES-D2	Unisense FertiliTech A/S	Advice regarding changes/updates made to instructions for use	24 April 2014	Manufacturer's FSN	Yes