



IRISH MEDICINES BOARD

FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- MAY 2013

Case ID	Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Link to FSN on IMB website	Is the Irish market affected?
V17502	ACRYSOFT® CACHET™ Phakic Lens	Alcon	Advice regarding the use of the device	02 April 2013	Manufacturer's FSN	Yes
V17768	Enterprise Bed 5000, 8000 & 9000 models.	ArjoHuntleigh	Advice regarding the use of the device	30 April 2013	Manufacturer's FSN	Yes
V14480	HomeChoice Disposable Sets / UV HomeChoice Automated PD Set with Cassette 4-Prong / HomeChoice Automated PD Set with Cassette 8-Prong / HomeChoice Automated PD Set with Cassette 4-Prong and Manifold Sets / 5-Prong Manifold Set with System II Connectors	Baxter Healthcare	Advice regarding changes/updates made to instructions for use	07 May 2013	Manufacturer's FSN	Yes
V17734	BBL DrySlide PYR and Oxidase Kit	BD	Advice regarding a device removal	22 April 2013	Manufacturer's FSN	Yes
V17952	BD Vacutainer® Multiple Sample Luer Adaptor	BD Diagnostics	Advice regarding a device removal	29 May 2013	Manufacturer's FSN	Yes
V17639	Synchron Systems Lactate	Beckman Coulter	Advice regarding a device modification	25 April 2013	Manufacturer's FSN	Yes
V17651	Zilver PTX Drug-Eluting Peripheral Stent (Delivery System)	Cook	Advice regarding a device removal	19 April 2013	Manufacturer's FSN	Yes
V17833	Soft tissue retractor, small, extendible	DePuy Synthes	Advice regarding a device removal	08 May 2013	Manufacturer's FSN	Yes
V17872	CODMAN® CERTAS™ Programmable Valves	DePuy Synthes	Advice regarding a device removal	15 May 2013	Manufacturer's FSN	Yes
V17819	XVI 5.5.1	Elekta	Advice regarding a software upgrade	01 April 2013	Manufacturer's FSN	Yes
V17907	3DLINE DMLC IV	Elekta	Advice regarding the use of the device	01 May 2013	Manufacturer's FSN	Yes
V17923	Temporary Cardiac Pacing Wire	Ethicon	Advice regarding a device removal	24 May 2013	Manufacturer's FSN	Yes
V17918	ECHOLON™ 60 ENDOPATH® STAPLER Endoscopic Linear Cutter Reload Black 4.4 mm, 6 rows	Ethicon Endo-Surgery	Advice regarding a device removal	24 May 2013	Manufacturer's FSN	Yes
V17423	HemoCue Glucose 201 RT system and HemoCue Glucose 201 DM RT system	HemoCue	Advice regarding the use of the device	07 May 2013	Manufacturer's FSN	Yes
V17807	Liko Overhead and Mobile Lifts - Standard Slingbar™ 450	Hill-Rom Liko Lulea	Advice regarding a device modification	08 May 2013	Manufacturer's FSN	Yes
V17337	ABX DIFFTROL LOT PX033	Horiba ABX SAS	Advice regarding changes/updates made to instructions for use	26 February 2013	Manufacturer's FSN	Yes
V17751	Primary Plumset	Hospira Inc	Advice regarding the use of the device	14 May 2013	Manufacturer's FSN	Yes
V17745	Barrier Matrix, Suturable DuraGen™ Dural Regeneration Matrix, + Layershield® Adhesion Barrier Matrix, + Neurawrap® Nerve Protector, NeuraGen® Nerve Guide	Integra Lifesciences	Advice regarding a device removal	24 April 2013	Manufacturer's FSN	Yes
V17821	da Vinci Surgical System - EndoWrist Instrument Hot Shears Monopolar Curved Scissors	Intuitive Surgical	Advice regarding the use of the device	10 May 2013	Manufacturer's FSN	Yes

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V17878	Spectra Series powered wheelchairs	Invacare Ltd.	Advice regarding the use of the device	14 May 2013	Manufacturer's FSN	Yes
V17748	Panbio Dengue IgM Capture ELISA	Inverness Medical Innovations Australia Pty Limited	Advice regarding the use of the device	29 April 2013	Manufacturer's FSN	Yes
V17339	SERVO-i Ventilators	Maquet	Advice regarding the use of the device	29 April 2013	Manufacturer's FSN	Yes
V17962	SynchroMed® II and SynchroMed EL Implantable Drug Pumps	Medtronic	Advice regarding the use of the device	03 June 2013	Manufacturer's FSN	Yes
V17960	SynchroMed® II and SynchroMed EL Implantable Drug Pumps	Medtronic	Advice regarding the use of the device	03 June 2013	Manufacturer's FSN	Yes
V17961	SynchroMed® II and SynchroMed EL Implantable Drug Pumps	Medtronic	Advice regarding the use of the device	03 June 2013	Manufacturer's FSN	Yes
V17785	NIM Flex™ EMG Endotracheal Tube	Medtronic Xomed	Advice regarding a device removal	06 May 2013	Manufacturer's FSN	Yes
V17739	PANTA Arthrodesis Nail System, Panta XL Arthrodesis Nail System	Newdeal SAS	Advice regarding changes/updates made to instructions for use	23 April 2013	Manufacturer's FSN	Yes
V17779	VITROS Chemistry Systems	Ortho Clinical Diagnostics	Advice regarding a device modification	01 May 2013	Manufacturer's FSN	Yes
V17788	Philips HeartStart MRx Monitor/Defibrillator	Philips Healthcare	Advice regarding a software upgrade	01 April 2013	Manufacturer's FSN	Yes
V16934	Metal Max Disposable Green System Laryngoscope Handles	Proact Medical Ltd.	Advice regarding a device removal	28 January 2013	Manufacturer's FSN	Yes
V17334	RayStation 2.0, 2.5 and 3.0	RaySearch Laboratories AB	Advice regarding a software upgrade	28 January 2013	Manufacturer's FSN	Unknown
V17822	CoaguChek XS Plus / CoaguChek XS Pro	Roche Diagnostics	Advice regarding the use of the device	08 May 2013	Manufacturer's FSN	Yes
V17822	CoaguChek XS	Roche Diagnostics	Advice regarding the use of the device	08 May 2013	Manufacturer's FSN	Yes
V16398	Mobilett Mira	Siemens Healthcare	Advice regarding a software upgrade	20 September 2012	Manufacturer's FSN	Unknown
V17875	Digital Linear Accelerators; Mevatron, PRIMUS™ and ONCOR™	Siemens	Advice regarding a software upgrade	17 May 2013	Manufacturer's FSN	Yes
V17786	Guide Wire Ø 2.5 mm, with drill tip, length 300 mm, Cobalt-Chrome Alloy	Synthes GmbH	Advice regarding a device removal	06 May 2013	Manufacturer's FSN	Yes
V17756	Trima Accel Automated Blood Collection System	Terumo BCT	Advice regarding a software upgrade	16 May 2013	Manufacturer's FSN	Yes
V17812	BLACKMAX-NS, BLACKMAX-NS-LP, XMAX, MICROMAX, MICROMAX-LP, MICROMAX-PLUS, MICROMAX-PLUS-LP, iMRI Instrument System	The Anspach Effort Inc.	Advice regarding a device removal	08 May 2013	Manufacturer's FSN	Yes
V17808	Oxoid Antimicrobial Susceptibility Testing Disc CN10 (Gentamicin), CT0024B	Thermofisher Scientific	Advice regarding a device removal	08 May 2013	Manufacturer's FSN	Yes
V17809	Oxoid Antimicrobial Susceptibility Testing Disc AMP10 (Ampicillin), CT0003B	Thermofisher Scientific	Advice regarding a device removal	08 May 2013	Manufacturer's FSN	Yes

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V17778	Bacterial filters for use in WASSENBURG® systems	Wassenburg Medical Devices	Advice regarding the use of the device	13 May 2013	Manufacturer's FSN	Yes
V17746	Mobile X-ray C-arms	Ziehm Imaging GmbH	Advice regarding a device modification	29 April 2013	Manufacturer's FSN	Yes