



IRISH MEDICINES BOARD

FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- MARCH 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?
V17256	2.3mm X 16mm Non-Togging Cortical Screw	Acumed	Advice regarding a device removal	28 February 2013	Manufacturer's FSN	Yes
V16097	A-dec 200 Dental Chair System	A-dec Inc.	Advice regarding a device modification	22 October 2012	Manufacturer's FSN	Yes
V17408	Alere Cholestech LDX® ALT•AST cassette	Alere San Diego, Inc	Advice regarding a device removal	20 March 2013	Manufacturer's FSN	Yes
V16864	Alere Cholestech LDX Multianalyte Control	Alere San Diego, Inc	Advice regarding a device removal	22 March 2013	Manufacturer's FSN	Yes
V17291	AMS 800® Urinary Control System Control Pump / Pressure-Regulating Balloon	American Medical Systems	Advice regarding a device removal	01 March 2013	Manufacturer's FSN	Yes
V17291	AMS 800® Urinary Control System Control Pump / Pressure-Regulating Balloon	American Medical Systems	Advice regarding a device removal	01 March 2013	Manufacturer's FSN	Yes
V15922	Saver One Defibrillator	AMI Italia	Advice regarding a device modification	20 May 2011	Manufacturer's FSN	Yes
V17249	Mini Cap Extended Life PD Transfer Set	Baxter Healthcare	Advice regarding changes/updates made to instructions for use	06 March 2013	Manufacturer's FSN	Yes
V17046	BBL Crystal Enteric/Nonfermenter ID Kit	Becton Dickinson & Company	Advice regarding a device removal	14 February 2013	Manufacturer's FSN	Yes
V17397	Hand pendants for OPERON D 850, D 820 and D760 operating tables	Berthold GmbH & Co. KG	Advice regarding a device modification	11 March 2013	Manufacturer's FSN	Yes
V17232	VITEK 2 Systems	BioMerieux Inc.	Advice regarding changes/updates made to instructions for use	06 March 2013	Manufacturer's FSN	Yes
V17236	Q-TECH™ Model 2020 programmers and SQ-RX® Model 1010 pulse generators	Boston Scientific	Advice regarding a software upgrade	07 March 2013	Manufacturer's FSN	Yes
V17465	ORTHOCORD 223111, 223113, 223114, 223115, & 223116	De Puy Mitek	Advice regarding changes/updates made to instructions for use	22 March 2013	Manufacturer's FSN	Yes
V17311	DePuy Specialist 2 Intramedullary Rod (SP2 IM Rod)	DePuy Orthopaedics, Inc.	Advice regarding changes/updates made to instructions for use	28 February 2013	Manufacturer's FSN	Yes
V15565	Digital Accelerator	Elekta	Advice regarding a device modification	01 November 2012	Manufacturer's FSN	Yes
V17362	Precise Treatment Table	Elekta Limited	Advice regarding a device modification	15 March 2013	Manufacturer's FSN	Yes
V17303	BiCision S/M/L; 20195-310 (S), 20195-311 (M), 20195-312 (L)	Erbe Elektromedizin GmbH	Advice regarding a device removal	05 February 2013	Manufacturer's FSN	Yes
V17341	EasyGas; SF6, C2F6, C3F8	Flouron GmbH	Advice regarding a device removal	04 March 2013	Manufacturer's FSN	Yes

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V17241	InstaTrak® 3500Plus, InstaTrak® 3500, ENTrak®, ENTrak® Plus	GE Healthcare	Advice regarding a software upgrade	28 February 2013	Manufacturer's FSN	Yes
V17367	FlexiView 8800 mobile C-Arms	GE Healthcare	Advice regarding a software upgrade	11 March 2013	Manufacturer's FSN	Yes
V17423	HemoCue Glucose 201 RT and Glucose DM RT Systems	HemoCue	Advice regarding changes/updates made to instructions for use	15 March 2013	Manufacturer's FSN	Yes
V17348	Hill-Rom® 900 Electric Bed	Hill-Rom	Advice regarding a device modification	20 November 2012	Manufacturer's FSN	Yes
V17096	Plum A+ and A+3 family of infusers	Hospira Inc.	Advice regarding the use of the device	05 March 2013	Manufacturer's FSN	Yes
V17286	GemStar™ Infusion System Lithium Battery	Hospira Inc.	Advice regarding a device modification	21 March 2013	Manufacturer's FSN	Yes
V16744	Intuitive Surgical Reprocessing Instructions for EndoWrist® Instruments and Accessories for the da Vinci® Surgical Systems	Intuitive Surgical Inc.	Advice regarding changes/updates made to instructions for use	22 March 2013	Manufacturer's FSN	Yes
V17378	Invacare REA Assist	Invacare UK Ltd.	Advice regarding changes/updates made to instructions for use	08 March 2013	Manufacturer's FSN	Yes
V17356	OneTouch Verio Pro	LifeScan	Advice regarding a device removal	22 March 2013	Manufacturer's FSN	Yes
V17359	OneTouch Verio IQ	LifeScan	Advice regarding a device removal	22 March 2013	Manufacturer's FSN	Yes
V17414	TRUE Dilatation(tm) Balloon Valvuloplasty Catheter	Loma Vista Medical Inc.	Advice regarding a device removal	19 March 2013	Manufacturer's FSN	Yes
V17374	CARDIOHELP-i	Maquet Cardiopulmonary AG	Advice regarding a software upgrade	12 March 2013	Manufacturer's FSN	Yes
V14978	Maquet Oxygenators - Blood outlet connector	Maquet Cardiopulmonary AG	Advice regarding a device modification	04 March 2013	Manufacturer's FSN	Yes
V17339	SERVO-i Ventilators	Maquet Critical Care AB	Advice regarding the use of the device	11 March 2013	Manufacturer's FSN	Yes
V17006	Medela Docking Station	Medela AG	Advice regarding a device removal	31 January 2013	Manufacturer's FSN	Yes
V15721	Valisafe Bowie & Dick Type Test Product Code V3501020	Medisafe International	Advice regarding changes/updates made to instructions for use	27 July 2012	Manufacturer's FSN	Yes
V17472	Paradigm Insulin Infusion Pump	Medtronic	Advice regarding the use of the device	28 March 2013	Manufacturer's FSN	Yes
V17472	Paradigm Insulin Infusion Pump	Medtronic	Advice regarding the use of the device	28 March 2013	Manufacturer's FSN	Yes
V17268	REAL 2000, REAL 9000, REAL 9000 PLUS, REAL 6100	Mercado Medic AB	Advice regarding a device modification	21 February 2013	Manufacturer's FSN	Yes
V17242	IntelliSpace Portal version 4.0.2	Philips Healthcare	Advice regarding a software upgrade	12 February 2013	Manufacturer's FSN	Yes
V17252	LIFEPAK CR® Plus and LIFEPAK EXPRESS® AEDs	Physio-Control	Advice regarding the use of the device	01 February 2013	Manufacturer's FSN	Yes
V17428	cobas® 4800 system –z480 instrument	Roche	Advice regarding a software upgrade	25 March 2013	Manufacturer's FSN	Yes

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V17259	Octenilin wound gel, octenilin wound irrigation solution and octenisept wound gel	Schülke & Mayr GmbH	Advice regarding changes/updates made to instructions for use	19 January 2013	Manufacturer's FSN	Yes
V17433	COHERENCE RT Therapist	Siemens	Advice regarding a software upgrade	25 March 2013	Manufacturer's FSN	Yes
V17156	Artis Zeego systems	Siemens Healthcare	Advice regarding a software upgrade	01 March 2013	Manufacturer's FSN	Yes
V17278	IMMULITE 2500 IGF-1	Siemens Healthcare Diagnostics	Advice regarding the use of the device	06 March 2013	Manufacturer's FSN	Yes
V17275	Centralink Version 14 System Database Anomaly	Siemens Healthcare Diagnostics	Advice regarding the use of the device	01 February 2013	Manufacturer's FSN	Yes
V17478	Sure-Pro® and Sure-Pro Ultra® Embryo Replacement	Smiths Medical International Ltd	Advice regarding the use of the device	28 March 2013	Manufacturer's FSN	Yes
V17345	Triathlon Baseplate Impactor / Extractor	Stryker Orthopaedics	Advice regarding a device removal	21 March 2013	Manufacturer's FSN	Yes
V17297	Midfoot Fusion Bolt Ø 6.5 mm	Synthes GmbH	Advice regarding changes/updates made to instructions for use	06 March 2013	Manufacturer's FSN	Yes
V17353	1st MTP Fusion Plate 2.4/2.7 VA Locking, medium, length 52mm, 5 degree, left.	Synthes GmbH	Advice regarding a device removal	11 March 2013	Manufacturer's FSN	Yes
V17420	pocH-Series and XP-Series	Sysmex Corporation	Advice regarding the use of the device	22 March 2013	Manufacturer's FSN	Yes
V17230	Guardian II and Guardian II NC hemostasis valve	Vascular Solutions Zerusa Ltd.	Advice regarding a device removal	27 February 2013	Manufacturer's FSN	Yes
V16319	GlideScope Video Laryngoscope	Verathon Medical (Europe) B.V.	Advice regarding a device removal	20 November 2012	Manufacturer's FSN	Unknown
V17269	VYGON AUTOFLUSH	Vygon - France	Advice regarding a device removal	06 March 2013	Manufacturer's FSN	Yes
V15891	Trilogy® Acetabular System Shells	Zimmer	Advice regarding the use of the device	06 February 2013	Manufacturer's FSN	Yes