



IRISH MEDICINES BOARD

FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET - March 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?
V19644	Pegasus Alternating Mattresses X2 Capacitor, affecting Biwave, Cairwave, Trinova and Viaclin Pumps	ArjoHuntleigh	Advice regarding a device modification	14 March 2014	Manufacturer's FSN	Yes
V20226	HomeChoice Automated PD System and HomeChoice PRO Automated PD System	Baxter Healthcare SA	Advice regarding changes/updates made to instructions for use	13 March 2014	Manufacturer's FSN	Yes
V19240	COULTER® LH 750 and LH 780 Analyzers	Beckman Coulter	Advice regarding a device removal	20 February 2014	Manufacturer's FSN	Yes
V19242	UniCel DxH 800 and DxH 600 Coulter Cellular Analysis Systems	Beckman Coulter	Advice regarding a device removal	20 February 2014	Manufacturer's FSN	Yes
V20224	FB, ZYM B, API Listeria, API NH	Biomerieux	Advice regarding a device removal	11 March 2014	Manufacturer's FSN	Yes
V20264	Alaris® SmartSite® Needle-Free Valve	CareFusion	Advice regarding a device removal	28 February 2014	Manufacturer's FSN	Yes
V20124	Cordis AVANTI®+ Transradial Kit; Cordis Obturator	Cordis Cashel	Advice regarding a device removal	27 February 2014	Manufacturer's FSN	Yes
V15174	Onyx Liquid Embolic System	Covidien	Advice regarding changes/updates made to instructions for use	14 November 2013	Manufacturer's FSN	Yes
V20219	DePuy S ROM Noiles Rotating Hinge Femur with Pin	DePuy Synthes	Advice regarding a device removal	11 March 2014	Manufacturer's FSN	Yes
V20373	Guide Wire 0 3.2 mm, length 400 mm	DePuy Synthes	Advice regarding the use of the device	26 March 2014	Manufacturer's FSN	Yes
V20231	Reusable latex breathing bags, test lung	Dräger	Advice regarding the use of the device	12 March 2014	Manufacturer's FSN	Yes
V20381	Dräger monitor holders with AC2000 spring-loaded arm	Dräger Medical GmbH	Advice regarding a device modification	26 March 2014	Manufacturer's FSN	Yes
V20033	XiO RTP System	Elekta Limited	Advice regarding a software upgrade	19 February 2014	Manufacturer's FSN	Yes
V20336	Innova 2100IQ, Innova 2121IQ, Innova 3100, Innova 3100IQ, Innova 3131IQ, Innova 4100, Innova4100IQ, Innova IGS 620, Innova IGS 630 Cardiovascular X-ray imaging systems equipped with CE marked PDB (Power Distribution Box).	GE Healthcare	Advice regarding a device modification	24 March 2014	Manufacturer's FSN	Yes
V20323	ReTurn 7400 and ReTurn 7500	Handicare AB	Advice regarding a device modification	19 March 2014	Manufacturer's FSN	Yes
V20097	samaritan PAD	HeartSine Technologies	Advice regarding a software upgrade	20 February 2014	Manufacturer's FSN	Yes
V20205	CUSA® Excel/CUSA® Excel+ 23 kHz Sterile Torque Wrench	Integra Lifesciences	Advice regarding a device removal	06 March 2014	Manufacturer's FSN	Yes
V20010	Keeler CRYOMASTER cryosurgical console	Keeler	Advice regarding a device modification	03 March 2014	Manufacturer's FSN	Yes
V20161	Kimal Procedure Packs containing 18G X7cm Sing Wall Cordis A4	Kimal Plc	Advice regarding a device removal	27 February 2014	Manufacturer's FSN	Yes
V20190	PowerLED 700	Maquet	Advice regarding a device modification	06 March 2014	Manufacturer's FSN	Yes
V20190	H LED 700	Maquet	Advice regarding a device modification	06 March 2014	Manufacturer's FSN	Yes

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V20232	PLEGIOX Cardioplegia Heat Exchanger	Maquet Cardiopulmonary AG	Advice regarding a device modification	12 March 2014	Manufacturer's FSN	Yes
V20418	Datascope Intra-Aortic Balloon Pump	Maquet Cardiopulmonary AG	Advice regarding a device removal	24 March 2014	Manufacturer's FSN	Yes
V20349	Measurement Specialties Reusable Temperature Probe Autoclavable	Measurement Specialites	Advice regarding changes/updates made to instructions for use	24 March 2014	Manufacturer's FSN	Yes
V20234	SynchroMed® II Implantable Drug Pumps	Medtronic B.V.	Advice regarding changes/updates made to instructions for use	04 March 2014	Manufacturer's FSN	Yes
V20034	Activa series	Medtronic Inc	Advice regarding changes/updates made to instructions for use	17 February 2014	Manufacturer's FSN	Yes
V20262	Paradigm Insulin Infusion Pump; MMT various models	Medtronic Minimed	Advice regarding the use of the device	17 March 2014	Manufacturer's FSN	Yes
V20262	Paradigm Insulin Infusion Pump; MMT various models	Medtronic Minimed	Advice regarding the use of the device	17 March 2014	Manufacturer's FSN	Yes
V20182	Hintegra Total Ankle Prosthesis	Newdeal SAS	Advice regarding a device removal	05 March 2014	Manufacturer's FSN	Yes
V20189	Giraffe Stand Alone Infant Resuscitation System (StAR)	Ohmeda Medical	Advice regarding a device modification	07 March 2014	Manufacturer's FSN	Yes
V19140	VITROS® Immunodiagnostic Products Anti-HBs Reagent Packs and Calibrators (Product Codes 1787753 and 1524693), VITROS® Immunodiagnostic	Ortho-Clinical Diagnostics	Advice regarding the use of the device	09 December 2013	Manufacturer's FSN	Yes
V20193	HeartStart MRx Defibrillator/Monitor	Philips Healthcare	Advice regarding a device modification	07 March 2014	Manufacturer's FSN	Yes
V20194	HeartStart MRx Defibrillator/Monitor	Philips Healthcare	Advice regarding a software upgrade	07 March 2014	Manufacturer's FSN	Yes
V20195	HeartStart MRx Defibrillator/Monitor	Philips Healthcare	Advice regarding a device modification	07 March 2014	Manufacturer's FSN	Yes
V20196	Philips HeartStart MRx M3538A Lithium Ion Batteries	Philips Healthcare	Advice regarding a device modification	07 March 2014	Manufacturer's FSN	Yes
V20244	HeartStart XL Defibrillator/Monitor	Philips Healthcare	Advice regarding a device modification	13 March 2014	Manufacturer's FSN	Yes
V20245	HeartStart MRx Defibrillator/Monitor	Philips Healthcare	Advice regarding a device modification	13 March 2014	Manufacturer's FSN	Yes
V20311	HeartStart FR3	Philips Healthcare	Advice regarding a software upgrade	20 March 2014	Manufacturer's FSN	Yes
V20312	HeartStart FR3	Philips Healthcare	Advice regarding a device removal	20 March 2014	Manufacturer's FSN	Yes
V20246	HeartStart MRx Defibrillator/Monitor	Philips Healthcare	Advice regarding a device modification	13 March 2014	Manufacturer's FSN	Yes
V20181	MagNA Pure 96 Instrument / FLOW PSH Instrument	Roche Diagnostics	Advice regarding a software upgrade	06 March 2014	Manufacturer's FSN	Yes
V20304	cobas c pack MULTI	Roche Diagnostics	Advice regarding the use of the device	19 March 2014	Manufacturer's FSN	Yes
V19694	XGEO GC80, XGEO GC80V 80, XGEO GC80V 65	Samsung Corporation	Advice regarding a software upgrade	07 January 2014	Manufacturer's FSN	Unknown
V20107	9003 Inspiration Cot	Sidhil Limited	Advice regarding changes/updates made to instructions for use	14 February 2014	Manufacturer's FSN	Yes

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V20335	Symbia T and Symbia T2 SPECT/CT systems	Siemens	Advice regarding a device modification	12 March 2014	Manufacturer's FSN	Yes
V20088	ADVIA Centaur® XP Immunoassay system	Siemens Healthcare	Advice regarding the use of the device	03 March 2014	Manufacturer's FSN	Yes
V20274	ACUSON P300 ultrasound systems	Siemens Medical Solutions USA Inc.	Advice regarding a software upgrade	18 March 2014	Manufacturer's FSN	Yes
V19661	Codman® - Quad-Lock™ Sterilization Container System and/or Symmetry Surgical - Quad-Lock™ Sterilization Container System	Symmetry Surgical	Advice regarding a device removal	02 December 2013	Manufacturer's FSN	Unknown
V20227	Various Weck® Vista™ Laparoscopic Access Ports, Cannulae and Balloon Access Ports	Teleflex	Advice regarding a device removal	13 March 2014	Manufacturer's FSN	Yes
V20065	Rusch Bronchopart®, Rusch Bronchopart® White, Rusch One-lumen bronchial tube, right, Rusch Tracheopart®	Teleflex Medical	Advice regarding a device removal	20 February 2014	Manufacturer's FSN	Yes
V20346	CAPIO™ Bondek® Green Braided-Coated Polyglycolic Acid Sutures, Synthetic Absorbable Surgical Sutures and others	Teleflex Medical	Advice regarding a device removal	24 March 2014	Manufacturer's FSN	Yes
V20122	AterX	Tenaxis Medical Inc	Advice regarding a device removal	12 February 2014	Manufacturer's FSN	Yes
V20169	HeartMate II LVAS System Controller	Thoratec Corporation	Advice regarding changes/updates made to instructions for use	04 March 2014	Manufacturer's FSN	Yes
V20160	Ovation Prime Abdominal Stent Graft System	Trivascular Inc.	Advice regarding the use of the device	28 February 2014	Manufacturer's FSN	Yes
V20333	On Board Imager	Varian	Advice regarding a device modification	20 March 2014	Manufacturer's FSN	Yes
V20407	Ring Applicator Set (45°, 60°,90°)	Varian Medical Systems	Advice regarding a device removal	20 March 2014	Manufacturer's FSN	Yes
V20405	STIMPOD NMS450 Nerve Stimulator	Xavant Technology	Advice regarding changes/updates made to instructions for use	20 March 2014	Manufacturer's FSN	Yes
V20406	STIMPOD NMS450 Nerve Stimulator	Xavant Technology	Advice regarding the use of the device	31 January 2014	Manufacturer's FSN	Yes