



IRISH MEDICINES BOARD

FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET - JUNE 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?
V18030	Abbott Medical Optics (AMO) STAR Excimer Laser System Models S3, S4 and S4 IR	Abbott Medical Optics	Advice regarding a device modification	04 June 2013	Manufacturer's FSN	Yes
V17748	Panbio Dengue IgM Capture ELISA	Alere	Advice regarding the use of the device	29 April 2013	Manufacturer's FSN	Yes
V17874	Epix Laparoscopic Graspers	Applied Medical	Advice regarding a device removal	17 May 2013	Manufacturer's FSN	Yes
V18084	Bard® UltraClip® Dual Trigger Tissue Marker	Bard Limited	Advice regarding a device removal	14 June 2013	Manufacturer's FSN	Yes
V11831	UniCel Dxl Immunoassay Systems	Beckman Coulter Inc	Advice regarding the use of the device	10 June 2013	Manufacturer's FSN	Yes
V16163	Access 2 Immunoassay Systems / Synchron Lxi 725 Clinical Systems / UniCel DxC 600i Synchron Access Clinical Systems	Beckman Coulter Inc	Advice regarding the use of the device	13 November 2013	Manufacturer's FSN	Yes
V16335	AHM Gen II ELISA	Beckman Coulter Inc	Advice regarding the use of the device	13 June 2013	Manufacturer's FSN	Yes
V17869	SYNCHRON System(s) Lactate (LACT)	Beckman Coulter Inc	Advice regarding a device removal	04 June 2013	Manufacturer's FSN	Yes
V18103	BD Stem Cell Control Kit	Becton Dickinson	Advice regarding a device removal	12 June 2013	Manufacturer's FSN	Yes
V18021	Alaris® GP, GP Guardrails®, GP Plus & GP Plus Guardrails® Infusion Pumps	CareFusion	Advice regarding a device modification	31 May 2013	Manufacturer's FSN	Yes
V18045	MEDSTREAM Programmable Infusion Pumps	Codman Neurosciences	Advice regarding a device removal	10 June 2013	Manufacturer's FSN	Yes
V17902	IH-1000	DiaMed GmbH	Advice regarding the use of the device	10 June 2013	Manufacturer's FSN	Yes
V17931	QuickDraw Venous Cannula 22Fr and 25Fr	Edwards LifeSciences	Advice regarding a device removal	28 May 2013	Manufacturer's FSN	Yes
V18122	Precise Digital Accelerator, Synergy Platform, Synergy, Synergy S, Infinity, Axesse	Elekta Ltd	Advice regarding the use of the device	18 June 2013	Manufacturer's FSN	Yes
V18068	Ministar Combination Valve	Gas Control Equipment (GCE)	Advice regarding a device removal	04 June 2013	Manufacturer's FSN	Yes
V18032	GE Healthcare Infinia Hawkeye 4 Nuclear Medicine systems - Infinia devices, manufactured from 2003 – 2013 VG and VG Hawkeye devices, manufactured from 1996 – 2003 Helix nuclear medicine systems, manufactured from 1992 – 1996	GE Healthcare	Advice regarding the use of the device	24 June 2013	Manufacturer's FSN	Yes
V18126	Aespire, Aespire View, Avance, Avance CS2, Aisys, ADU, 9100, M900, M904, 9300 systems	GE Healthcare	Advice regarding a device removal	19 June 2013	Manufacturer's FSN	Yes
V18132	LeGoo Endovascular Occlusion Gel	Genzyme	Advice regarding a device removal	19 June 2013	Manufacturer's FSN	Yes
V17958	RadialSource Transradial Access Kit	Greatbatch Medical	Advice regarding a device removal	05 June 2013	Manufacturer's FSN	Yes
V17288	GemStar Infusion System	Hospira Inc.	Advice regarding the use of the device	20 June 2013	Manufacturer's FSN	Yes

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V16988	Deep Brain Stimulation (DBS) Lead Kits	Medtronic	Advice regarding a device removal	13 June 2013	Manufacturer's FSN	Yes
V18031	Medtronic Consulta CRT-P and Syncra CRT-P	Medtronic BV	Advice regarding a device removal	10 June 2013	Manufacturer's FSN	Yes
V18070	Paradigm Insulin Infusion sets	Medtronic MiniMed	Advice regarding the use of the device	14 June 2013	Manufacturer's FSN	Yes
V18201	Paradigm Insulin Reservoirs	Medtronic MiniMed	Advice regarding a device removal	28 June 2013	Manufacturer's FSN	Yes
V18159	Nordipen durable device	Novo Nordisk	Advice regarding the use of the device	24 June 2013	Manufacturer's FSN	Yes
V17894	Flocare® Infinity™ II enteral feeding pumps	Nutricia Medical Devices BV	Advice regarding the use of the device	24 June 2013	Manufacturer's FSN	Yes
V18093	Custom Procedure Packs	Pennine Healthcare	Advice regarding a device removal	10 June 2013	Manufacturer's FSN	Yes
V17788	HeartStart MRx Monitor/Defibrillator	Philips Healthcare	Advice regarding a software upgrade	01 May 2013	Manufacturer's FSN	Yes
V17976	Brilliance CT Systems and Gemini and Precedence Systems utilizing Brilliance CT	Philips Healthcare UK	Advice regarding changes/updates made to instructions for use	15 May 2013	Manufacturer's FSN	Yes
V18139	V60 Ventilators	Respironics California Inc	Advice regarding a software upgrade	25 June 2013	Manufacturer's FSN	Yes
V17244	Laparoscope filter and tubing sets	Richard Wolf UK Ltd	Advice regarding a device removal	25 February 2013	Manufacturer's FSN	Unknown
V17749	RPM Respiratory Gating System	RPM Respiratory Gating System	Advice regarding a software upgrade	02 May 2013	Manufacturer's FSN	Yes
V17903	ADVIA Centaur / Dimension / Dimension Vista / IMMULITE Thyroid Stimulating Hormone (TSH);	Siemens Healthcare Diagnostics	Advice regarding the use of the device	14 June 2013	Manufacturer's FSN	Yes
V17648	Neptune Waste Management System	Stryker	Advice regarding changes/updates made to instructions for use	30 May 2013	Manufacturer's FSN	Yes
V17995	Medullary Reamers 6.0mm to 10.5mm	Synthes GmbH	Advice regarding a device removal	17 May 2013	Manufacturer's FSN	Yes
V18069	Dynamic Locking Screw Stardrive® Ø 5.0 and 3.7 mm	Synthes GmbH	Advice regarding a device removal	14 June 2013	Manufacturer's FSN	Yes
V18090	Reduction Instrument for Spondylolisthesis	Synthes GmbH	Advice regarding a device removal	14 June 2013	Manufacturer's FSN	Yes
V18119	Soft Tissue Retractor - Technique Guide	Synthes GmbH	Advice regarding changes/updates made to instructions for use	13 June 2013	Manufacturer's FSN	Yes
V16771	Angiography Procedure Packs	Unisurge International Limited	Advice regarding the use of the device	25 January 2013	Manufacturer's FSN	Yes
V18036	All high energy C-Series Clinac® linear accelerators, including Clinac®, Trilogy®, Trilogy Tx™ and Novalis Tx™	Varian	Advice regarding a device modification	10 June 2013	Manufacturer's FSN	Yes

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