



IRISH MEDICINES BOARD

FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET - September 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?
V18844	A-dec 300 Dental Chairs	A-dec Dental UK Limited	Advice regarding a device modification	16 September 2013	Manufacturer's FSN	Yes
V18854	Star Excimer Laser System	AMO Ireland	Advice regarding a device modification	20 September 2013	Manufacturer's FSN	Yes
V18858	Sterrad 200 System	ASP	Advice regarding the use of the device	19 September 2013	Manufacturer's FSN	Yes
V18833	Colleague Pump	Baxter	Advice regarding changes/updates made to instructions for use	17 September 2013	Manufacturer's FSN	Yes
V18607	ISE REF Valve for the AU Chemistry Analyzers	Beckman Coulter Inc	Advice regarding the use of the device	05 September 2013	Manufacturer's FSN	Yes
V17685	VIDAS® D-Dimer Exclusion II	BioMerieux Inc	Advice regarding the use of the device	11 September 2013	Manufacturer's FSN	Yes
V18782	Endosseous Dental Implant	BIOMET 3i	Advice regarding a device removal	30 September 2013	Manufacturer's FSN	Yes
V18753	THERMO(OOL®SMARTT OUCH™ Catheter	Biosense Webster, Inc.	Advice regarding a device removal	03 September 2013	Manufacturer's FSN	Yes
V18677	COGNIS® CRT-Ds and TELIGEN® ICDs	Boston Scientific	Advice regarding the use of the device	04 September 2013	Manufacturer's FSN	Yes
V18825	AVEA Ventilator	Carefusion	Advice regarding a software upgrade	03 September 2013	Manufacturer's FSN	Yes
V18856	200 mm EverFlex™ Self-expanding Peripheral Stent with Entrust™ Delivery System	Covidien	Advice regarding a device removal	23 September 2013	Manufacturer's FSN	Yes
V18802	Argyle™ Single Lumen Polyurethane Umbilical Vessel Catheters	Covidien Ireland	Advice regarding the use of the device	17 September 2013	Manufacturer's FSN	Yes
V18712	FMS Intermediary Tubing with One-Way valve / FMS Outflow Tubing with One-Way valve (FMS VUE™ or FMS DUO®+)	DePuy Mitek	Advice regarding a device removal	05 September 2013	Manufacturer's FSN	Yes
V18790	Burr Hole Latex Free Probe Cover	Ecolab-Microtek	Advice regarding a device removal	10 July 2013	Manufacturer's FSN	Yes
V18875	Edwards Lifesciences EMBOL-X Glide Protection System, Model codes: EXGF24, EXGF24LL, EXGF24MM, EXGF24SS, EXGF24XL, EXGF24XS	Edwards Lifesciences	Advice regarding a device removal	24 September 2013	Manufacturer's FSN	Yes
V18914	Trolley Molift Nomad for Climbing	Etac AS	Advice regarding a device removal	26 September 2013	Manufacturer's FSN	Yes
V18740	Tec 6 and Tec 6 Plus Vaporizers	GE Healthcare	Advice regarding a device modification	04 September 2013	Manufacturer's FSN	Yes
V18608	Getinge 46-Series Washer Disinfector with PACS 300	Getinge Group	Advice regarding a device modification	09 September 2013	Manufacturer's FSN	Yes
V18243	Ibis Comfort wheelchair	Handicare BV	Advice regarding a device modification	01 July 2013	Manufacturer's FSN	Yes
V18478	HemoCue Glucose 201 RT Microcuvettes	HemoCue AB	Advice regarding the use of the device	08 August 2013	Manufacturer's FSN	Yes

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V18865	ClinActiv® and ClinActiv® Plus Therapy Surface	HillRom	Advice regarding the use of the device	24 September 2013	Manufacturer's FSN	Yes
V18432	Receptal System Liners and Canisters	Hospira Inc.	Advice regarding changes/updates made to instructions for use	06 September 2013	Manufacturer's FSN	Yes
V18551	Aquatec® Ocean VIP Mobile Shower and Toilet Commode	Invacare	Advice regarding a device modification	19 July 2013	Manufacturer's FSN	Yes
V18705	Whole Blood Collection Set, Quad-Pack System	MacoPharma	Advice regarding a device removal	06 September 2013	Manufacturer's FSN	Yes
V18159	NordiPen 5 mg, 10 mg and 15 mg	Novo Nordisk	Advice regarding the use of the device	30 August 2013	Manufacturer's FSN	Yes
V18852	Oxoid Minerals Modified Glutamate Medium + Sodium Glutamate 800g, CM0607G	Oxoid Ltd	Advice regarding a device modification	20 September 2013	Manufacturer's FSN	Yes
V18900	BrightView XCT Imaging System	Philips	Advice regarding a device modification	30 August 2013	Manufacturer's FSN	Yes
V18713	Crocodile Size 3 Walker	R82 A/S	Advice regarding a device modification	26 August 2013	Manufacturer's FSN	Yes
V17514	Freedom60 Syringe Infusion Syringe F10050	RMS Medical Products	Advice regarding changes/updates made to instructions for use	22 March 2013	Manufacturer's FSN	Yes
V18784	SBi rHead and uHead Sterile Packaged Stems	SBI International - Small Bone Innovations	Advice regarding a device removal	10 September 2013	Manufacturer's FSN	Yes
V18830	Artis systems running software Artis VC1 x	Siemens	Advice regarding the use of the device	13 September 2013	Manufacturer's FSN	Yes
V18723	Eon Mini™ IPG Charging	St. Jude Medical	Advice regarding a device removal	04 September 2013	Manufacturer's FSN	Yes
V18835	Torque Wrench	Stryker	Advice regarding a device removal	17 September 2013	Manufacturer's FSN	Yes
V17545	OtisMed ShapeMatch Cutting Guides	Stryker Orthopaedics	Advice regarding a device removal	22 August 2013	Manufacturer's FSN	Yes
V18902	Helical Blade for TFN, Titanium Alloy	Synthes	Advice regarding a device removal	27 September 2013	Manufacturer's FSN	Yes
V18904	TomoFix Medial High Tibial Plate	Synthes	Advice regarding a device modification	25 September 2013	Manufacturer's FSN	Yes
V18226	TRACOE twist Tracheostomy Tube	Tracoe	Advice regarding the use of the device	07 August 2013	Manufacturer's FSN	Yes
V18798	Captia Cytomegalovirus (CMV) IgG	Trinity Biotech	Advice regarding a device modification	06 September 2013	Manufacturer's FSN	Yes
V18757	Zimmer LDPE Bag	Zimmer	Advice regarding the use of the device	05 September 2013	Manufacturer's FSN	Yes