



IRISH MEDICINES BOARD

FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET - August 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?
V18580	GlucoMen® LX Sensor test strips	A.Menarini Diagnostics	Advice regarding a device removal	19 August 2013	Manufacturer's FSN	Yes
V18565	Phosphorus Reagent	Abbott Laboratories	Advice regarding the use of the device	12 August 2013	Manufacturer's FSN	Yes
V18430	STERRAD® 100NX® System cassette	Advanced Sterilization Products	Advice regarding the use of the device	29 July 2013	Manufacturer's FSN	Yes
V18446	C-QUR Mesh, C-QUR Edge Mesh, C-QUR V-Patch and C-QUR TacShield	Atrium Medical Corporation	Advice regarding changes/updates made to instructions for use	26 July 2013	Manufacturer's FSN	Yes
V18147	COILED TUBE INFUSORS (Portable Elastomeric Infusion Systems)	Baxter Healthcare Corporation	Advice regarding a device removal	04 July 2013	Manufacturer's FSN	Yes
V16337	SYNCHRON® Systems Glucose (GLU) Cartridge Reagent	Beckman Coulter	Advice regarding changes/updates made to instructions for use	08 August 2013	Manufacturer's FSN	Yes
V18479	XLD Agar	BioMérieux	Advice regarding the review of patient results/patient recall/sample retesting is required	13 August 2013	Manufacturer's FSN	Yes
V18542	BioMatrix NeoFlex	Biosensors Europe SA	Advice regarding a device removal	07 August 2013	Manufacturer's FSN	Yes
V18469	4.00mm x 15mm Flextome™ Cutting Balloon™ Monorail™ Microsurgical Dilatation Device	Boston Scientific	Advice regarding a device removal	05 August 2013	Manufacturer's FSN	Yes
V18469	4.00mm x 15mm Small Peripheral Cutting Balloon™ Monorail™ Microsurgical Dilatation Device	Boston Scientific	Advice regarding a device removal	05 August 2013	Manufacturer's FSN	Yes
V18582	Codman Programmable Infusion Pumps and Refill Kits	Codman Neurosciences	Advice regarding the use of the device	13 August 2013	Manufacturer's FSN	Yes
V18291	Connectable Pusher CH/FR 4.8/75cm REF YN2813 included in the following kits: VORTEK Double Loop Ureteral Stent Open/Open With Connectable Pusher and VORTEK Hydro-Coated Double Loop Ureteral Stents	Coloplast	Advice regarding a device removal	19 July 2013	Manufacturer's FSN	Yes
V17329	DePuy ReClaim® Reamer Extension	DePuy Orthopaedics Inc.	Advice regarding the use of the device	31 March 2013	Manufacturer's FSN	Yes
V18710	Application Instrument for Sternal ZipFix™	DePuy Synthes	Advice regarding the use of the device	29 August 2013	Manufacturer's FSN	Yes
V18256	Liaison® Control Mumps IgG	Diasorin S.p.A.	Advice regarding a device removal	03 July 2013	Manufacturer's FSN	Yes
V18484	Ceiling supply units CSU 80xx / CSU 60xx	Dräger Medical	Advice regarding changes/updates made to instructions for use	01 July 2013	Manufacturer's FSN	Yes
V18602	3DLINE DMLC	Elekta	Advice regarding a software upgrade	01 August 2013	Manufacturer's FSN	Yes
V18453	Centricity PACS RA1000 Workstation	GE Healthcare	Advice regarding the use of the device	30 July 2013	Manufacturer's FSN	Yes
V18694	Advantx, Innova 2000, Innova 2100IQ, Innova 3100, Innova 3100IQ, Innova 4100, Innova 4100IQ Cardiovascular X-ray imaging systems	GE Healthcare	Advice regarding the use of the device	29 August 2013	Manufacturer's FSN	Yes
V18608	Getinge 46-Series Washer Disinfector with PACS 300	Getinge	Advice regarding a device modification	16 August 2013	Manufacturer's FSN	Yes

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V18478	HemoCue Glucose 201 RT Microcuvettes	HemoCue AB	Advice regarding the use of the device	29 July 2013	Manufacturer's FSN	Yes
V17285	GemStar™ Infusion System	Hospira Inc.	Advice regarding the use of the device	31 July 2013	Manufacturer's FSN	Yes
V18373	PRIMARY PLUMSET™ Clave secondary port; Administration sets (infusion pump, intravenous & blood transfusion)	Hospira Inc.	Advice regarding the use of the device	08 August 2013	Manufacturer's FSN	Yes
V18515	HPC GN85 Violet Accelerator Free Nitrile Examination Gloves	HPC Healthline	Advice regarding a device removal	05 August 2013	Manufacturer's FSN	Yes
V18516	HEMOSIL SYNTHASIL APTT REAGENT	Instrumentation Laboratory	Advice regarding the use of the device	07 July 2013	Manufacturer's FSN	Yes
V18530	Bond Polymer Refine Red Detection (DS9390) & ChromoPlex 1 Dual Detection for BOND (DS9477)	Leica Biosystems	Advice regarding a device removal	30 July 2013	Manufacturer's FSN	Yes
V18705	Blood Filtration Pack FQE6283LB	MacoPharma	Advice regarding the use of the device	28 August 2013	Manufacturer's FSN	Yes
V18705	Blood Filtration Pack FQE6283LB (Revised FSN)	MacoPharma	Advice regarding the use of the device	28 August 2013	Manufacturer's FSN	Yes
V18524	Quadrox Oxygenators -Quadrox-i / Quadrox-iD / Quadrox-iR / PLS module.	Maquet	Advice regarding a device removal	02 August 2013	Manufacturer's FSN	Yes
V18471	XOMED INSTRUMENT TRAYS	Medtronic	Advice regarding the use of the device	02 August 2013	Manufacturer's FSN	Yes
V18467	Vector TAS Screw (8mm)	Ormco Corporation	Advice regarding a device removal	01 August 2013	Manufacturer's FSN	Yes
V18200	ORTHO BioVue® System Cassettes	Ortho Clinical Diagnostics	Advice regarding a device removal	04 July 2013	Manufacturer's FSN	Yes
V18200	ORTHO BioVue® System Cassettes	Ortho Clinical Diagnostics	Advice regarding a device removal	31 July 2013	Manufacturer's FSN	Yes
V18552	Brilliance iCT and iCT SP up to and including Software Version 3.2.5, model no: 728311, 728306	Philips Healthcare	Advice regarding the use of the device	15 July 2013	Manufacturer's FSN	Yes
V18593	MX 16-Slice	Philips Healthcare	Advice regarding the use of the device	22 July 2013	Manufacturer's FSN	Yes
V18606	Uretero-renoscopes	Richard Wolf GmbH	Advice regarding a device removal	20 August 2013	Manufacturer's FSN	Yes
V18520	PRIMUS™, ONCOR™ and ARTISTE™	Siemens AG	Advice regarding a device modification	02 August 2013	Manufacturer's FSN	Yes
V17802	Sysmex CS2000i System	Siemens Healthcare Diagnostics	Advice regarding a software upgrade	16 May 2013	Manufacturer's FSN	Yes
V18692	IMMULITE, IMMULITE 1000, IMMULITE 2000, IMMULITE 2000 XPI Free T3 Assays	Siemens Healthcare Diagnostics	Advice regarding a device removal	29 August 2013	Manufacturer's FSN	Yes
V18523	Suture anchors of the BIORAPTOR™, OSTEORAPTOR™ and TWINFIX™ ULTRA product lines	Smith & Nephew Inc.	Advice regarding a device removal	06 August 2013	Manufacturer's FSN	Yes

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V18556	DIGORA Optime, DXR-60	Soredex	Advice regarding a device modification	20 August 2013	Manufacturer's FSN	Yes
V18476	HYDROSET INJECTABLE HA BONE SUBSTITUTE ALL SIZES	Stryker	Advice regarding a device removal	12 August 2013	Manufacturer's FSN	Yes
V18480	Triathlon Tibial Alignment Ankle Clamp EM	Stryker	Advice regarding the use of the device	06 July 2013	Manufacturer's FSN	Yes
V18611	Various Multiloc, Locking and LISS Screws - VA-LCP Anterolateral Distal Tibial Plate 2.7/3.5	Synthes GmbH	Advice regarding a device removal	16 August 2013	Manufacturer's FSN	Yes
V18526	Oxoid Antimicrobial Susceptibility Testing Disc AMC3 AMOXYCILLIN / CLAVULANIC ACID	Thermofisher Scientific	Advice regarding a device removal	06 August 2013	Manufacturer's FSN	Yes
V18615	Aequalis Reversed II and Reversed Fracture impactors	Tornier	Advice regarding a device removal	13 August 2013	Manufacturer's FSN	Yes