



IRISH MEDICINES BOARD

FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET - OCTOBER 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
V18580	GlucoMen® LX Sensor test strips	A.Menarini Diagnostics	Advice regarding a device removal	19 August 2013	Manufacturer's FSN	Yes
V19159	i-STAT PT/INR cartridges	Abbott Point of Care	Advice regarding a device removal	30 October 2013	Manufacturer's FSN	Yes
V18844	A-dec 300 chair / 7285 Cuspidor products	A-dec	Advice regarding a device modification	26 September 2013	Manufacturer's FSN	Yes
V18944	STERRAD® Boosters and Adaptors, Product Codes 15400, 15401, 15402, 15403 and 15407	Advanced Sterilization Products (ASP)	Advice regarding the use of the device	02 October 2013	Manufacturer's FSN	Yes
V19089	STERRAD® 100NX, product code: 10104, 10104-002, 10104-003, 10104-004	Advanced Sterilization Products (ASP)	Advice regarding the use of the device	22 October 2013	Manufacturer's FSN	Yes
V19152	Alcon AcrySof® CACHET® Phakic Lens	Alcon Laboratories	Advice regarding the use of the device	28 October 2013	Manufacturer's FSN	Yes
V18969	LifeStent Vascular Stent System	Angiomed GmbH & Co. Medizintechnik KG	Advice regarding a device removal	03 October 2013	Manufacturer's FSN	Yes
V18953	Contoura 1000/1080	ArjoHuntleigh	Advice regarding the use of the device	04 October 2013	Manufacturer's FSN	Yes
V18978	TRANSRADIAL ARTERY ACCESS KIT	Arrow International c/o Teleflex	Advice regarding a device removal	09 October 2013	Manufacturer's FSN	Yes
V18850	Infusor / Folfusor / Intermate Portable Elastomeric Infusion Systems	Baxter Healthcare Ltd.	Advice regarding a device removal	26 September 2013	Manufacturer's FSN	Yes
V19113	Osseocare Pro console; Set Osseocare Pro	Bien Air Dental SA	Advice regarding a software upgrade	24 October 2013	Manufacturer's FSN	Yes
V19084	Human IgM Kit for use on SPAPLUS	Binding Site	Advice regarding changes/updates made to instructions for use	14 October 2013	Manufacturer's FSN	Yes
V18239	BacT/ALERT® MP Culture Bottle	bioMérieux	Advice regarding a device removal	11 June 2013	Manufacturer's FSN	Yes
V18870	Endobon Xenograft Granules 0.5ml	Biomet	Advice regarding a device removal	16 September 2013	Manufacturer's FSN	Yes
V19164	Navigator® Surgical Kit / Tapered Navigator® Certain® Surgical Kit / Contra-Angle Torque Driver Kit / Prosthetic Instrumentation System	Biomet 3i	Advice regarding the use of the device	01 July 2013	Manufacturer's FSN	Yes
V18825	AVEA Ventilator	Carefusion	Advice regarding a software upgrade	07 October 2013	Manufacturer's FSN	Yes
V19107	QuantiFERON-TB Gold (QFT) Test	Celtestis Limited	Advice regarding the use of the device	23 October 2013	Manufacturer's FSN	Yes
V18272	SIGMA® Tibial Inserts Compatibility Label	DePuy Synthes	Advice regarding the use of the device	09 July 2013	Manufacturer's FSN	Unknown
V19091	SynReam Medullary Reamer Head 8.5mm	DePuy Synthes	Advice regarding a device removal	22 October 2013	Manufacturer's FSN	Yes
V19060	Liaison® Control Mumps IgG	DiaSorin S.p.A	Advice regarding a device removal	15 October 2013	Manufacturer's FSN	Yes
V18602	3DLINER DMLC	Elekta	Advice regarding a device modification	01 July 2013	Manufacturer's FSN	Yes

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V18724	ETHICON SECURESTRAP	Ethicon	Advice regarding the use of the device	16 August 2013	Manufacturer's FSN	Yes
V19147	Yersinia Agar W11390	Fannin Ltd - LIP	Advice regarding the review of patient results/patient recall/sample retesting is required	24 October 2013	Manufacturer's FSN	Yes
V18493	Genius Eco with analysis system and Factum	Frei AG Aktive Reha	Advice regarding a software upgrade	01 August 2013	Manufacturer's FSN	Yes
V18943	GSI Viewer	GE Healthcare	Advice regarding a software upgrade	02 October 2013	Manufacturer's FSN	Yes
V19150	Discovery NM/CT670, Optima NM/CT640, Discovery NM630, Brivo NM615	GE Healthcare	Advice regarding a software upgrade	29 October 2013	Manufacturer's FSN	Yes
V19156	Avance, Amingo, Avance CS2, and Aisys potential tidal volume over delivery when using Pressure Control Ventilation – Volume Guarantee (PCV-VG)	GE Healthcare	Advice regarding a software upgrade	30 October 2013	Manufacturer's FSN	Yes
V18894	Hamilton-C2 Ventilator	HAMILTON Medical AG	Advice regarding the use of the device	27 September 2013	Manufacturer's FSN	Yes
V19016	Samaritan® PDU 400	HeartSine	Advice regarding a device removal	17 October 2013	Manufacturer's FSN	Yes
V18478	HemoCue Glucose 201 RT Microcuvettes	HemoCue AB	Advice regarding a device removal	07 October 2013	Manufacturer's FSN	Yes
V19001	Liko® SlingBar™ 350, SlingBar™ 360, SlingBar™ Wide 670, and SideBar™ Standard	Hill-Rom Liko Lulea	Advice regarding a device modification	09 October 2013	Manufacturer's FSN	Yes
V16521	GemStar™ Infusion System	Hospira Inc.	Advice regarding the use of the device	07 October 2013	Manufacturer's FSN	Yes
V18919	Venisystems Blood Bottle Pumpset with CAIR Clamp (List Number 04643-97-01)	Hospira Inc.	Advice regarding a device removal	04 October 2013	Manufacturer's FSN	Yes
V18977	Tecotherm Neo	Inspiration Healthcare Limited	Advice regarding a device modification	01 September 2011	Manufacturer's FSN	Yes
V18516	ACL TOP	Instrumentation Laboratory	Advice regarding a software upgrade	08 October 2013	Manufacturer's FSN	Yes
V18705	Whole Blood Collection Set, Quad-Pack System	MacoPharma	Advice regarding a device removal	04 October 2013	Manufacturer's FSN	Yes
V18918	Model 8870 Software Application Card used in the 8840 N'Vision™	Medtronic	Advice regarding a software upgrade	01 October 2013	Manufacturer's FSN	Yes
V18949	Basin Liner within Mölnlycke ProcedurePak®	Mölnlycke Health Care AB	Advice regarding a device removal	03 October 2013	Manufacturer's FSN	Yes
V19005	TRUEtrack, Wellion Smart System, STADA Gluco Check, TRUEbalance, Wellion Smart System 2	Nipro Diagnostics	Advice regarding a device removal	04 October 2013	Manufacturer's FSN	Yes
V18200	ORTHO BioVue System Cassettes	Ortho-Clinical Diagnostics	Advice regarding the use of the device	02 October 2013	Manufacturer's FSN	Yes
V19090	VITROS Chemistry Products Na+ Slides (Product Code 8379034) / VITROS Chemistry Products Calibrator Kit 2 (Product Code 1662659)	Ortho-Clinical Diagnostics	Advice regarding the use of the device	23 October 2013	Manufacturer's FSN	Yes
V19066	MobileDiagnost wDR	Philips Medical Systems	Advice regarding changes/updates made to instructions for use	25 September 2013	Manufacturer's FSN	Yes
V18942	Sapphire Multi Therapy Pump With Software Rev 09 Ver 07 (List Number 16311)	QCore Medical	Advice regarding a software upgrade	01 October 2013	Manufacturer's FSN	Yes
V18292	942-063 pCO2Membrane Box (D788) used with ABL700 and ABL800 Series Analyzers	Radiometer Medical Aps	Advice regarding a device modification	30 August 2013	Manufacturer's FSN	Yes

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V19151	Innov8 Low Siderails – Standard & High – INNOV8/LOW/SR & INNOV8/LOW/HSR	Sidhil	Advice regarding a device modification	24 October 2013	Manufacturer's FSN	Yes
V18950	ADM®/MDM® Ball Impactor Tip and ADM® Rim Impactor Tip	Stryker	Advice regarding the use of the device	30 September 2013	Manufacturer's FSN	Yes
V19141	TISSUE-GUARD Family of Products Recall;VASCU-GUARD, DURA-GUARD, PERI-GUARD, and SUPPLE PERI-GUARD	Synovis	Advice regarding a device removal	21 October 2013	Manufacturer's FSN	Yes
V18970	XN-Series analyser	Sysmex Corporation	Advice regarding the use of the device	09 October 2013	Manufacturer's FSN	Yes
V19027	COBE® Spectra Bone Marrow Processing Set	Terumo BCT, Inc.	Advice regarding a device removal	16 October 2013	Manufacturer's FSN	Yes
V19052	Oxoid Yersinia Selective Supplement SR0109E	ThermoFisher Scientific	Advice regarding a device removal	15 October 2013	Manufacturer's FSN	Yes
V19118	VitreaCore® Software	Vital Images Inc.	Advice regarding the use of the device	29 October 2013	Manufacturer's FSN	Yes
V18945	MEDUCORE Standard	WEINMANN Geräte für Medizin GmbH + Co. KG	Advice regarding a device removal	30 September 2013	Manufacturer's FSN	Yes