



IRISH MEDICINES BOARD

## FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET - NOVEMBER 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?
V19286	FreeStyle Lite Blood Glucose Test Strips	Abbott Diabetes Care	Advice regarding a device removal	14 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19286	FreeStyle Lite Blood Glucose Test Strips	Abbott Diabetes Care	Advice regarding a device removal	14 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19170	AxSYM Valproic Acid Reagent	Abbott Laboratories	Advice regarding a device removal	29 October 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19354	HT Connect Peripheral Guide Wires	Abbott Vascular / Synapse Medical	Advice regarding a device removal	25 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19387	Targon FN Screws	Aesculap AG	Advice regarding changes/updates made to instructions for use	22 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19182	Inzii 12/15mm retrieval system	Applied Medical	Advice regarding a device removal	29 October 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19299	Multi-X X-ray Detectable Swabs	Aquilant Medical	Advice regarding the use of the device	15 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19183	FiberOptix IAB Catheter	Arrow International Inc.	Advice regarding a device removal	06 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19344	STERRAD® Booster & STERRAD® Adaptor	ASP	Advice regarding changes/updates made to instructions for use	20 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19277	Sterrad Sterilizer	ASP	Advice regarding the use of the device	14 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19401	STERRAD 100S Steriliser	ASP	Advice regarding the use of the device	29 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19402	STERRAD CycleSure 24 Biological Indicator	ASP	Advice regarding the use of the device	28 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19323	Original-Perfusor® Syringe 50 ml without cannula	B Braun Medical Limited	Advice regarding a device removal	20 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19239	HomeChoice Pro Devices using Version 10.4 Software	Baxter Healthcare	Advice regarding the use of the device	19 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V18934	BBL MGIT Mycobacteria Growth Indicator Tube	BD Diagnostics	Advice regarding a device removal	30 September 2013	<a href="#">Manufacturer's FSN</a>	Yes
V18816	UniCel DxH 800 and DxH 600 Coulter Cellular Analysis Systems	Beckan Coulter	Advice regarding a device modification	03 October 2013	<a href="#">Manufacturer's FSN</a>	Yes
V18817	COULTER® LH 750 and LH 780 Analyzers	Beckan Coulter	Advice regarding a device modification	03 October 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19218	BacT/ALERT FA PLUS Culture Bottle / BacT/ALERT PF PLUS Culture Bottle	bioMérieux	Advice regarding a device removal	15 October 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19268	ZYM B reagent / API NH / API Listeria	bioMérieux	Advice regarding a device removal	14 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19228	Tibial Resction Guide	Biomet UK Limited	Advice regarding a device removal	31 October 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19399	Mallory Acetabular Shell	Biomet UK Limited	Advice regarding a device removal	26 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19288	AGC Tibial Impactor & AGC Femoral Impactor	Biomet UK Limited	Advice regarding the use of the device	13 November 2013	<a href="#">Manufacturer's FSN</a>	Yes

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V19230	13F/15F Navigator™ HD Ureteral Access Sheath Set	Boston Scientific	Advice regarding a device removal	14 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19179	Alaris® SE Pump Infusion Set	CareFusion	Advice regarding a device removal	05 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19357	HP M.B.T. Keel Punch Knee Instrument	DePuy Synthes	Advice regarding the use of the device	22 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19364	LIAISON Biotrin Control Parvovirus B19 IgM	DiaSorin Ireland Limited	Advice regarding a device modification	22 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17362	Precise Treatment Table	Elekta Limited	Advice regarding a device modification	13 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19213	W14036 Triple Sugar Iron Agar	Fannin Ltd (LIP)	Advice regarding a device removal	05 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19156	Aisys, Amingo, Avance, and Avance CS2	GE Healthcare	Advice regarding a software upgrade	30 October 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19191	TotalCare Bariatric	Hill-Rom	Advice regarding changes/updates made to instructions for use	04 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19383	Large and Mega Needle Drivers / Endowrist® Instruments	Intuitive Surgical	Advice regarding a device removal	15 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19212	IN.PACT® Amphirion drug-eluting PTA balloon catheter	Invatec Technology Centre GmbH	Advice regarding a device removal	11 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19222	FLOW-i Anesthesia System	Maquet Critical Care AB	Advice regarding a device modification	06 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19173	Nu-Cidex	Medos International	Advice regarding a device removal	31 October 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19362	CoreValve™ AccuTrak™ Delivery Catheter System	Medtronic CoreValve LLC	Advice regarding the use of the device	26 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19200	Metran R100 Diaphragm	Metran Co. Ltd.	Advice regarding a device removal	18 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19211	3 cell screen Cell 2	NHS BT Reagents	Advice regarding a device removal	25 October 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19351	Rechargeable Li-Polymer Battery Pack	Nova Biomedical	Advice regarding a device removal	18 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19140	VITROS® Immunodiagnostic Products Anti-HBs Calibrators (Product Code 1524693), VITROS® Immunodiagnostic Products Anti-HBs Reagent Packs (Product Code 1787753)	Ortho-Clinical Diagnostics	Advice regarding a device removal	25 October 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19265	Philips Model EPIQ 7 Ultrasound system, software version 1.0 and 1.0.1	Philips Healthcare	Advice regarding a software upgrade	13 October 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19229	IntelliSpace PACS 4.4	Phillips Healthcare Informatics Ltd	Advice regarding a software upgrade	14 October 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19278	Q Tube with Integrated Gas Sampling Line	Qpark Asia Limited	Advice regarding a device removal	31 October 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19194	ALBAcyte Reagent Red Cells	Quotient	Advice regarding changes/updates made to instructions for use	30 October 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19139	ABL90 FLEX	Radiometer Limited	Advice regarding the use of the device	28 October 2013	<a href="#">Manufacturer's FSN</a>	Yes

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V19378	Artis Q Ceiling	Siemens	Advice regarding a device modification	26 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19292	E-cam	Siemens	Advice regarding a device modification	14 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19221	Artis zee Ceiling System	Siemens	Advice regarding the use of the device	06 October 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19219	Artis systems with software version Artis VC21B	Siemens	Advice regarding a software upgrade	06 October 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19345	Portex® Arterial Blood Sampling Line Draw Syringes	Smiths Medical	Advice regarding a device removal	22 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19058	Amplatzer Septal Occluder	St Jude Medical	Advice regarding changes/updates made to instructions for use	22 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19358	Stryker Dekompressor® Percutaneous Discectomy Probes	Stryker	Advice regarding the use of the device	25 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19231	Fully Automated Blood Coagulation Analyzer CS-2000i/CS-2100i	Sysmex	Advice regarding a software upgrade	22 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19297	3D Optical Coherence Tomography	Topcon Corporation	Advice regarding the use of the device	11 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19367	Aplio XG & MX, Xario & Xario XG	Toshiba	Advice regarding a software upgrade	26 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19332	C-Series Clinac®, Trilogy®, Trilogy Tx™ Novalis Tx™ or Unique accelerators	Varian	Advice regarding a software upgrade	04 November 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19080	Medumat Transportable Ventilator	Weinmann Geräte für Medizin GmbH + Co. KG	Advice regarding a software upgrade	27 September 2013	<a href="#">Manufacturer's FSN</a>	Yes
V19023	Welch Allyn Propaq LT / Propaq 802	Welch Allyn	Advice regarding a device modification	31 October 2013	<a href="#">Manufacturer's FSN</a>	Yes