



IRISH MEDICINES BOARD

**FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET - APRIL 2014**

Case ID	Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Link to FSN on IMB website	Is the Irish market affected?
V20480	ARCHITECT Clinical Chemistry Lipase Reagent 7D80	Abbott	Advice regarding changes/updates made to instructions for use	07 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20026	ARCHITECT Intact PTH Assay	Abbott Laboratories	Advice regarding the use of the device	18-Mar-14	<a href="#">Manufacturer's FSN</a>	Yes
V20455	Tyvek® Self-Seal Pouches with STERRAD® Chemical Indicator / Tyvek® Rolls / Tyvek® Heat Seal Pouches	Advanced Sterilization Products Inc.	Advice regarding the use of the device	27 March 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20442	Cavafix Certo, Cavafix Certodyn	B Braun Melsungen AG	Advice regarding a device removal	02 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20533	Coiled Tube Infusor system	Baxter Healthcare Corporation	Advice regarding the use of the device	15 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20485	Colleague Volumetric Infusion Pump	Baxter Healthcare Corporation	Advice regarding a device modification	09 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V18947	UniCel Dxl Immunoassay Systems	Beckman Coulter	Advice regarding a software upgrade	30 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20579	Mueller Hinton 2 Agar	bioMérieux	Advice regarding the use of the device	16 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20450	ThermoCool® SF NAV Catheters	Biosense Webster Inc.	Advice regarding changes/updates made to instructions for use	01 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20264	Alaris® SmartSite® Needle-Free Valve	CareFusion International	Advice regarding a device removal	14 March 2014	<a href="#">Manufacturer's FSN</a>	Yes
V18951	OPTEASE® Retrievable Vena Cava Filter	Cordis	Advice regarding a device removal	08 October 2013	<a href="#">Manufacturer's FSN</a>	Yes
V20556	FEM FLEX II Arterial Cannulae	Edwards Lifesciences LLC	Advice regarding a device removal	15 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20618	Carescape Patient Data Module	GE Medical Systems LLC	Advice regarding a device modification	23 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20619	Carescape Patient Data Module	GE Medical Systems LLC	Advice regarding a device modification	23 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20690	Thermablate Endometrial Ablation System	Idoman Teoranta	Advice regarding changes/updates made to instructions for use	04 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20654	MobileDiagnost wDR	Philips Medical Systems DMC GmbH	Advice regarding a software upgrade	28 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20605	Codman Programmable Infusion Pump	Codman Neurosciences	Advice regarding a device modification	14 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20660	Model 5348 Single-Chamber External Pulse Generator	Medtronic Inc	Advice regarding the use of the device	29 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20592	SynchroMed Refill Kit	Medtronic Inc.	Advice regarding a device removal	18 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20432	Surfix® Screw diameter 3.5mm length 22mm – Sterile & Surfix® Screw diameter 3.5mm length 30mm – Sterile	Newdeal SAS	Advice regarding a device removal	02 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20542	A200 Power Wheelchair / Skippi Power Wheelchair / Skippi Plus Power Wheelchair	Ottobock Mobility Solutions GmbH	Advice regarding a device modification	11 April 2014	<a href="#">Manufacturer's FSN</a>	Yes

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V20491	Oxoid Antimicrobial Susceptibility Testing (AST) Discs - Meropenem MEM10	Oxoid	Advice regarding changes/updates made to instructions for use	03 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20564	PENTAX Ultrasound Video Gastroscopes EG-3830UT, EG-3630U and PENTAX Ultrasound Fibre Gastroscope FG-36UX	Pentax Medical	Advice regarding changes/updates made to instructions for use	08 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20538	Screening Centre	Perkin Elmer	Advice regarding a software upgrade	07 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20440	EPIQ 5 Ultrasound System	Philips Healthcare	Advice regarding a software upgrade	02 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20441	EPIQ 7 Ultrasound System	Philips Healthcare	Advice regarding a software upgrade	02 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20621	Brilliance and Ingenuity range	Philips Healthcare Inc - USA	Advice regarding a device modification	25 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20644	Brilliance and Ingenuity range	Philips Healthcare Inc - USA	Advice regarding the use of the device	25 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20554	Philips HeartStart XL Monitor/Defibrillator,	Philips Healthcare Inc - USA	Advice regarding a software upgrade	01 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20486	ADAC Vertex Classic, Vertex Plus, Solus and Vertex V60 Systems	Philips Medical Systems (CLE), Inc.	Advice regarding the use of the device	08 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20482	Ingenuity Core	Philips Medical Systems (Cleveland) Inc	Advice regarding a software upgrade	06 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20615	DigitalDiagnost	Philips Medical Systems DMC GmbH	Advice regarding the use of the device	23 April 2014	<a href="#">Manufacturer's FSN</a>	yes
V20611	Seating kits - W2 size Kaye Walkers	Quest 88	Advice regarding a device modification	07 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V16088	Lactate membrane units (942-066) when used with ABL700 and ABL800 analysers	Radiometer Limited	Advice regarding the use of the device	21 January 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20553	Roche Modular CA2	Roche Diagnostics	Advice regarding the use of the device	16 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20508	Accu-Chek® Compact test strips and Accu-Chek® Mobile Tests	Roche Diagnostics	Advice regarding changes/updates made to instructions for use	19 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19795	Rociale Bulb Syringe RMT06-065	Rociale Medical Limited	Advice regarding the use of the device	13 January 2014	<a href="#">Manufacturer's FSN</a>	Unknown
V20606	ACUSON X700 ultrasound systems	Siemens	Advice regarding a software upgrade	22 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20577	Somatom Emotion CT scanner	Siemens AG	Advice regarding a device modification	17 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20590	syngo Workflow MLR	Siemens Healthcare	Advice regarding the use of the device	24 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20588	syngo Imaging	Siemens Healthcare	Advice regarding the use of the device	16 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20474	ADVIA Centaur Folate Assay	Siemens Healthcare Diagnostics	Advice regarding a device removal	02 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20643	ADVIA Centaur Systems TSH3 Ultra, Vitamin D and ADVIA Centaur BRAHMS Procalcitonin Assays	Siemens Healthcare Diagnostics	Advice regarding changes/updates made to instructions for use	22 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20642	ADVIA Centaur HIV Ag/Ab Combo (CHIV) Assay	Siemens Healthcare Diagnostics	Advice regarding changes/updates made to instructions for use	07 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20483	Fraxel® DUAL 1550/1927 Laser System	Solta Medical	Advice regarding the use of the device	09 April 2014	<a href="#">Manufacturer's FSN</a>	Yes

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V20586	Panbio Leptospira IgM ELISA	Standard Diagnostics Inc	Advice regarding changes/updates made to instructions for use	25 March 2014	<a href="#">Manufacturer's FSN</a>	Yes
V19091	SynReam Medullary Reamer Head 8.5mm	Synthes GmbH	Advice regarding a device removal	20 December 2013	<a href="#">Manufacturer's FSN</a>	Yes
V20584	Synthes Trauma External Fixation System	Synthes GmbH	Advice regarding the use of the device	14 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20602	Craniomaxillofacial (CMF) Distraction System	Synthes GmbH	Advice regarding a device removal	22 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20640	SynFix-LR Implant Holder	Synthes GmbH	Advice regarding changes/updates made to instructions for use	22 April 2014	<a href="#">Manufacturer's FSN</a>	Yes
V20546	Humidifier Adaptor, Shelfpak / AquaPak / Humidifier Adaptor	Teleflex Medical	Advice regarding a device removal	16 April 2014	<a href="#">Manufacturer's FSN</a>	Yes