



IRISH MEDICINES BOARD

FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET - DECEMBER 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?
V19574	STERRAD 50, 100S, NX Sterilisation Systems	ASP	Advice regarding the use of the device	17 December 2013	Manufacturer's FSN	Yes
V19421	ATS Drains - Ocean 2050 Blood Recovery / Ocean 2052 Dual Blood Recovery / Oasis 3650 Blood Recovery / Oasis 3652 Dual Blood Recovery	Atrium Medical	Advice regarding a device removal	03 December 2013	Manufacturer's FSN	Yes
V19335	Perfusor Space Infusion Pump	BBraun Medical	Advice regarding the use of the device	10 December 2013	Manufacturer's FSN	Yes
V19240	COULTER® LH 750 and LH 780 Analyzers	Beckman Coulter	Advice regarding the use of the device	21 November 2013	Manufacturer's FSN	Yes
V19242	UniCel DxH 800 and DxH 600 Coulter Cellular Analysis Systems	Beckman Coulter	Advice regarding the use of the device	21 November 2013	Manufacturer's FSN	Yes
V19435	NOxBOXi Inhaled Nitric oxide delivery and monitoring device	Bedfont Scientific Limited	Advice regarding a software upgrade	02 December 2013	Manufacturer's FSN	Yes
V19557	Cordis POWERFLEX® PRO PTA Dilatation Catheter	Cordis Corporation	Advice regarding a device removal	17 December 2013	Manufacturer's FSN	Yes
V19551	RT Desktop Pro 6.0, 6.1 and 7.01	Elekta Limited	Advice regarding a software upgrade	25 November 2013	Manufacturer's FSN	Yes
V19552	Integrity 1.1	Elekta Limited	Advice regarding a software upgrade	26 November 2013	Manufacturer's FSN	Yes
V19554	Agility (with Integrity 3.1)	Elekta Limited	Advice regarding a software upgrade	27 November 2013	Manufacturer's FSN	Yes
V19418	Precision 500D, Legacy, Prestilix, Monitrol, RFX, SFX, Tilt-C, Prestige VH, Prestige SI, and Prestige SII X-Ray imaging systems	GE Healthcare	Advice regarding a device modification	02 December 2013	Manufacturer's FSN	Yes
V19507	Optima XR220amx and Optima XR200amx	GE Healthcare	Advice regarding a software upgrade	10 December 2013	Manufacturer's FSN	Yes
V19608	SERVO-U and SERVO-n intensive care ventilator	Maquet	Advice regarding a software upgrade	19 December 2013	Manufacturer's FSN	Yes
V19465	Medrad Veris 8600 Vital Signs Monitor	Medrad B.V. / Bayer	Advice regarding a device modification	09 Dember 2013	Manufacturer's FSN	Yes
V19449	ORTHO BioVue® System Cassettes	Ortho-Clinical Diagnostics	Advice regarding the review of patient results/patient recall/sample retesting is required	06 December 2013	Manufacturer's FSN	Yes
V19301	A-642100 Fixed Offset Adapter	Ossur	Advice regarding a device removal	19 December 2013	Manufacturer's FSN	Yes
V16246	Procedure Pack rigid tip suction wand	Pennine Healthcare	Advice regarding a device removal	05 November 2012	Manufacturer's FSN	Yes
V19433	Philips HeartStart FRx, HeartStart HS1 Home, and HeartStart HS1 OnSite Automated External Defibrillators	Philips	Advice regarding the use of the device	26 July 2012	Manufacturer's FSN	Yes
V19433	Philips HeartStart FRx, HeartStart HS1 Home, and HeartStart HS1 OnSite Automated External Defibrillators	Philips	Advice regarding the use of the device	11 December 2013	Manufacturer's FSN	Yes

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V18681	R40PED (Sparky) powerchairs with tilt seating system	Pride Mobility	Advice regarding a device modification	22 August 2013	Manufacturer's FSN	Yes
V19047	Pride Powerchair, model Q600, Q600XL, Q600 Sport, Q6 Edge, Q600 Sport HD	Pride Mobility	Advice regarding changes/updates made to instructions for use	11 October 2013	Manufacturer's FSN	Yes
V19405	AQURE V1.5.4	Radiometer Medical Aps	Advice regarding a device modification	29 November 2013	Manufacturer's FSN	Yes
V19454	SOMATOM Definition software version syngo	Siemens	Advice regarding a software upgrade	06 December 2013	Manufacturer's FSN	Yes
V19485	Digital Linear Accelerators: Primus, Oncor and Artiste - 550 TxT™ Treatment Table Modification	Siemens	Advice regarding a device modification	18 December 2013	Manufacturer's FSN	Yes
V19329	REPLY, ESPRIT and FACIL1 Pacemakers	Sorin	Advice regarding a software upgrade	20 November 2013	Manufacturer's FSN	Yes
V19360	SunTech Orbit ABP Cuffs	Spacelab	Advice regarding a device removal	15 November 2013	Manufacturer's FSN	Yes
V19520	Neptune Waste Management System	Stryker	Advice regarding a device removal	12 December 2013	Manufacturer's FSN	Yes
V19437	Eclipse version 11 and 13	Varian	Advice regarding a software upgrade	05 December 2013	Manufacturer's FSN	Yes
V19391	X-Bolt Orthopaedics Bone Compactor	X-Bolt Orthopaedics	Advice regarding the use of the device	12 December 2013	Manufacturer's FSN	Yes
V19391	X-Bolt Orthopaedics Bone Compactor	X-Bolt Orthopaedics	Advice regarding the use of the device	12 December 2013	Manufacturer's FSN	Yes
V19410	Wartie Wart & Verruca Remover	YouMedical	Advice regarding a device removal	29 November 2013	Manufacturer's FSN	Yes