



IRISH MEDICINES BOARD

FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- JULY 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?
V18430	STERRAD® 100NX® System cassette	Advanced Sterilization Products, Inc.	Advice regarding the use of the device	29 July 2013	Manufacturer's FSN	Yes
V18276	Custom procedural trays	ArcRoyal	Advice regarding a device removal	31 May 2013	Manufacturer's FSN	Yes
V18147	Coiled Tube Infusors	Baxter Healthcare Corporation	Advice regarding a device removal	04 July 2013	Manufacturer's FSN	Yes
V18345	Winged Surecan needles, Winged Surecan needles Y site	B Braun	Advice regarding a device removal	15 July 2013	Manufacturer's FSN	
V11831	Access 2 Immunoassay Systems	Beckman Coulter Diagnostics Limited	Advice regarding the use of the device	11 July 2013	Manufacturer's FSN	Yes
V17397	OPERON - OR Table	Berchtold	Advice regarding the use of the device	08 July 2013	Manufacturer's FSN	Yes
V18288	VITEK® 2 Software version 6.01	Biomerieux Inc.	Advice regarding a software upgrade	11 July 2013	Manufacturer's FSN	Yes
V18288	VITEK® 2 Software version 6.01	Biomerieux Inc.	Advice regarding a software upgrade	11 July 2013	Manufacturer's FSN	Yes
V18436	Seraclone Anti-S, Ref. N° 808052	Bio-Rad Medical Diagnostics GmbH	Advice regarding a device removal	29 July 2013	Manufacturer's FSN	Yes
V18394	Bodyguard & TPCA Bolus Handsets 140 000X, 140 000XM, 140 100X, 140 100XM	Caesarea Medical Electronics Limited	Advice regarding changes/updates made to instructions for use	16 July 2013	Manufacturer's FSN	Yes
V18287	CardioQ-ODM/CardioQ-ODM+ Cardiac Function and Fluid Status Monitoring Systems	Deltex Medical	Advice regarding the use of the device	08 July 2013	Manufacturer's FSN	Yes
V18248	STA® - COAG CONTROL (N + ABN) PLUS (REF. 00677)	Diagnostica Stago	Advice regarding a device removal	02 July 2013	Manufacturer's FSN	Yes
V18129	IH-1000, 001000	Dia-Med AG	Advice regarding a software upgrade	10 June 2013	Manufacturer's FSN	Yes
V18408	LIAISON Control Direct Renin 310471	DiaSorin S.p.A.	Advice regarding the use of the device	22 July 2013	Manufacturer's FSN	Yes
V18225	Eco table	Evans Instruments	Advice regarding a device modification	04 June 2013	Manufacturer's FSN	Yes
V18273	GamCath Short-Term Catheters and Vessel Dilator	Gambro Lundia AB	Advice regarding a device removal	10 July 2013	Manufacturer's FSN	Yes
V18453	Centricity PACS RA1000 Workstation	GE Healthcare	Advice regarding a software upgrade	30 July 2013	Manufacturer's FSN	Yes
V18032	VG and VG Hawkeye Nuclear Medicine systems, Helix nuclear medicine systems, Brivo NM615, Discovery NM630, Optima NM/CT640, Discovery NM/CT670	GE Healthcare	Advice regarding a device modification	04 July 2013	Manufacturer's FSN	Yes
V18245	HemoCue Glucose 201 Microcuvettes	HemoCue AB	Advice regarding a device removal	05 July 2013	Manufacturer's FSN	Yes
V17466	1L Receptal System (Liner and Canister)	Hospira Inc.	Advice regarding a device removal	05 July 2013	Manufacturer's FSN	Yes
V18428	OmniPro-Accept, Version 7.4a	IBA Dosimetry AB	Advice regarding the use of the device	26 July 2013	Manufacturer's FSN	Yes

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V17991	da Vinci S Surgical System, Model IS2000, da Vinci Si Surgical System, Model IS3000, da Vinci Si-e Surgical System, Model IS3000	Inuitive Surgical	Advice regarding changes/updates made to instructions for use	14 June 2013	Manufacturer's FSN	Yes
V18077	Kimal Procedure Packs containing BD Plastipak 50ml LuerLok Syringe	Kimal Plc	Advice regarding a device removal	14 June 2013	Manufacturer's FSN	Yes
V16769	Ceiling Mounted Rail Systems for all Liko Stationary Lifts including Likorall®, Multirall® and Masterlift® Systems	Liko Hill Rom	Advice regarding a device modification	19 November 2012	Manufacturer's FSN	Yes
V18002	Sutureless Connector (SC) Intrathecal Catheters	Medtronic Inc.	Advice regarding a device removal	05 June 2013	Manufacturer's FSN	Yes
V18359	Telemetry Systems WEP-5204K and WEP-5208K	Nihon Kohden	Advice regarding a software upgrade	01 August 2013	Manufacturer's FSN	Yes
V18460	Oxoid Antimicrobial Susceptibility Testing Disc MEM10 MEROPENEM, CT0774B	Oxoid Limited	Advice regarding a device removal	22 July 2013	Manufacturer's FSN	Yes
V18004	Patterson Walking Crutches – 125A, 119E, 124AT, 124A	Patterson	Advice regarding a device removal	01 June 2013	Manufacturer's FSN	Yes
V18007	Patterson Walking Sticks – 404 model	Patterson	Advice regarding a device removal	01 June 2013	Manufacturer's FSN	Yes
V18008	Patterson Walking Frames	Patterson	Advice regarding a device removal	01 June 2013	Manufacturer's FSN	Yes
V18298	HeartStart MRx	Philips Healthcare	Advice regarding a software upgrade	01 June 2013	Manufacturer's FSN	Yes
V18155	Allura Xper FD10 F, FD10/10	Philips Healthcare	Advice regarding the use of the device	08 July 2013	Manufacturer's FSN	Yes
V18262	Respironics V60 Ventilator	Philips Healthcare	Advice regarding the use of the device	21 June 2013	Manufacturer's FSN	Yes
V18222	Protac SenSit chair	Protac	Advice regarding the use of the device	24 June 2013	Manufacturer's FSN	Yes
V18292	942-063 pCO2 Membrane Box (D788)	Radiometer Medical Aps	Advice regarding a device removal	11 July 2013	Manufacturer's FSN	Yes
V18207	IMMULITE/IMMULITE 1000 and the IMMULITE 2000/2000XPi PSA Assay	Siemens Healthcare Diagnostics	Advice regarding a device removal	28 June 2013	Manufacturer's FSN	Yes
V18204	ADVIA Centaur Homocysteine Diluent	Siemens Healthcare Diagnostics Inc.	Advice regarding the use of the device	25 June 2013	Manufacturer's FSN	Yes
V18208	ADVIA 120	Siemens Healthcare Diagnostics Inc.	Advice regarding a device modification	27 June 2013	Manufacturer's FSN	Yes
V10894	Riata and Riata ST silicone endocardial leads	St. Jude Medical	Advice regarding the use of the device	08 July 2013	Manufacturer's FSN	Yes
V18025	Stryker T4/T5 Hytreil Toga	Stryker	Advice regarding a device removal	17 June 2013	Manufacturer's FSN	Yes
V18218	Sonopet Ultrasonic Aspirator Console	Stryker	Advice regarding a device modification	02 July 2013	Manufacturer's FSN	Yes
V18226	TRACOE twist tracheostomy tube	Tracoe Medical GmbH	Advice regarding the use of the device	20 June 2013	Manufacturer's FSN	Yes