



IRISH MEDICINES BOARD

FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- MARCH 2011

Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Is the Irish market affected?
Tyvek Heat Seal Pouch	Advanced Sterilization Products	Advice regarding a device removal	14 March 2011	Yes
WaveLight® EX500 Excimer Laser	Alcon	Advice regarding the use of the device	23 March 2011	Yes
Anchor Tissue Retrieval System	Anchor Products Company	Advice regarding a device removal	08 March 2011	Yes
Mikro 120	Andreas Hettich GmbH & Co.	Advice regarding the use of the device	09 December 2010	Unknown
Sterican 30G	B Braun Medical Limited	Advice regarding a device removal	10 March 2011	Yes
MSC2 Manifold Control Panel	Beacon Medaes	Advice regarding a device modification	02 March 2010	Yes
BD Microlance™ Needle REF 304000 used in Beaver-Visitec CustomEyes® Kit	Beaver-Visitec International Limited	Advice regarding the use of the device	07 March 2011	Yes
CME T34 Syringe pump administration sets	Caesare Medical Electronics Ltd	Advice regarding a device removal	14 February 2011	Yes
PleurX Drainage Kits	CareFusion	Advice regarding the use of the device	23 February 2011	Yes
Intermediary Tube Sets for Fluid Management	DePuy Mitek	Advice regarding a device removal	07 December 2010	Yes
XVI	Elekta	Advice regarding the use of the device	09 March 2011	Yes
Applix Smart and Applix Vision Nutrition Pumps	Fresenius Kabi Limited	Advice regarding a device removal	04 March 2011	Yes
Samba Chairs	G&S Smirthwaite Ltd.	Advice regarding a device modification	24 January 2011	Yes
AK 200 Ultra S and AK 200 Ultra	Gambro Lundia AB	Advice regarding a software upgrade	31 January 2011	Yes
Reporting Tool	GE	Advice regarding a software upgrade	04 March 2011	Yes
Harvest Stand-up Lifter, Harvest Graduate Lifter, Harvest Junior Lifter & Harvest Extreme Lifter	Harvest Healthcare Limited	Advice regarding a device modification	17 January 2011	Yes
AvantGuard™, CareAssist®, Hill-Rom®1000, and Advanta® 2	Hill-Rom	Advice regarding a device modification	21 January 2011	Yes
PLUM A+ Family of Infuser	Hospira	Advice regarding a device modification	08 March 2011	Yes
Plum XL Infusors	Hospira	Advice regarding the use of the device	16 March 2011	Yes
GEM Premier 4000	Instrumentation Laboratory Co.	Advice regarding the use of the device	01 February 2011	Yes
RELI SSO HLO Typing kits & RELI SSO Mastermixes	Invitrogen	Advice regarding a device removal	08 March 2011	Yes
RELI SSO HLA-DRB Typing Kit	Invitrogen Corporation	Advice regarding changes/updates made to instructions for use	10 March 2011	Yes
RELI SSO HLA-B Typing Kit	Invitrogen Corporation	Advice regarding the review of patient results/patient recall/sample retesting is required	10 February 2011	Yes
RELI SSO HLA-DRB Typing Kit	Invitrogen Corporation	Advice regarding the review of patient results/patient recall/sample retesting is required	10 February 2011	Yes

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RELI SSO HLA-DQB1 Typing Kit	Invitrogen Corporation	Advice regarding the review of patient results/patient recall/sample retesting is required	10 February 2011	Yes
Gendex Dental Systems' eXpert® DC Intraoral X-Ray System	KaVo	Advice regarding a device modification	16 March 2011	Yes
Cardiohelp Emergency Drive	Maquet	Advice regarding a device modification	07 March 2011	Yes
System 98/98XT, CS100/CS100i and CS300 Intra-Aortic Balloon Pumps	Maquet	Advice regarding a device modification	16 March 2011	Yes
1180.16 Magnus Carbon-Fibre Table Top	Maquet GmbH & Co. KG	Advice regarding a device modification	30 March 2011	Yes
MTP Rhino Fiberscope Sheath	Medical Technical Promotion GmbH	Advice regarding a device removal	24 February 2011	Yes
SynchroMed and IsoMed intrathecal drug delivery systems	Medtronic	Advice regarding the use of the device	02 September 2010	Yes
Dual Chamber Models of Pacemakers: Kappa 600, 700, 800, 900, EnPulse, Adapta, Versa, Sensia, Relia, Vitatron Models E50A1, E60A1, and G70A1	Medtronic	Advice regarding the use of the device	4 April 2011	Yes
Molift Smart 150 Patient Hoist	Molift	Advice regarding a device modification	16 March 2011	Yes
OptiLube Lubricating Jelly 150x5gram sachets	Optimum Medical Solutions	Advice regarding a device removal	07 February 2011	Yes
Liftmaster 160, Liftmaster 190	Patterson Medical	Advice regarding a device modification	25 May 2010	Yes
Liftmaster 160, Liftmaster 190	Patterson Medical	Advice regarding a device modification	13 December 2010	Yes
Spirit 1700 Dental Chair with the Cuspidor Rear Swing-Mount with Assistant's Vacuum Kit	Pelton & Crane	Advice regarding a device removal	10 March 2011	Yes
Crystal ® Metal Miller Disposable Blades (sizes 0 and 00)	Penlon	Advice regarding the use of the device	07 March 2011	Yes
MX 16-slice CT	Philips Healthcare	Advice regarding a software upgrade	10 March 2011	Yes
IntelliVue Clinical Information Portfolio (ICIP)	Philips Healthcare	Advice regarding a software upgrade	11 March 2011	Yes
PulseCath iVAC3L (21 Fr)	PulsCath	Advice regarding the use of the device	08 March 2011	Yes
Calcium Test used on COBAS Integra System	Roche Diagnostics	Advice regarding a device removal	24 February 2011	Yes
Romachair Model 4740	Roma Medical	Advice regarding a device modification	21 February 2011	Yes
Axiom Aristos FX and FX Plus	Siemens	Advice regarding a device modification	17 February 2011	Yes
Syngo Plaza	Siemens	Advice regarding a software upgrade	10 March 2011	Yes
ARTISTE™ digital linear accelerators with syngo ® RT Therapist version 4.1	Siemens	Advice regarding a software upgrade	28 March 2011	Yes
Level 1® Normothermic IV Fluid Administration Sets	Smiths Medical	Advice regarding a device removal	28 February 2011	Yes
Scorpio T72 Tibial Insert Trial	Stryker Orthopaedics	Advice regarding the use of the device	01 March 2011	Yes
CS-2x00i Series	Sysmex Europe	Advice regarding the use of the device	28 February 2011	Yes
Ureter Catheter, curved, coaxial with no eyes	Teleflex Medical	Advice regarding a device removal	30 March 2011	Yes
Aequalis Fracture Stem	Tornier	Advice regarding a device removal	11 February 2011	Yes

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Operating table TITAN	Trumpf Medizin Systeme GmbH	Advice regarding a device modification	25 January 2011	Yes
Oxygen Masks and Face Tent Masks	Unomedical	Advice regarding a device removal	11 January 2011	Yes
Oxygen Masks and Face Tent Masks	Unomedical	Advice regarding a device removal	15 February 2011	Yes
BLAKE Silicone Drain/Silicone Drain Kit/Cardio Connector and J-VAC Reservoir/Drain Adapter	BLAKE Silicone Drain/Silicone Drain Kit/Cardio Connector and J-VAC Reservoir/Drain Adapter	Advice regarding a device removal	28 March 2011	Yes
Clinacs using the collimator cover P/N 1106900-xx, including Clinacs equipped with the Millennium and HD-120 Multi Leaf Collimators (MLC)	Varian	Advice regarding a device modification	17 March 2011	Yes