



## IRISH MEDICINES BOARD

## FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- OCTOBER 2012

Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Is the Irish market affected?
24 fr Arterial perfusion Canulae	Andocor	Advice regarding a device removal	21 August 2012	Unknown
Animas Insulin Pump	Animas / J&J	Advice regarding the use of the device	25 September 2012	Yes
Animas 2020 / Animas IR1200	Animas / J&J	Advice regarding the use of the device	01 October 2012	Yes
Animas 2020 / Animas IR1200	Animas / J&J	Advice regarding the use of the device	01 October 2012	Yes
AU5800 Clinical Chemistry Analyzer	Beckman Coulter Inc	Advice regarding the use of the device	26 October 2012	Yes
BacT/ALERT 3D	BioMerieux	Advice regarding changes/updates made to instructions for use	26 October 2012	Yes
PREVI Isola	BioMérieux	Advice regarding changes/updates made to instructions for use	04 September 2012	Yes
Full OSSEOTITE Parallel Walled Certain® Implant	Biomet 3i	Advice regarding a device removal	24 October 2012	Yes
MobiCath Bi-Directional Guiding Sheath	Biosense Webster	Advice regarding the use of the device	24 September 2012	Yes
Insertion Tool of the Encore™ 26 Advantage Kit	Boston Scientific	Advice regarding the use of the device	22 October 2012	Yes
QuantifERON-TB Gold TB Antigen tubes	Cellestis GmbH	Advice regarding a device removal	09 October 2012	Yes
ExoSeal™ Vascular Closure Device (VCD)	Cordis	Advice regarding a device removal	29 October 2012	Yes
Illumena 150 mL Linden Luer Syringe with Handi-Fil Straw / Illumena 150 mL Regular Luer Syringe with Handi-Fil Straw	Covidien	Advice regarding a device removal	17 October 2011	Yes
Quinton Beta Cap Adapter	Covidien	Advice regarding the use of the device	26 September 2012	Yes
Peritoneal Dialysis Devices containing Quinton Beta Cap Adapter	Covidien	Advice regarding the use of the device	04 October 2012	Yes
Kryptonite Bone Cement	Doctors Research Group Inc.	Advice regarding changes/updates made to instructions for use	23 April 2012	Yes
Temporary Cardiac Pacing Wire, FEP13E, FEP15E	Ethicon	Advice regarding a device removal	10 October 2012	Yes
PSX Proximate® Skin Staple Extractor	Ethicon Endo-Surgery	Advice regarding a device removal	17 October 2012	Yes
Centricity RIS-i	GE Healthcare	Advice regarding a software upgrade	11 September 2012	Yes
Dash 3000/4000/5000 Patient Monitor	GE Healthcare	Advice regarding the use of the device	04 October 2012	Yes
Discovery NM/CT 670 and Discovery NM 630	GE Healthcare	Advice regarding the use of the device	11 October 2012	Yes
Centricity PACS	GE Healthcare	Advice regarding a software upgrade	22 October 2012	Yes
Carescape Patient Monitor, B20 and B40	GE Healthcare	Advice regarding a software upgrade	29 October 2012	Yes

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TEG® Analytical Software	Haemonetics Corporation	Advice regarding a software upgrade	24 October 2012	Yes
Plum A+ Single Channel Family Of Infusers	Hospira	Advice regarding the use of the device	29 October 2012	Yes
FDX Electrical Power Wheelchair	Invacare	Advice regarding a device modification	11 October 2012	Yes
Liko Bathing Chair 3156025	Liko / Hill-Rom	Advice regarding a device modification	14 September 2012	Yes
Liko Sabina and Capella Sit-to-Stand Mobile Lifts	Liko AB	Advice regarding a device modification	11 June 2012	Yes
Liko Sabina and Capella Sit-to-Stand Mobile Lifts - Hook Retrofit Kit	Liko AB	Advice regarding a device modification	28 September 2012	Yes
Macopharma Whole Blood Collection System, Product Code FQE6280LB	Macopharma	Advice regarding the use of the device	10 September 2012	Yes
Macopharma Whole Blood Collection System, Product Code FQE6280LB	Macopharma	Advice regarding the use of the device	10 September 2012	Yes
Valisafe Bowie & Dick Type Test	Medisafe International	Advice regarding changes/updates made to instructions for use	27 July 2012	Yes
Lentis Intra Ocular Lens Hydrosmart Yellow models	Oculentis GmbH	Advice regarding the use of the device	26 October 2012	Yes
Oxoid Antimicrobial Susceptibility Testing Disc F100 (Nitrofurantoin), CT0034B	Oxoid	Advice regarding a device removal	16 October 2012	Yes
MicroPace 4580	Pace Medical	Advice regarding a device modification	14 September 2012	Yes
Extended Brilliance Workstation	Philips Healthcare	Advice regarding a software upgrade	28 September 2012	Yes
LIFEPAK® 500	PhysioContorl	Advice regarding the use of the device	07 June 2011	Yes
Lactate Membrane Units	Radiometer	Advice regarding the use of the device	01 October 2012	Yes
Elecsys Thyroglobulin (Tg)	Roche Diagnostics GmbH	Advice regarding the use of the device	15 October 2012	Yes
ALP2, CREJ2, CRPL3, UREAL, ALT, CO2-L for cobas c systems	Roche Diagnostics GmbH	Advice regarding a software upgrade	24 October 2012	Yes
ADVIA Centaur Calibrator C	Siemens Healthcare Diagnostics	Advice regarding a device modification	08 October 2012	Yes
Waters ACQUITY® TQD, ACQUITY® SQD, LCT Premier™ XE, Quattro Premier™, Quattro Premier™ XE, Quattro™ micro, Xevo® G2 Tof, Xevo® TQ, Xevo® TQD & ZQ 2000 Mass Spectrometers	Waters Corporation	Advice regarding a device modification	18 October 2012	Yes
VSM 200 & 300 series, SPOT Vital Signs, SPOT Lxi Power Cords & Transformers	Welch Allyn	Advice regarding the use of the device	27 March 2012	Yes