



IRISH MEDICINES BOARD

FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- OCTOBER 2011

Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Is the Irish market affected?
ARCHITECT Cyclosporine Reagents	Abbott Laboratories	Advice regarding the use of the device	07 October 2011	Yes
Clinical Chemistry Urea Nitrogen	Abbott Laboratories	Advice regarding a device removal	03 October 2011	Yes
m2000sp Instrument	Abbott Molecular Inc	Advice regarding the use of the device	10 October 2011	Yes
UniCel DxI 800 Access Immunoassay Systems, UniCel DxI 600 Access® Immunoassay Systems, UniCel Dx C 660i, 680i, 860i, 880i SYNCHRON Access Clinical Systems	Beckman Coulter Inc	Advice regarding a software upgrade	13 October 2011	Yes
Model 2868 software application for the COGNIS, TELIGEN, INCEPTA, PUNCTUA and ENERGEN, LATITUDE Remote Monitoring System server software	Boston Scientific	Advice regarding a software upgrade	18 October 2011	Yes
AVEA® ventilator all models	CareFusion	Advice regarding a device modification	12 September 2011	Yes
Spectra Optia Apheresis System	Caridian BCT	Advice regarding the use of the device	06 October 2011	Yes
Simpa Foley Catheters	Coloplast	Advice regarding changes/updates made to instructions for use	21 October 2011	Yes
Speedicath Compact CH10 female catheters	Coloplast A/S	Advice regarding a device removal	07 October 2011	Yes
DePuy Sigma HP FB Tibial Tray Impactor	DePuy	Advice regarding a device removal	24 October 2011	Yes
Elekta XVI	Elekta	Advice regarding a device modification	20 October 2011	Yes
XVI	Elekta	Advice regarding a software upgrade	14 October 2011	Yes
Carescape B650	GE Healthcare	Advice regarding a software upgrade	28 October 2011	Yes
HemoCue Glucose 201+ Analyzers	HemoCue	Advice regarding the use of the device	14 October 2011	Yes
HOSPIRA PLUM™ A+ FAMILY OF INFUSERS	Hospira	Advice regarding the use of the device	04 October 2011	Yes
HOSPIRA PLUM™ A+ FAMILY OF INFUSERS	Hospira	Advice regarding the use of the device	04 October 2011	Yes
Complement Control Cells	Immucor Gamma	Advice regarding a device removal	20 October 2011	Yes
Panocell-16	Immucor Gamma	Advice regarding the use of the device	18 July 2011	Yes
Luxtec UltraLite Pro Headlight	Integra	Advice regarding a device removal	10 October 2011	Yes
Leo Scooter	Invacare	Advice regarding a device modification	28 September 2011	Yes
SOLO SUPRA Needle 30G Short	J&S Davis	Advice regarding a device removal	23 September 2011	Yes
TIBIAXYS® compression guide	Newdeal SAS	Advice regarding the use of the device	21 October 2011	Yes
Nikkiso Blood Tubing Lines AV-05 series	Nikkiso	Advice regarding a device modification	28 September 2011	Yes

