



IRISH MEDICINES BOARD

FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- AUGUST 2011

Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Is the Irish market affected?
ALBAcheck® - BGS Simulated Whole Blood Controls	Alba Bioscience Inc	Advice regarding the use of the device	11 July 2011	Yes
Stockert EP-Shuttle	Biosense Webster	Advice regarding the use of the device	27 July 2011	Yes
Stockert EP-Shuttle	Biosense Webster	Advice regarding the use of the device	27 July 2011	Yes
BrainLAB Navigation Software / Microscope Integration Kit	Brainlab AG	Advice regarding the use of the device	18 July 2011	Yes
Cameron Health SQ RX® Pulse Generator, Model Number 10 10	Cameron Health	Advice regarding the use of the device	01 June 2011	Yes
Delta and Gamma XXL	Dräger	Advice regarding a device modification	06 July 2011	Yes
GE Centricity™ Laboratory Data Innovations (DI) Instrument Manager used with PSM	GE Healthcare IT	Advice regarding the use of the device	06 May 2011	Unknown
Linet Eleganza Standard and Deluxe Model Bedframes	Linet Spol. s.r.o.	Advice regarding a device modification	15 July 2011	Yes
Marus brand LuxStar dental lights	Marus	Advice regarding a device modification	28 July 2011	Yes
Magnus hybrid operating table columns 1180.01A1 and 1180.01B1	Maquet	Advice regarding a device modification	31 August 2011	Yes
Mercia Syphilis M	Microgen Bioproducts Limited	Advice regarding a device removal	21 August 2011	Yes
AQT90 Flex	Radiometer Medical Aps	Advice regarding the use of the device	22 August 2011	Yes
Syngo Imaging XS	Siemens	Advice regarding a software upgrade	24 August 2011	Yes
Syngo Imaging XS	Siemens	Advice regarding the use of the device	03 August 2011	Yes
Syngo Plaza	Siemens	Advice regarding a software upgrade	03 August 2011	Yes
Omnifuse and Omnifuse PCA Syringe Pumps	Smiths Medical	Advice regarding the use of the device	25 July 2011	Yes
Xcelerate Ceramic 4:1 Cutting Blocks	Stryker Orthopaedics	Advice regarding a device removal	30 June 2011	Yes
HMRS Distal Femur and Femoral Joint	Stryker Orthopaedics	Advice regarding a device removal	10 August 2011	Yes
Scorpio T72 Tibial Insert Trials	Stryker Orthopaedics	Advice regarding a device removal	01 August 2011	Yes
Acheeva Learning Station	The Helping Hand Company	Advice regarding a device modification	07 June 2011	Yes
Clinac, Trilogy, Trilogy Tx and Novalis Tx	Varian	Advice regarding a device modification	02 August 2011	Yes
Eclipse Treatment Planning System	Varian	Advice regarding the use of the device	17 August 2011	Yes
4D Integrated Treatment Console (4DITC) H51	Varian	Advice regarding a software upgrade	17 August 2011	Yes
Ziehm Solo	Ziehm Imaging	Advice regarding a device modification	18 April 2011	Yes
NexGen® Complete Knee Solution Stemmed & Rotating Hinge KneeTibial Broach Impactors	Zimmer	Advice regarding a device removal	31 July 2011	Yes