IRISH MEDICINES BOARD

FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- SEPTEMBER 2011

Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Is the Irish market affected?
Clinical Chemistry Alkaline Phosphatase	Abbott Laboratories	Advice regarding a device removal	26 August 2011	Yes
m2000rt Instrument System	Abbott Molecular Inc	Advice regarding the use of the device	08 September 2011	Yes
Cutting Burs and Irrigation Clips packaged in a Tyvek pouch/Tube configuration	Anspach	Advice regarding a device removal	09 September 2011	Yes
Contoura C880 Model No C885L/R/ZP	ArjoHuntleigh	Advice regarding a device modification	23 June 2010	Yes
Celsite (various)	B. Braun	Advice regarding the use of the device	09 September 2011	Yes
Access Immunoassay Systems Total T4 Calibrators	Beckman Coulter Inc	Advice regarding the use of the device	27 July 2011	Yes
AVEA® ventilator all models	Carefusion Respiratory System	Advice regarding a device modification	12 September 2011	Yes
OPMI Microscopes	Carl Zeiss Surgical GmbH	Advice regarding the use of the device	14 September 2011	Yes
Cochlear Nucleus CI500 Series cochlear implant	Cochlear	Advice regarding a device removal	13 September 2011	Yes
SenSura® Sterile Post-Operative ostomy bag and Assura® Sterile Post-Operative ostomy bag	Coloplast	Advice regarding a device removal	15 August 2011	Yes
Zenith Branch Endovascular Graft Iliac Bifurcation	Cook	Advice regarding a device removal	08 December 2010	Yes
Legionella V-TesT	Coris BioConcept	Advice regarding a device removal	21 September 2011	Yes
DUET TRS Universal Straight and Articulating Single Use Loading Units	Covidien	Advice regarding a device removal	23 August 2011	Yes
ARTIS and ARTIS PL	Cristalens Industrie	Advice regarding a device removal	27 June 2011	Unknown
Indigo Carmin Sterile	Derm Tech France	Advice regarding a device removal	01 September 2011	Yes
Drive WA007 Rollators	Drive Medical	Advice regarding a device modification	26 August 2011	Yes
Drive Medical Nimbo Paediatric Walkers	Drive Medical	Advice regarding the use of the device	06 September 2011	Yes
Orthoralix 8500 DDE, Orthoralix 9200 DDE	Gendex Dental System	Advice regarding the use of the device	16 August 2011	Yes
Orthoralix 8500 DDE, Orthoralix 9200 DDE	Gendex Dental System	Advice regarding the use of the device	16 August 2011	Yes
Eosinofix	Horiba ABX SAS	Advice regarding a device removal	31 August 2011	Yes
Lojer 200-Series treatment tables	Lojer Oy	Advice regarding a device modification	01 August 2011	Yes
MAGNUS Hybrid Operating Table Columns	Maquet	Advice regarding a device modification	31 August 2011	Yes
EnRhythm and EnRhythm MRI SureScan Pacemeker	Medtronic	Advice regarding the use of the device	25 August 2011	Yes
ProcedurePak®	Molnlycke Healthcare	Advice regarding the use of the device	31 August 2011	Yes
ProcedurePak®	Molnlycke Healthcare	Advice regarding the use of the device	31 August 2011	Yes
NRG devices	Neuro Research Group	Advice regarding the use of the device	01 September 2011	Yes

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EF-02 D Filter for Dialysate Purification	Nikkiso	Advice regarding the use of the device	26 September 2011	Yes
Aquarius Hemofiltration Device	Nikkiso	Advice regarding the use of the device	31 August 2011	Yes
LABScreen Single Antigen HLA Class II Antibody Detection Test - Group 1	One Lambda Inc	Advice regarding the review of patient results/patient recall/sample retesting is required	22 August 2011	Yes
Crystal Metal Disposable Blades (sizes Mac 4 and Mac 3)	Penlon	Advice regarding a device removal	14 September 2011	Yes
Delight Operating Light	Planmeca	Advice regarding a device modification	26 August 2011	Yes
SulcoFlex® lenses	Rayner	Advice regarding the use of the device	09 August 2011	Yes
Armboard 10-380 och 10-387	Reison Medical AB	Advice regarding the use of the device	18 August 2011	Yes
ADVIA 120/2120/2120i Hematology Sytems	Siemens Healthcare Diagnostics	Advice regarding the use of the device	12 September 2011	Yes
Accent DR and Anthem CRT-P pacemakers	St Jude Medical	Advice regarding the use of the device	23 September 2011	Yes
AMSCO® V-PROTM 1 AND V-PROTM 1 PLUS LOW TEMPERATURE STERILIZATION SYSTEMS VOLUNTARY FIELD CORRECTION SERIAL NUMBERS 033250701 TO 031581115	Steris	Advice regarding a device modification	05 August 2011	Yes
G8 Hemoglobin F & A2 Calibrator	TOSOH Europe	Advice regarding the use of the device	07 September 2011	Yes
Silhouette Clinacs in the specified serial number range	Varian	Advice regarding a device modification	28 September 2011	Yes
Eclipse Treatment Planning System	Varian	Advice regarding a software upgrade	25 August 2011	Yes
Clinac with OBI (On-Board Imager)	Varian	Advice regarding a device modification	12 September 2011	Yes
GammaMed Plastic Needle with Mandrin	Varian	Advice regarding a device removal	16 September 2011	Yes
GammaMed Flexible Applicator Probe	Varian	Advice regarding a device removal	16 September 2011	Yes
GammaMed Flexible Probe with Blocking Washer	Varian	Advice regarding a device removal	16 September 2011	Yes
GammaMed Titanium intrauterine probe with stopper	Varian	Advice regarding a device removal	16 September 2011	Yes
Illuminated Sigmoidoscope and Anoscope Systems and Accessories	Welch Allyn	Advice regarding the use of the device	01 September 2011	Yes