



IRISH MEDICINES BOARD

FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- JUNE 2011

Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Is the Irish market affected?
Baxa EVA & Multilayer Bags for Total Parenteral Nutrition (TPN) - All Sizes	Baxa Limited	Advice regarding the use of the device	20 June 2011	Yes
IMMAGE® Immunochemistry Systems Rheumatoid Factor Reagent	Beckman Coulter Inc	Advice regarding a device removal	31 May 2011	Yes
SYNCHRON® Rheumatoid Factor (RF) Reagent	Beckman Coulter Inc	Advice regarding a device removal	20 June 2011	Yes
VITEK 2 60 and VITEK 2 XL systems	bioMérieux	Advice regarding the use of the device	14 June 2011	Yes
Cranial/ENT Navigation Software Unlimited 1.0, Cranial/ENT Navigation Software Essential 1.0, VectorVision Navigation Software Cranial/ENT 7.9, Kolibri Navigation Software Cranial/ENT 2.7	Brainlab	Advice regarding a software upgrade	08 June 2011	Yes
CambridgeEndo Autonomy Laparo-Angle Metzzenbaum Scissors	CambridgeEndo	Advice regarding a device removal	02 June 2011	Yes
Cypher Select+ Sirolimuseluting Coronary Stent	Cordis	Advice regarding the use of the device	07 June 2011	Yes
DMLC	Elekta	Advice regarding the use of the device	25 May 2011	Yes
Discovery VCT, Discovery RX VCT, Discovery STE, Discovery RX and Discovery ST systems	GE Healthcare	Advice regarding a software upgrade	30 May 2011	Yes
Vital Signs Broselow Pediatric Emergency System Kit	GE Healthcare	Advice regarding a device removal	31 May 2011	Yes
Vital Signs Cuffable® Blood Pressure Cuffs	GE Healthcare	Advice regarding a device removal	29 June 2011	Yes
IT2500, IT2500 Plus, IT3000, IT3500, IT3500Plus; All Transmitter Sensor Cables (P/N: 1002008; 1004587; 1007914-NAV) and All Receiver Sensor Cables (P/N: 1001989; 1001990; 1004069; 1007907-NAV)	GE Healthcare	Advice regarding changes/updates made to instructions for use	10 June 2011	Yes
Biometer Lenstar LS 900 with EyeSuite versions i.2000 or i3.000	Haag-Streit	Advice regarding a software upgrade	20 June 2011	Yes
Gamma-clone® Anti-Leb (Murine Monoclonal) Blood Grouping Reagent	IMMUCOR Medizinische Diagnostik GmbH	Advice regarding a device removal	17 June 2011	Yes
GEM Premier 4000	Instrumentation Laboratory Co.	Advice regarding the use of the device	10 June 2011	Yes
Cryomatic Probes	Keeler Limited	Advice regarding the use of the device	06 June 2011	Yes
All HL 20 – 4 pump consoles and all HL 20 – 5 pump consoles manufactured before the year 2011	Maquet	Advice regarding a device modification	27 June 2011	Yes
All HL 20 Twin Pump Modules, Release Version 11 REF: 703323 (Anti-Clockwise) and REF: 706159 (Clockwise) manufactured before 2011	Maquet	Advice regarding a software upgrade	27 June 2011	Yes
BE-HLS 7050 Set Advanced - bloodlines	Maquet Cardiopulmonary AG	Advice regarding a device removal	30 May 2011	Yes
Navigation Dicom Query/Retrieve, Version 1.1.4	Medtronic	Advice regarding a software upgrade	02 June 2011	Yes
Filter for dialysate purification EF-02 D	Nikkiso	Advice regarding the use of the device	18 May 2011	Yes
Olympus Chair Couch	Olympus Keymed	Advice regarding changes/updates made to instructions for use	01 April 2011	Yes

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Pelispac Vaginal Speculum including Smoke Extractor and those in the Light Source Packs and IUD Procedure Packs	Pelican Feminine Healthcare Limited	Advice regarding a device removal	31 May 2011	Yes
SureSigns Patient Monitors, Vital Signs Monitors	Philips	Advice regarding a device modification	27 June 2011	Yes
Single Use LED Macintosh Combination Set size 3 & 4	SG Manufacturers	Advice regarding a device removal	30 March 2011	Yes
COHERENCE® Therapist	Siemens	Advice regarding a software upgrade	24 May 2011	Yes
syngo® RT Therapist 4.2 & syngo® RT Oncologist 4.2	Siemens	Advice regarding a software upgrade	09 June 2011	Yes
ARTISTE™ digital linear accelerators	Siemens	Advice regarding a software upgrade	09 June 2011	Yes
ACUSON S2000 Ultrasound System	Siemens	Advice regarding a software upgrade	01 June 2011	Yes
Siemens Magnetom Systems Symphony and Sonata	Siemens AG	Advice regarding a device modification	31 March 2011	Yes
RAPIDQC Complete Controls	Siemens Healthcare Diagnostics Inc.	Advice regarding the use of the device	01 June 2011	Yes
Level 1 Normothermic IV Fluid Administration Sets equipped with the F-50 Gas Vent Filter Assembly, Product Reorder Numbers F-50, DI-65HL, DI-75, DI-150 and DI-350	Smiths Medical	Advice regarding a device removal	21 June 2011	Yes
CS-2x00i Series	Sysmex	Advice regarding the use of the device	24 May 2011	Yes
Minutex D-Dimer	Tcoag Ireland Limited	Advice regarding a device modification	02 June 2011	Yes
Terumo CDI Monitoring Systems	Terumo	Advice regarding the use of the device	13 June 2011	Yes
Operating Table TITAN	Trumpf	Advice regarding a software upgrade	07 June 2011	
Clinacs® and TrueBeam™	Varian	Advice regarding a device modification	10 May 2011	Yes
Propaq LT, Viewsonic Large Display	Welch Allyn	Advice regarding changes/updates made to instructions for use	09 June 2011	Yes