



IRISH MEDICINES BOARD

FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- SEPTEMBER 2012

Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Is the Irish market affected?
ARCHITECT HAVAb IgG	Abbott	Advice regarding the use of the device	20 September 2012	Yes
Vascular Catheters	Applied Medical	Advice regarding a device removal	03 September 2012	Yes
Heated Ventilator and CPAP Breathing Circuits Manufactured Using Corrugated Tubing	Armstrong Medical	Advice regarding a device removal	26 September 2012	Yes
Bard® Thrombectomy Catheters and Bard® Biliary and Cholangiography Catheters	Bard Limited	Advice regarding a device modification	25 September 2012	Yes
Stellaris PC Vision Enhancement System, Posterior Fluidics Module	Bausch & Lomb	Advice regarding a device modification	06 September 2012	Yes
Actifuse ABX, Actifuse MIS	Baxter	Advice regarding the use of the device	06 September 2012	Yes
GLUCOFACETS DELUXE Diabetes Data Management Software, version 3.01	Bayer Healthcare	Advice regarding a software upgrade	05 September 2012	Yes
AU2700/AU2700 Plus & AU5400 Clinical Chemistry Analyzers	Beckman Coulter	Advice regarding the use of the device	07 September 2012	Yes
Brainlab m3 Micro-Multileaf Collimator	Brainlab AG	Advice regarding changes/updates made to instructions for use	27 August 2012	Yes
Carestream DRX Evolution	Carestream Health Inc.	Advice regarding the use of the device	28 August 2012	Yes
SPIRALOK Suture Anchors (Various)	DePuy Mitek	Advice regarding a device removal	06 September 2012	Yes
Kryptonite Bone Cement	Doctor's Research Group Inc	Advice regarding the use of the device	18 September 2012	Yes
MOSAIQ	Elekta	Advice regarding the use of the device	22 September 2012	Yes
LIP W11055 Columbia Agar + Sheep Blood	Fannin Limited LIP	Advice regarding the use of the device	04 September 2012	Yes
Minor Surgery Pack Standard 5050	Farla Medical Limited	Advice regarding a device removal	02 July 2012	Unknown
Mediline O2/N2O Demand Valves	GCE Limited	Advice regarding changes/updates made to instructions for use	05 September 2012	Yes
Tonometer Measuring Prisms	Haag-Streit International	Advice regarding changes/updates made to instructions for use	17 September 2012	Yes
LifeCare PCA Plus II, LifeCare PCA 3, LifeCare PCA/LifeCare PCA with MedNet and LifeCare 4200 PCA	Hospira	Advice regarding the use of the device	07 September 2012	Yes
Lima SMR Anatomical Polyethylene Liner	Lima Orthopaedics	Advice regarding a device removal	27 September 2012	Yes
SERVO-i and SERVO-s Ventilator Systems	Maquet Critical Care AB	Advice regarding the use of the device	05 May 2011	Yes
MAVIG PORTEGRA 2 system	Mavig (installed by Siemens)	Advice regarding the use of the device	28 August 2012	Yes

Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Is the Irish market affected?
SureSigns VS Series Monitor	Philips	Advice regarding a device modification	01 August 2012	Yes
DigitalDiagnost	Philips	Advice regarding a device modification	15 August 2012	Yes
MX 16 Slice	Philips and Neusoft Medical Systems	Advice regarding a device modification	24 August 2012	Yes
Heartstart XL Defibrillator/Monitor	Philips Healthcare	Advice regarding the use of the device	06 September 2012	Yes
ABL505/555, EML105, ABL600, ABL700 Series, and ABL800 Analyzers	Radiometer	Advice regarding the use of the device	01 April 2012	Yes
Specific Protein Control	Randox	Advice regarding the use of the device	11 September 2012	Yes
LightCycler® 1.2 Control Unit / LightCycler® 2.0 Control Unit	Roche Diagnostics	Advice regarding the use of the device	21 September 2012	Yes
Flex Large 4 Coil for MAGNETOM Skyra, Verio, Spectra and Biograph Mmr	Siemens AG Healthcare Sector	Advice regarding changes/updates made to instructions for use	05 September 2012	Yes
IMMULITE Osteocalcin Module	Siemens Diagnostic Healthcare	Advice regarding the use of the device	25 September 2012	Yes
IMMULITE® 2000/IMMULITE® 2000 XPI Troponin I	Siemens Healthcare Diagnostics	Advice regarding a device modification	06 September 2012	Yes
Birmingham Hip Modular Heads	Smith and Nephew	Advice regarding changes/updates made to instructions for use	19 September 2012	Yes
S5 Perfusion System and C5 Perfusion System	Sorin	Advice regarding a device modification	11 September 2012	Yes
LightMix Kit HFE	TIB MOLBIOL	Advice regarding a device removal	31 August 2012	Yes
Eclipse Treatment Planning System	Varian	Advice regarding the use of the device	21 September 2012	Yes
Vitrea or Vitrea Enterprise Suite	Vital Images Inc.	Advice regarding a software upgrade	13 August 2012	Yes
Trilogy® Acetabular System Shell	Zimmer	Advice regarding the use of the device	26 September 2012	Yes