



IRISH MEDICINES BOARD
FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- APRIL 2010

Product	Manufacturer	Type	Link to FSN
Rea Assist Backrest Bow	Invacare	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Various products	Medical Device Technologies, Inc., d.b.a Angiotech	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Cobra Adhere XL	Estech	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
ApexPro Telemetry System (ApexPro Telemetry version 3.9 software)	GE Healthcare	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN
Siesta i TS	Dameca a*s	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
BHM Floor Lifts	BHM Medical	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Journeq Uni Tibial Baseplates and Insets	Smith & Nephew	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Tessier Osseous Microtome (TOM®) – BONE MILL 01-15400, 01-15401 & 01-15402	Stryker Osteosynthesis Freiburg	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Access Progesterone Reagent Kit	Beckman Coulter Inc	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
HomeChoice Automated PD System and HomeChoice PRO Automated PD System	Baxter	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Wassenburg WD440 AdaptaScope, WD440 Compact and Wassenburg WD440-PT endoscope washer disinfectors.	Wassenburg Medical Devices B.V.	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Chiron RIBA HCV 3.0 SIA	Novartis Diagnostics	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Integrated UniCel® DxC 600i/660i/680i/860i/880i Synchron Systems (with serial numbers <2760) Software version 4.9 build 01	Beckman Coulter Inc	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Revitan® Disassembly Instrument and Threaded rod for Disassembly Instrument	Zimmer GmbH	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Impella 2.5, Impella 5.0, Impella LD; 002137 (2.5), 004000 (LD), 004996 (5.0)	Abiomed Europe GmbH	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Neonatal Resuscitation Systems with variable PEEP	Intersurgical UAB	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Access AccuTnl Reagent Kit	Beckman Coulter Inc	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
AQT90 Flex Analyser	Radiometer	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN

Product	Manufacturer	Type	Link to FSN
e.cam SPECT camera with Profile AC option	Siemens Medical Solutions	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
3.2mm guide pin sleeve	Smith & Nephew Inc.	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Galileo System Liquid Concentrate	Immucor Inc.	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
G-SCAN	Esate	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
CELL-DYN Emerald System	Abbott	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
GE Centricity™ Web Diagnostic 1.0 (Web DX), software versions 3.7.4.x	GE Healthcare	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
GE Centricity™ PACS-IW, software versions: 3.x	GE Healthcare	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Crossfire Consoles	Stryker Endoscopy	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
VNS Therapy® Demipulse and Demipulse Duo Generators and Model 250 Programming Software (Version 7.1)	Cyberonics	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Corpuls3 defibrillator	GS Elektromedizinisches Gerate G Stemple GmbH	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
ArjoHuntleigh Minstrel Lift (without scale)	ArjoHuntleigh / Medibo	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Zimmer Spine - Universal Clamp Instrument	Zimmer Spine	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN
Synthes Handle, flexible, for No. 355.220	Synthes	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Continuum trilogy® IT acetabular systems shell inserter adapter with rotational control	Zimmer	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Hamilton-C2 Ventilator	Hamilton Medical	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
iPlan RT Dose Version 4.1.1	BrainLab	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Ascendra Balloon Catheter Loader Assembly	Edwards Lifescience	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
GoldLine® Rocker Switch Pencil	ConMed Electrosurgery	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Visionary Single Use Laryngeal Airway Device	Marshall	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
VINCI 600Ss	MDARImed Medizintechnik GmbH	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Smith & Nephew Obturators	Smith & Nephew Inc.	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN

Product	Manufacturer	Type	Link to FSN
Trabecular Metal Acetabular Revision System Buttress Augments and Trabecular Metal Acetabular Revision System Column Buttress Augments	Zimmer	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Phosphate Buffered Saline	Baxter Healthcare Ltd	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Dimension LOCI FT4L, TSHL, TNI, NTP, and LNTP Flex Reagent Cartridges	Siemens Healthcare Diagnostics Inc.	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Kimal Long Term Haemodialysis Catheters	Kimal	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Stryker® Dual Irrigation Adaptor	Stryker Endoscopy	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Hemochron Signature Elite	International Technidyne Corporation	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Sinus Packing	Fuhrmann Verbandstoffe GmbH	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Disinfection block (spare part) for 5008 & 5008S dialysis system	Fresenius Medical Care	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
iPlan RT Dose 4.0.0, 4.1.0 and 4.1.1	BrainLAB	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
VINCI 600s	MADRImed Medizintechnik GmbH	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Acute Care Troponin I TestPak	Siemens Healthcare Diagnostics	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Inion CPS and Inion CPS Baby Bioabsorbable Fixation System	Inion	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN
PERI-LOC 3.5mmX14mm Self Tapping Non Locking Cortex Screw, product code 71804014, lot numbers 09MM05974 & 09MM08859	Smith & Nephew	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
CH203 RX Monza	Randox Laboratories	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN
NexGen® Complete Knee Solution Stemmed & Rotating Hinge Knee Tibial Broach Impactors	Zimmer	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
NovaFlex Delivery System	Edwards Lifesciences	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
IDS Ostase® BAP ELISA	Immunodiagnosics	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Ulnar Shortening saw Blade – Hub Style S	Acumed	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Access HBs Ab QC Kit	Beckman Coulter	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
EV1000 Platform (Monitor and databox); EV1000A (EV1000DB and EV1000M)	Edwards Lifesciences	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN

Product	Manufacturer	Type	Link to FSN
PORT PUR / 6 Fr catheters	Creat Medic Co Ltd	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Shiley™ Tracheostomy Products	Covidien	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
BD Visitec™ EdgeAhead™ MVR Knife 0.90mm (20G)	BD Medical Ophthalmic Systems	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Synchron Systems Modular Glucose Reagent	Beckman Coulter Inc	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Immulite 2000 3gAllergy Specific IgE Universal Kit	Siemens Healthcare Diagnostics Products Ltd	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Metanephrynes	BioSystems	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
U-Clip® V100D Approximation Device	Medtronic	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Murex HIV 1.2.0	Abbott Laboratories	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Unitray and AllSet Gold Plus B High Resolution SSP trays and B22 Unitray and AllSet Gold Plus SSP trays	Invitrogen	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Cannulated Polyaxial Screwdriver II - Modular	Zimmer	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
End Screw Extender Sleeve	Zimmer	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Low flow cannulas E1301 and E1615	Salter Labs	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Bioplate cranial fixation sterile kits	BioPlate	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Access® Immunoassay Systems Alpha-fetoprotein (AFP) QC	Beckman Coulter Inc	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
HeartStart MRx Defibrillator Monitors M3535A, M3536A	Philips Healthcare UK	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Access Immunoassay Systems HBc Ab & Vitamin B12	Beckman Coulter Inc	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Access HAV Ab assay	Beckman Coulter Inc	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
MicroScan Gram Negative MIC Type 37 (B1016-147) Panels	Siemens Healthcare Diagnostics Inc.	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
AIA-PACK PA CALIBRATOR SET	Tosoh Corporation	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN