



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

Product	Manufacturer	Type	Link to FSN
i-STAT Level 2 Control Value Assignment Sheets for i-Stat controls	Abbott Point of Care	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Synchron Systems LX 20 & UniCel DxC Systems GLU Reagent	Beckman Coulter	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Navigation PoleStar® N20/N30 Surgical MRI System FlexiCoil PN 9733063	Medtronic Navigation	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
ARCHITECT Pre-Trigger Solution	Abbott Ireland - Sligo	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
DELPHIN Wheelchair	Sunrise Medical	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
SonoSite NanoMaxx Ultrasound System	SonoSite	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Oxford Weigh-scale	Joerns Healthcare	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Medi-Vac Non Conductive Sterile Suction Tubing	Cardinal Health	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Connector Re #0286 (1/2"x1/2")	Maquet Cardiopulmonary AG	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
3M™ Red Dot™ Monitoring Electrode with Foam Tape and Sticky Gel, Catalogue Number 2560	3M	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Skippi Power Wheelchair	Ottobock	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Genesis II LIS Sizer	Smith&Nephew	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Bilirubin Auto Total FS / Bilirubin Jendrassik-Gróf FS	DiaSys Diagnostic Systems GmbH	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Corflo cuBBY and Gastrostomy Tube Kits	Merck Serono	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Panocell-20	Immucor Gamma	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN

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Ziploop Extended ToggleLoc	Biomet Sports Medicine	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
All Freeway Shower Chairs with integral drop down armrests	Prism Medical UK	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Cell-Dyn 3500 Analyser	Abbott Laboratories Diagnostics Division	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Cell-Dyn 3200 Analyser	Abbott Laboratories Diagnostics Division	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Thoratec HeartMate II® Left Ventricular Assist System (HM II LVAS) System Controllers	Thoratec	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
ATEC® Breast Biopsy and Excision System 9 gauge, 12 centimeter handpiece	Hologic Inc.	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Cepheid LightCycler VZV Qual Kit	Roche Molecular Systems Inc	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
HemoStat Thromboplastin	Human Gesellschaft fur Biochemica und Diagnostica GmbH	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
4DITC, ARIA, VARiS Vision - any version, when used in conjunction with the Novalis (low energy) system	Varian	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
VIDAS HIV Duo Quick	Biomerieux	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
PAL Series Pool Lifts	RehanMed International Limited	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN
Blease Anesthesia Ventilator Series 700 and 900; BleaseSirius and BleaseFocus systems)	Spacelabs Healthcare	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
ARTISTE™ digital linear accelerators; ONCOR™ digital linear accelerators configured with 160 MLC; Primus™ digital linear accelerators configured with HPD head; Previous models of linear accelerators configured with HPD head	Siemens	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Hydrolift Implants	B Braun/Aesculap AG	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
CD10 APC, CD10 PE, CD10 PE-Cy7, CD10 FITC and BD Oncomark CD5/CD10/CD19	Becton Dickinson Biosciences	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
XiO	Elekta	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN

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Transactive Xtra Hoist	Prism Medical UK	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Coronary Control Syringes	Merit Medical	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Umbilical cord clamp	Rociale	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Pentax Light Sources BS-LH1; BS-LH2; BS-LL1	Pentax Europe GmbH	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Eclipse and RT Chart (ARIA Radiation Oncology)	Varian	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Stopcock with PVC Line 13.5cm x 2.5mm ID	BMS Critical care	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
ARCHITECT Tacrolimus reagent	Abbott Laboratories Diagnostics Division	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
ARCHITECT iVancomycin Reagent	Abbott Laboratories Diagnostics Division	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Modular Screwdriver, 3.5mm A/F HEX	Corin	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Uniglide Unicondylar Knee, Femoral Component	Corin Limited	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Optima CT660	GE Healthcare	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Leica Peloris Rapid Tissue Processor	Leica Biosystems	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
BagEasy Manual Resuscitation Devices	Westmed Inc.	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Tibial Base Trial, size 3 - Instrument for the Gemini SL Total Knee Replacement	Waldemar Link GmbH & Co. KG	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Image-Com	TomTec Imaging Systems	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
AU Clinical Chemistry Analyzer	Beckman Coulter	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Core TDM Multi-Calibrator	Beckman Coulter	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
AV-SET FMC PAED S, 4008 Paediatric Bloodlines	Fresenius Medical Care	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
SAD with red detector	B Braun	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN

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LightSpeed VCT Computed Tomography X-ray System	GE Healthcare	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Rotacrush	Medwork Medical Products and Services GmbH	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Aisys Carestation, S/5 Avance Anesthesia Carestation, Amingo Carestation	GE Healthcare Systems	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Synchron Systems Glucose Cartridge Reagent	Beckman Coulter	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
ACUSON and SONOLINE Antares diagnostic ultrasound systems	Siemens	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
SY0001, ETO Sterile 1ml Syringe	Helapet	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
BA721 Skin-GRFT CARRF/BA720R1:1.5STER	Aesculap AG	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Pride Colt XL8 Scooter	Pride Mobility	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Therascreen K-Ras mutation kit	Roche Diagnostics	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Access Total T4 Calibrators	Beckman Coulter	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Extension Line, Ref no. 68380 (accessory to Bellovac ABT)	Astra Tech	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
External Sterilizable Defibrillation Paddle and Sterilizable Pediatric Paddle	Medtronic/PhysioControl	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
VITEK® 2 Piperacillin/Tazobactam Test	Biomerieux	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
NexGen® Complete Knee Solution Legacy® Knee-Posterior Stabilized LPS Components	Zimmer	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
ETD3plus washer disinfectant	Olympus/Miele	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Philips IntelliVue X2 and IntelliVue MP2 monitors	Philips	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
X220 & X221 Bariatric Commodes	Cefndy Healthcare	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Scorpio/NRG 4:1 Cutting Block	Stryker Orthopaedics	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
IMMULITE 2500 HCG	Siemens Healthcare Diagnostics	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN

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GE Centricity Laboratory	GE Healthcare	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
21210E Planning Software iPlan Stereotaxy versions 3.0.0 and 3.0.1 in combination with 21242 iPlan AC/PC planning.	BrainLab	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
COBAS Integra® systems	Roche Diagnostics	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
cobas c311, cobas c 501, cobas c 502	Roche Diagnostics	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
cobas c701	Roche Diagnostics	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
DiaPlastin-E liquid	DiaMed AG	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Enzygnost HBsAg	Siemens Healthcare Diagnostics	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
BrightSpeed Excel/Edge/Elite Select and BrightSpeed Elite Computed Tomography X-ray System	GE Healthcare	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Medical Wireless Monitors, models 91367, 91369 & 91370 with Wireless Option	Spacelabs Healthcare	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Amanitin ELISA	Bühlmann Laboratories AG	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Cell-Dyn 3700 Analyser	Abbott Laboratories Diagnostics Division	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Stratus CS Acute Care Troponin I TestPak	Siemens Healthcare Diagnostics	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Synchron Systems Modular Glucose (GLUCm) Reagent	Beckman Coulter	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
GE Responder 2000 Defibrillators	Cardiac Science	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
19506B, 19506C Kolibri Navigation Station 2.0 (with mobile camera stand 2.0), 19801A Kolibri Mobile Camera Stand 2.0	Brain Lab	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Thermablate AES	MDMI Technologies Inc	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Eleganza 3 Bedframe fitted with Split Siderails	Linet Spol.	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN