



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

Product	Manufacturer	Type	Link to FSN
Bristol Maid Baby Crib Trolleys	Bristol Maid	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN
SafeSheath CSG Coronary Sinus Guide Hemostatic Introducer System with Infusion Sideport	Thomas Medical Products, a GE Healthcare Company	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
PowerPro. PowerProMax, Mpower Handpieces	Conmed Linvatec	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Arjo Maxilift Patient Lifter	Arjo Medical	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
23G Microflex	Vygon	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Histopaque	Sigma-Aldrich	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
WarmCloud Mattress	KanMed AB	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
COBRA Adhere XL	Estech	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Kryptonite	Doctors Research Group	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Nexiva Closed IV Catheter System	Becton Dickinson	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
CBCII Blood Conservation System	Stryker Instruments	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
ITD Compact Cart	ITD GmbH	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
AXIOM Iconos R200 C20 / R200 C90 / R200 T20 / R200 T90	Siemens Healthcare	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN

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Warm Air Cardiac Blanket	Cincinnati Sub-Zero	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Modified Novy Cornual Cannulation Set	Cook Ireland Limited	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
ElecSys Folate III assay	Roche Diagnostics Gmbh	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Axiom Artis MP, Artis dMP, Artis Zee Multipurpose	Siemens	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
SmartTemp (Temperature) Probe Covers for use with VS-800 Vital Signs Monitor	Shenzen Mindray bio-Medical Ellectronics	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Syngo Imaging XS	Siemens AG Healthcare Sector	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
9 FR Epiduroscopy Access Kit	Myelotec	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Backcheck Valves in Symbiq® Administration Sets	Hospira	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
BD 10ml LS Plastipak Syringe	BD Medical	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Implant Extraction Set Brochure / Guide	Stryker	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN
Input TS Introducer sets with needle	Medtronic Inc.	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
RELI SSO HLA-B Typing Kit	Invitrogen	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
SMA 4525FP STERILE RECTOSCOPY KITS	Sapimed SpA	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Exeter Cement Centralizer	Stryker	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN

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SpineCath and Acutherm Catheters	Smith & Nephew	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN
10F Bioflex Tesio Kit with cutting trocar	Medcomp	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Elecsys Reagents	Roche Diagnostics Gmbh	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Compat Go sets / Compat Go Portable Set with dust cap	Nestle Healthcare Nutrition	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Allura Xper Systems and Allura Integris Systems with Velara Generator	Philips Healthcare	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
AXIOM Artis	Siemens	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Dimension Vista ® Chemistry 2 Calibrator	Siemens Healthcare Diagnostics Inc	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
ABC SSP Unitray, B Low Res AllSet Gold, ABDR Unitray, ABDR AllSet Gold, ABDRDQ Unitray, ABDRDQ AllSet Gold, ABC Unitray, B Locus Unitray, ABDR AllSet Gold, ABC AllSet Gold	Invitrogen	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
StatSpin Express 4 Centrifuge	Iris Sample Processing	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Epicardial Lead Models 5071, 4965, and 4968 Sterile Tray	Medtronic Inc.	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
AXIOM Artis models	Siemens	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
TARGON PFT STEP DRILL (KH536R) and TARGON PFT DEPTH STOP (KH535R)	Aesculap AG	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Vitesse Biopsy Needle, Delta-Cut, 2 part, 0.95/19.5G, 150mm	OptiMedGmbH	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
HLS-Cannulate BE-PVL 2955	Maquet	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN

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Wassenburg WD440 and Wassenburg WD440-PT endoscope washer disinfectors	Wassenburg Limited	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
HYDROLIFT Insertation Instr.F/Implants; FW453R	Aesculap AG	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Femoral Saw Guide / Instrument for Endo-Model® Rotational and Hinge Knee System	Waldemar Link GmbH	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
RambaChrom KPC M/N 11500 and RambaChrom VRE M/N 11600	Gibson Laboratories	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Ankylos C/X Dental Implant	Friadent GmbH	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Stryker® Eye Surgery Stretcher 1069 / Stryker® Eye Surgery Stretcher 1079	Stryker Medical Kalamazoo	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Right Hallu®-C Plate Size 1-40mm, non-sterile	Newdeal	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Synthes Compression Connecting Screw	Synthes	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
AMSCO 3085SP Surgical Table	Steris	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Exxcel Soft Thin Wall Vascular Grafts	Maquet	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
SmitCare SNE343 Ringwood Bathseat	SmitCare Limited	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN
One Source Kits and MAXPAC/Total System	Medtronic	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
ANA Screen	Trinity Biotech	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Implant extraction set	Stryker UK Limited	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN

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MPO QuickCard	Bio-Diagnostics	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
GE Centricity™ PACS-IW, software versions: 3.7.3	GE Healthcare	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
XCaliber Fixator	Orthofix	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Neuroform 3™ Microdelivery Stent System	Boston Scientific	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Tubing set for blood purification equipment Plasanto Sigma	Naniwa Rubber	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
4003201 Disposable Long Scissors 22cm	Farla Medical Limited	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Intracranial Stent SILK	Balt Extrusion	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN
ARCHITECT HAVAb-IgM Reagents	Abbott	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Electri-Cord AC Power Cords (Part Number WW3005, 8404) used with BCI® 3180 Pulse Oximeter, 9200 Advisor® Vital Signs Monitor, 8400 Capnocheck® Capnometer and V6400 Invasive Pressure Monitor (Veterinary use)	Smiths Medical	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
AMPLILINK Software version 3.3.1	Roche Diagnostics GmbH	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
LIFEPAK 15 Monitor/Defibrillator	Physio-Control	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
M2a-Magnum™ Modular Heads - Size 44mm	Biomet	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Auto D-Dimer Control, Level 2	Trinity Biotech	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Baxter INFUSOR Devices and Pre-filled Baxter INFUSOR Devices	Baxter	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN

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Abiomed AB 5000 Console	Abiomed	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Lipase (LIP) Flex® reagent cartridges (DF55A)	Siemens Healthcare Diagnostics Inc	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Diagnostic sets for UIBC determination - PRESTIGE 24i UIBC cat. no. 4-186, PRESTIGE 24i UIBC cat. no. 4-494, ACCENT-300 UIBC cat. no. 7-359, ACCENT-200 UIBC cat. no. 7-259	PZ Cormay S.A.	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
PR3 QuickCard	Bio-Diagnostics	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
IPP ON® Interphalangeal Implmnt	Newdeal	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Baylis Medical TorFlex™ Transseptal Guiding Sheath	Baylis	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Primedix HeartSave Series	Metrax GmbH	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
ASR™ Articular Surface Replacement and ASR™XL Monoblock Metal-on-Metal System	Depuy	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Oxoid Ready Poured Plate, Yersinia Agar (CIN Medium)	Thermofisher Scientific	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Unilect ECG Electrodes	Unomedical Limited	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Oncentra Brachy	Nucletron	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
All BrainSUITE iMRI systems with BrainLAB IMRI OR Power Management	BrainLAB AG	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Trigen Internal Hex Screw 4.5mm X 20mm Product code 71642120 Lot: all lots prior to May 2009	Smith & Nephew	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
UniCel DxH 800 Coulter Cellular Analysis System	Beckman Coulter	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN

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Aisys and Avance Anesthesia Machine and Monitor	GE Healthcare	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Wayne Pneumothorax Sets/Trays	Cook Medical	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN
A High res SSP UniTray and AllSet Gold A high res kits	Invitrogen	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Nova Statstrip Glucose Test Strips	Nova Biomedical	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Clinical Chemistry Albumin BCG	Abbott Laboratories	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Dimension Vista® LOCI® Reaction Vessel	Siemens Healthcare Diagnostics Inc.	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
AMPLILINK Software version 3.3.1	Roche Diagnostics GmbH	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
ADVIA Centaur / Centaur XP	Siemens Healthcare Diagnostics Inc.	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
ADVIA® Chemistry Systems - Chloride Electrodes	Siemens Healthcare Diagnostics Inc.	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Captia Measles IgM	Trinity Biotech	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Captia Mumps IgM	Trinity Biotech	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
FastPlan™ Conical Collimator Plans	Varian	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
ARCHITECT Anti-HCV	Abbott Laboratories	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Infusion Pumps A707V / A708V	Argus	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Access Estradiol Reagent kit	Beckman Coulter	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN

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Sterile Trauma Parts packet in two pouches Ti-Interference Screws	Zimmer	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
CD7 PE and CD7 FITC	Becton Dickinson Biosciences	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
GreenLightPV® Laser	American Medical Systems	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
5 second CONTOUR® Blood Glucose Monitoring System	Bayer HealthCare Diabetes Care	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
PowerPro, PowerMax and Mpower I Handpieces	Conmed Linvatec	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Healing Abutment (IWITH56, Lot#602691)	Biomet 3i	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Seraclone Anti-k (KEL2)	Biotest Medical Diagnostics GmbH	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Animas® 2020 and Animas® IR1200 Insulin Pumps	Animas	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Innova® 2100IQ, 3100IQ, 4100IQ cardiovascular x-ray imaging system	GE Healthcare	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Triage TOXDrug Screen	Biosite	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
C.A.T.S. Auto Transfusion System	Fresenius Kabi	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Mölnlycke ProcedurePak®	Mölnlycke	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
HeartStart MRX Monitor / Defibrillator	Phillips	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN
FC4 Fibro Cleaner Automatic Endoscope Reprocessor	Lancer	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Antimicrobial Susceptibility Testing Discs Ciprofloxacin 1ug CT0623B	Thermofisher Scientific	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN

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SKY fast & fixed impression cap open tray	Bredent Medical	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN