



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

Product	Manufacturer	Type	Link to FSN
Tesla Plus EFTE503D	MIPM Mammendorfer Institut für Physik und	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
directCHECK Whole Blood Control DCJPT-A	ITC	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
XiO	Eleka	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Sae-Flo MD Extension Set with Y- Connector	Wescott Medical Limited	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Cell-Dyn 4000 Vent Needle, Cell-Dyn 4000 Accessory Kit	Abbott Laboratories	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
CELL-DYN Sapphire Vent Head Assembly, CELL-DYN Sapphire Accessory Kit	Abbott Laboratories	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Liaison Instrument	DiaSorin	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN Manufacturer's FSN
XLT wheelchair	Invacare	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN
Freedom Self-Cath Nelaton CH12	Coloplast	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
in2it A1c Test Cartridges	Bio-Rad Laboratories	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
EBV VCA IgM	Trinity Biotech Plc	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Capture-R Ready-Screen (3)	Immucor Gamma	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Eclipse Client Software	Varian	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
VITROS Chemistry Products mALB Reagent	Ortho Clinical Diagnostics	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Torx T7 Screwdriver, model: 219127	Newdeal SAS	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
CIBA VISION® FreshLook® Colors contact lenses	CIBA VISION®	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Wallaby I Knee Insert	Zimmer	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Karl Storz Suction Tubing Set	Karl Storz Endoscopy (UK) Limited	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN

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Quantum PBL	PAA Laboratories GmbH	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
GE OEC 9800 with version 29 software and Celeron Single Board Compute	GE Healthcare	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
IntelliVue Patient Monitors	Philips	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Dyonics Bonecutter Electroblade	Smith & Nephew	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN
Panoscreen III	Immucor Gamma	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Gyrus ACMI dissector PlasmaKnife	Olympus	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
MTP Fiberscope Cover	Karl Storz Endoscopy (UK) Limited	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Peri-Loc 3.5mm Anterolateral Distal Tibial Plate, Product Code 71800710, Lot number 08GM01799	Smith & Nephew	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Thermosept Alka Clean Forte / Thermosept NKZ	Schülke & Mayr GmbH	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Invacare TDX® SP Power Wheelchair with Stability Lock	Invacare	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Oxylog 3000	Dräger	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
CyberKnife System	Accuray	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
klinoPORT and incarePORT	Trumpf	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN
BrachyVision	Varian	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Drive Rigid Walking Frames	Drive Medical Ltd.	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Mölnlycke Procedure Pak	Mölnlycke Healthcare	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
BuckyDiagnost	Philips	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
HeartStart MRx	Philips	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Engage 6F Venous Introducer	St. Jude Medical	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
AXIOM Artis VB23A - VB23H	Siemens	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN

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Kimal Minibore Extension Sets	Kimal	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Genesis II Resection Cutting Blocks Size 4 & 5	Smith & Nephew	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Orthopilot Dispos. passive marker sterile	Aesculap AG	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
GII IM Long Stem Drill Collet	Smith & Nephew	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Philips IntelliVue G1, IntelliVue G5 and Anesthesia Gas Modules	Philips	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Solysafe Septal Occluder	Swissimplant	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Optical Guidance Platform used for Clinac® or Novalis® TX machines	Varian	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Walking Aid Quadruped Adult (121150), Walking Aid Quadruped Junior (121160)	Swereco Rehab	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Easyband® Telemetric Gastric Band Version 2 and Version 3	Allergan	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Easyband® Telemetric Gastric Band Gen0	Allergan	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Access Immunoassay Systems SHBG	Beckman Coulter Inc.	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
SYNCHRON® System(s) Creatinine Reagent	Beckman Coulter Inc.	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Peri-Loc K Wires	Smith & Nephew	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Vitros 5600 Integrated System And Vitros 3600 Immunodiagnostic System	Ortho Clinical Diagnostics	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Compact Dental Unit	Palanmeca	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
INOMAX® DS Drug Delivery System	Ikaria	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Dimension Vista® V-LYTE® Standard A	Siemens Healthcare Diagnostics Inc.	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Tibia Offset Stems Cemented 18/92mm	Aesculap AG	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Hydrolift instrumentation	B Braun Aesculap AG	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
RSP Glenoid Head Inserter	DJO Surgical	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Access / Access 2 Systems	Beckman Coulter Inc.	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
UniCel Dxl Systems	Beckman Coulter Inc.	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN

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VARIAN Treatments (VT)	Varian	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Oxoid G.C. Selective Agar with Lysed Blood and LCAT	Thermofisher Scientific Microbiology	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Pride Riser Recliner Chair	Pride Mobility Products Corporation	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
PDQ 1 Reagent	Trinity Biotech Plc	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Coulter AC.T 5diff Instruments	Beckman Coulter UK Ltd	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Targon TX Access Reamer, Part no. KH451R	Aesculap AG	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Coulter PrepPlus2	Beckman Coulter	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
CoreValve® Delivery system	Medtronic	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
NC281T - METHA µCAP	B Braun	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
GE Centricity Laboratory, software versions: 3.3 GA and prior	GE Healthcare	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
GE Centricity™ Laboratory Instrument Interface, software versions: 4.0.0 series (4.0.0.9 or higher only)	GE Healthcare	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
GE Centricity Laboratory, software versions: All CUI (Character User Interface)	GE Healthcare	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
GE Centricity Laboratory, software versions: 3.3A, 3.3GA & customers using customised version of label program	GE Healthcare	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
HMRS Anchorage Stems	Stryker	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
ASR(TM) XL Acetabular System and DePuy ASR(TM) Hip Resurfacing System	DePuy Orthopaedics	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Micron Bobbin Vent Tube	Gyrus ACMI	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
CELL-DYN Emerald	Abbott Laboratories	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Tete A Jope Inox Cone	Zimmer	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
GE Datex-Ohmeda Aespire, Avance, Amingo, and ADS 180 Anesthesia Machines	GE Healthcare	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
BP Hip, Shoulder and Knee Implants	Endotec	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN

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Ronocath catheter Nelaton Male CH12	Coloplast	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Quick Suction bottles	Medicoplast	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
AV-SET FMC (FA404E/FV404E)	Fresenius Medical Care	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
AMO WaveScan WaveFront Systems and Offline Programming Module (OPM)	AMO Germany GmbH	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
4008 E-beam bloodlines, 4008 ETO bloodlines, Genius bloodlines and multiFiltrate bloodlines	Fresenius Medical Care	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Giraffe Scale	GE Healthcare	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Heartstring II Proximal Seal System	Maquet Getinge Group	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Codman Surgical Patties	Codman	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Captia VZV IgM Kit	Trinity Biotech Plc	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
(Angle stable) Distal femur plates	Königsee Implantate GmbH	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
HEARTSTRING Aortic Cutter 4.3mm	Maquet Getinge Group	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Suction Catheters with Funnel Connectors (Sizes CH05 and CH06)	Unomedical	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Ashby Raised Toilet Seats	Gordon Ellis & Co.	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN