IRISH MEDICINES BOARD

FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- AUGUST 2009

Product	Manufacturer	Type
Viking XL/L/M/S/XS, LikoLight and Uno lifts	Liko	Advice has been provided by the manufacturer regarding a device modification
EP-4™ Computerised Cardiac Stimulator	St. Jude Medical	Advice has been provided by the manufacturer regarding a device modification
MDA II Axis Coiled Tubing	Trinity Biotech Plc	Advice has been provided by the manufacturer regarding a device removal
LeVeen Needle Electrodes	Boston Scientific	Advice has been provided by the manufacturer regarding a device removal
Factor V Leiden Kit	Roche Molecular Systems, Inc.	Advice has been provided by the manufacturer regarding a device removal
INNO-LIA HCV Score	Innogenetics	Advice has been provided by the manufacturer regarding a device removal
IMMULITE 2000 AlaTOP Allergy Screen, IMMULITE 2500 AlaTOP Allergy Screen	Siemens Healthcare Diagnostics	Advice has been provided by the manufacturer regarding a device removal
Versant Molecular System 440 DMS Version 7.5.2.1302	Siemens Healthcare Diagnostics Inc.	Advice has been provided by the manufacturer regarding a software upgrade
LCS Duofix Femoral Component	DePuy International Limited	Advice has been provided by the manufacturer regarding a device removal
Dimension Vista System with Software Version 3.2.1 or Earlier	Siemens Healthcare Diagnostics Products GmbH	Advice has been provided by the manufacturer regarding a software upgrade
LDH (SFBC)	Quimica Clinica Aplicada	Advice has been provided by the manufacturer regarding a device removal
Coagulation Factor VIII Deficient Plasma (OTXW)	Siemens Healthcare Diagnostics Inc	Advice has been provided by the manufacturer regarding a device removal
TriniCLOT PT Excel	Trinity Biotech	Advice has been provided by the manufacturer regarding a device removal
Infusor Pumps	Baxter Healthcare Corporation	Advice has been provided by the manufacturer regarding the use of the device
Acrobat 2000, AC 2000	Ondal Industrietechnik GmbH	Advice has been provided by the manufacturer regarding a device modification
Fem-Flex Femoral Arterial Cannula	Edwards Lifesciences LLC	Advice has been provided by the manufacturer regarding a device removal
PO0794A Brilliance U.T.I. Medium	Thermofisher Scientific	Advice has been provided by the manufacturer regarding a device removal

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Lightcycler Capillaries (100µL, M-Grade)	Roche Diagnostics UK	Advice has been provided by the manufacturer regarding a device removal
AV-Set Dialog GB Art. No. 7210697	B Braun Auitum (UK) Limited	Advice has been provided by the manufacturer regarding the use of the device
Silverfil	Minerva Dental	Advice has been provided by the manufacturer regarding a device removal
Stryker PainPump Catheters packaged with PainPump2	Stryker UK Limited	Advice has been provided by the manufacturer regarding a device removal
Careline Easy MT	Unomedical Limited	Advice has been provided by the manufacturer regarding a device removal
Synchron UniCel DxC Clinical Systems	Beckman Coulter UK Limited	Advice has been provided by the manufacturer regarding the use of the device
Escape Lite Manual Wheelchair	Days Healthcare UK	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use
Separator for Neuron Intracranial Access System PSS032 and PSS041	Penumbra Inc	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use
Cyberknife Robotic Radiosurgery System	Accuray Europe	Advice has been provided by the manufacturer regarding a software upgrade
Artis Zee / Axiom Artis MP / Axiom Artis dMP	Siemens Healthcare GmbH	Advice has been provided by the manufacturer regarding the use of the device
New Hemtube	Fujirebio Inc	Advice has been provided by the manufacturer regarding the use of the device
PlasmaKinetic SuperSect™/PK SuperSect Instrument	Gyrus ACMI Inc	Advice has been provided by the manufacturer regarding a device modification
Architect i2000 & i200SR Analyser	Abbott Laboratories Diagnostics Division	Advice has been provided by the manufacturer regarding the use of the device
InLign ARC (TrueDyne PDS)	Disc Motion Technologies	Advice has been provided by the manufacturer regarding a device removal
Targon PFT Depth Stop KH535R for Drill KH536R	Aesculap AG	Advice has been provided by the manufacturer regarding the use of the device
Olympus PK7300	Olympus Corporation	Advice has been provided by the manufacturer regarding the use of the device
Harnstoff CT FS; 1 3115 99 10 026, 1 31515 9910 021, 1 3115 99 90 305	DiaSys Diagnostic Systems GmbH	Advice has been provided by the manufacturer regarding a device removal
Coroskop / Bicor / Angiostar / Multistar	Siemens Medical Solutions	Advice has been provided by the manufacturer regarding the use of the device

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Wiseguide Guide Catheter, Impulse Angiographic (Diagnostic) Catheter, Expo Angiographic (Diagnostic) Catheter	Boston Scientific Corporation	Advice has been provided by the manufacturer regarding a device removal
Image Server/xd	Sectra Imtec AB	Advice has been provided by the manufacturer regarding a software upgrade
Multifit Nebulizer and Multifit Nebulizer with BOC Adapter	Teleflex Medical	Advice has been provided by the manufacturer regarding a device removal
Twin-Pass Dual Access Catheter	Vascular Solutions Inc	Advice has been provided by the manufacturer regarding a device removal
WaveScan WaveFront System Offline Programming Module (OPM), International Version	AMO Manufacturing USA, LLC	Advice has been provided by the manufacturer regarding the use of the device
Auto D Dimer / TriniLIA D Dimer Kit	Trinity Biotech Plc	Advice has been provided by the manufacturer regarding a device removal
Unicel DxH 800 Coulter Cellular Analysis System	Beckman Coulter Inc	Advice has been provided by the manufacturer regarding the use of the device
Philips IntelliVue Clinical Information Portfolio	Philips Healthcare Inc	Advice has been provided by the manufacturer regarding a software upgrade
Multi-plane transoesophageal transducer, model PET-511BTM	Toshiba Medical Systems Ltd	Advice has been provided by the manufacturer regarding the use of the device
SHER-I-SWIV, SHER-I-BRONCH	Teleflex Medical USA	Advice has been provided by the manufacturer regarding a device removal
Ventri	GE Healthcare	Advice has been provided by the manufacturer regarding the use of the device
iViewGT	Elekta Limited	Advice has been provided by the manufacturer regarding a software upgrade
Bicontact N Plasmapore 8/10 gr. 9mm	Aesculap AG	Advice has been provided by the manufacturer regarding the use of the device
NN340 Columbus RP Gliding Surface T4/4+ 10MM and NN222 Columbus DD Tibial Insert SZ 2/2+ 14MM	Aesculap AG & Co. KG	Advice has been provided by the manufacturer regarding a device removal
UltraPower Diamond Wheel Burs	ConMed Linvatec	Advice has been provided by the manufacturer regarding a device removal
Eleganza 3 and Latera bedframes	Linet UK	Advice has been provided by the manufacturer regarding a device modification
Scorpio Femoral Components	Stryker Europe, Middle East & Africa	Advice has been provided by the manufacturer regarding a device removal
Targeting guide instruments for the Zimmer Natural Nail system	Zimmer Inc	Advice has been provided by the manufacturer regarding a device removal

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MIS Diarmond Burs	Stryker UK Limited	Advice has been provided by the manufacturer regarding a device removal
Cobas e 411 - software v.02-01	Roche Diagnostics GmbH	Advice has been provided by the manufacturer regarding a software upgrade
M Series Humidifier- Important Safety Information from Phillips Respironics Products	Philips Respironics	Advice has been provided by the manufacturer regarding a device removal
Hiptric Frame	Ossur UK Limited	Advice has been provided by the manufacturer regarding a device removal
QuantiFERON-TB Gold TB-Antigen blood collection tubes	Cellestis Limited	Advice has been provided by the manufacturer regarding a device removal
Cell-Dyn 3700	Abbott Laboratories Diagnostics Division	Advice has been provided by the manufacturer regarding a device modification
PKS SEAL Open Forceps	Gyrus ACMI, Incorporated	Advice has been provided by the manufacturer regarding a device removal
Lightwave Suction Ablator	ConMed Linvatec Corporation	Advice has been provided by the manufacturer regarding a device removal
Heartstart MRx	Philips Healthcare Inc	Advice has been provided by the manufacturer regarding the use of the device
STERRAD® CYCLESURE® and CYCLESURE® 24 Biological Indicator(s)	Advanced Sterilization Products	Advice has been provided by the manufacturer regarding the use of the device
Ambix Activ	Fresenius Kabi	Advice has been provided by the manufacturer regarding a device removal
N-DISVENT-02	GE Healthcare	Advice has been provided by the manufacturer regarding a software upgrade
Spacelabs Medical ECG Cable with Integrated Leadwires	Spacelabs Healthcare Limited	Advice has been provided by the manufacturer regarding a device removal
IMTEC-ANA Screen and IMTEC-ANA Screen (cut-off)	Human Gesellschaft für Biochemica und Diagnostica mbH	Advice has been provided by the manufacturer regarding the use of the device
Arthro-Knife Sheathed Knife	ConMed Linvatec	Advice has been provided by the manufacturer regarding a device removal
Pride Riser Recliner	Pride Mobility	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use
110v AC power cords manufactured by Electri-Cord Manufacturing Corp	Hospira Inc	Advice has been provided by the manufacturer regarding a device removal
Total Knee® Junior	Össur	Advice has been provided by the manufacturer regarding a device removal

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Ondal Acrobat 2000 spring arms	Gebrüder MARTIN GmbH & Co. KG	Advice has been provided by the manufacturer regarding a device removal
ADVIA Centaur software version 4.0 and ADVIA Centaur XP software version 6.0	Siemens Healthcare Diagnostics Inc.	Advice has been provided by the manufacturer regarding a software upgrade
PediCap End-Tidal CO2 Detector	Covidien	Advice has been provided by the manufacturer regarding a device removal
GlucoTel blood measuring devices	Bodytel Europe GmBH	Advice has been provided by the manufacturer regarding a device removal
4Z1c Matrix Array Transducer on the ACUSON SC2000 Ultrasound System	Siemens Medical Solutions USA Inc.	Advice has been provided by the manufacturer regarding a device removal
Stryker Medical Stretchers	Stryker Medical	Advice has been provided by the manufacturer regarding a device modification