IRISH MEDICINES BOARD

FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- OCTOBER 2009

Product	Manufacturer	Type
WD440 Endoscope Washer Disinfector	Wassenburg	Advice has been provided by the manufacturer regarding a device modification
SynchroMed II	Medtronic	Advice has been provided by the manufacturer regarding the use of the device
Magic and HydroSil	Rochester Medical Corporation	Advice has been provided by the manufacturer regarding a device removal
Enterra Therapy System	Medtronic	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use
Sutureless Connector (SC) Intrathecal Catheters & IsoMed Implantable Infusion Pump	Medtronic	Advice has been provided by the manufacturer regarding the use of the device
Innova 2121IQ, 3131IQ, 2100IQ, 3100IQ and 4100IQ	GE Healthcare	Advice has been provided by the manufacturer regarding the use of the device
Innova 2000 and 4100	GE Healthcare	Advice has been provided by the manufacturer regarding a software upgrade
Cervical Disc Prosthesis	Signus Medizintechnik GmbH	Advice has been provided by the manufacturer regarding the use of the device
Concerto CRT-D and Virtuoso ICD	Medtronic	Advice has been provided by the manufacturer regarding the use of the device
Fixation Posts	Elekta	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use
Latitude Communicator	Boston Scientific	Advice has been provided by the manufacturer regarding the use of the device
Cutting Edge and Accolade	Stryker Orthopaedics	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use
Synex II ™ Central Body	Synthes	Advice has been provided by the manufacturer regarding a device removal
MDA Auto Dimer	Trinity Biotech	Advice has been provided by the manufacturer regarding a device modification
GE Centricity Laboratory, sofware version 3.3 Almp	GE Healthcare	Advice has been provided by the manufacturer regarding a software upgrade
ONLINE TDM Gentamicin	Roche Diagnostics	Advice has been provided by the manufacturer regarding a device removal

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Duo Range Wheelchairs	Invacare	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use
Revolution sterile ventricular pump	Sorin Group Italia S.r.l.	Advice has been provided by the manufacturer regarding a device removal
ABX Pentra 400	Horiba ABX SAS	Advice has been provided by the manufacturer regarding a software upgrade
Navigation Software Knee / Planning Software Knee	BrainLAB	Advice has been provided by the manufacturer regarding a software upgrade
Nucleus® Non-magnetic plug (Ref Z50100) and Nucleus® Implant Magnet (Ref Z50101)	CochlearLtd	Advice has been provided by the manufacturer regarding a device removal
Calcium P FS	DiaSys Diagnostics Systems	Advice has been provided by the manufacturer regarding the use of the device
Siregraph CF	Siemens Medical Solutions	Advice has been provided by the manufacturer regarding the use of the device
Compax 40E	GE Healthcare Technologies	Advice has been provided by the manufacturer regarding a device modification
Toppen 77 Orthotic Helmet	RPG Group AB	Advice has been provided by the manufacturer regarding the use of the device
Xeno Electric Wheelchair	Otto Bock	Advice has been provided by the manufacturer regarding a device modification
C-series Clinac®, Trilogy™ and Novalis Tx™	Varian	Advice has been provided by the manufacturer regarding a device modification
RC Cementable Abutment	Institut Straumann AG	Advice has been provided by the manufacturer regarding a device removal
BRYAN Cervical Disc System	Medtronic	Advice has been provided by the manufacturer regarding the use of the device
SwabX	Richardson Healthcare	Advice has been provided by the manufacturer regarding a device removal
BBOP Lock plantar basal plates		Advice has been provided by the manufacturer regarding the use of the device
Columbia CNA with 5% Sheep Blood; Improved II	Becton Dickinson GmbH	Advice has been provided by the manufacturer regarding a device removal
Medena Tapered Tip	Astra Tech AB	Advice has been provided by the manufacturer regarding a device removal
neoBlue mini Phototherapy Device	Natus	Advice has been provided by the manufacturer regarding a device modification

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cobas b 221 MSS cassette	Roche Diagnostics	Advice has been provided by the manufacturer regarding a device removal
Guider Softtip XF Guide Catheter	Boston Scientific International S.A.	Advice has been provided by the manufacturer regarding the use of the device
Self Tapping Cancellous Screw, 5x38mm	Smith & Nephew	Advice has been provided by the manufacturer regarding a device removal
4D Integrated Treatment Console	Varian	Advice has been provided by the manufacturer regarding a software upgrade
HeartStart FR2+ Automated External Defibrillator	Philips Healthcare	Advice has been provided by the manufacturer regarding a device removal
Philips Avalon Fetal Monitors	Philips Healthcare	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use
Dopplex Centrale DC11	Huntleigh Healthcare	Advice has been provided by the manufacturer regarding a software upgrade
BHR Acetabular Cups	Smith & Nephew	Advice has been provided by the manufacturer regarding a device removal
Tisseel Spray Set and Duploject Spray Set	Baxter	Advice has been provided by the manufacturer regarding the use of the device
Durom Acetabular Cup	Zimmer	Advice has been provided by the manufacturer regarding the use of the device
Prometheus CiCa; M201241	Fresenius Medical Care	Advice has been provided by the manufacturer regarding the use of the device
Disposable Irrigation Cannula with Bulbous Tip G-34335	Geuder	Advice has been provided by the manufacturer regarding the use of the device
Equalizer™ Occlusion Balloon Catheter	Boston Scientific	Advice has been provided by the manufacturer regarding a device removal
Gynecare Morcellex Tissue Morcellator	Ethicon	Advice has been provided by the manufacturer regarding a device removal
enGen Laboratory Automation System	Ortho-Clinical Diagnostics	Advice has been provided by the manufacturer regarding the use of the device
Connection Bracket 1180.36AO	Maquet	Advice has been provided by the manufacturer regarding the use of the device
Syngo Workflow MLR	Siemens	Advice has been provided by the manufacturer regarding a software upgrade
Surgical Cutter, Lindemann, Dental	Meisinger	Advice has been provided by the manufacturer regarding a device removal
Dimension Vista Chemistry 3 Calibrator	Siemens Healthcare Diagnostics Inc	Advice has been provided by the manufacturer regarding the use of the device
HeartMate® XVE and HeartMate II® Left Ventricular Assist Systems	Thoratec	Advice has been provided by the manufacturer regarding a device removal

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RapidPoint400 and 405 System Measurement Cartridges	Siemens Healthcare Diagnostics Inc.	Advice has been provided by the manufacturer regarding a software upgrade
Powerheart®, Cardio Vive® and Responder automated external defibrillators	Cardiac Services	Advice has been provided by the manufacturer regarding a device removal
Dimension Vista V-Lyte fluids	Siemens Healthcare Diagnostics Inc	Advice has been provided by the manufacturer regarding the use of the device
ISKD Intramedullary Skeletal Kinetic Distractor	Orthofix	Advice has been provided by the manufacturer regarding a device removal
Advance Canal Filling Stem Extension 11mm x 140mm & 13mm x 140mm	Wright Medical Technology	Advice has been provided by the manufacturer regarding a device removal
Antimicrobial Susceptibility Testing Discs - Moxifloxacin	Oxoid Ltd	Advice has been provided by the manufacturer regarding a device removal
COBAS AmpliPrep/COBAS AMPLICOR HIV-1 MONITOR Test	Roche Molecular Diagnostics	Advice has been provided by the manufacturer regarding a device removal
TheraScreen K-RAS Mutation Kit	Roche Diagnostics	Advice has been provided by the manufacturer regarding a device removal