



IRISH MEDICINES BOARD
FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- NOVEMBER 2009

Product	Manufacturer	Type
Evolution 3E Console	Moria	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use
Gamma ELU-Kit II	Immucor Gamma	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use
Clearview hCG Combo	Unipath Limited	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use
CO2 Based Cryosurgical Instruments	Wallach	Advice has been provided by the manufacturer regarding the use of the device
Flat Foot Resorbable Implant	Stryker Orthopaedics	Advice has been provided by the manufacturer regarding a device removal
coPort F6 and F8 and Clip-a-Port F6 and F8	A.M.I.	Advice has been provided by the manufacturer regarding a device removal
Manual Pulmonary Resuscitator	Unomedical	Advice has been provided by the manufacturer regarding a device removal
Titan® Anchor	Medtronic	Advice has been provided by the manufacturer regarding the use of the device
Vitrax II Ophthalmic Viscosurgical Device (Sodium Hyaluronate 3%), 0.65 mL	Abbott Medical Optics	Advice has been provided by the manufacturer regarding a device removal
BD Q Syte & MPS Acacia with BD Q-Syte	BD Medical	Advice has been provided by the manufacturer regarding a device removal
PK7300 Blood Grouping System	Beckman Coulter Biomedical Ltd	Advice has been provided by the manufacturer regarding the use of the device
Trigen Internal Hex Screw	Smith and Nephew Orthopaedics	Advice has been provided by the manufacturer regarding a device removal
Berichrom Heparin OWLD11	Siemens Healthcare Diagnostics GmbH	Advice has been provided by the manufacturer regarding a device removal
Bicarbonate FS; 10950	DiaSys Diagnostic Systems GmbH	Advice has been provided by the manufacturer regarding the use of the device
Voluson E6 and Voluson E8 Diagnostic Ultrasound Systems	GE Healthcare	Advice has been provided by the manufacturer regarding a software upgrade
Oxford Hoists	Joerns Healthcare	Advice has been provided by the manufacturer regarding the use of the device

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No. 27 Sterile Carbon Steel Surgical Blade	Swann-Morton	Advice has been provided by the manufacturer regarding a device removal
TCAutomation / enGen Laboratory Automation System	Siemens Healthcare Diagnostics Inc.	Advice has been provided by the manufacturer regarding the use of the device
FRED easyport	Schiller Medical	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use
Responder 2000	Cardiac Science	Advice has been provided by the manufacturer regarding the use of the device
XiO	Elekta/CMS	Advice has been provided by the manufacturer regarding the use of the device
C01A KyphX HV-R Bone Cement	Medtronic / Elmdown Limited	Advice has been provided by the manufacturer regarding a device removal
ASX Alternating Pressure System	Novacare GmbH	Advice has been provided by the manufacturer regarding a device removal
Omega or Omega S Package in combination with the Trident NMT and/or PiCCO SmartPod	Dräger Medical	Advice has been provided by the manufacturer regarding a software upgrade
Colleague Triple Channel Mono, CX and CXE Volumetric Infusion Pumps	Baxter Healthcare	Advice has been provided by the manufacturer regarding the use of the device
Innova 2121 and 3131 Cardiovascular X-ray imaging system	GE Healthcare	Advice has been provided by the manufacturer regarding the use of the device
Stryker Navigation PC SPC - 1	Stryker	Advice has been provided by the manufacturer regarding a software upgrade
Exafit Stem	Zimmer	Advice has been provided by the manufacturer regarding the use of the device
Von Willebrand Reagent	Siemens Healthcare Diagnostics Product GmbH	Advice has been provided by the manufacturer regarding a device modification
REA Azalea wheelchair range	Invacare	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use
Oxford Slings	Joerns Healthcare	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use
Uni-Gold Legionella Urinary Antigen	Trinity Biotech	Advice has been provided by the manufacturer regarding the use of the device

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Medfusion® Syringe Infusion Pumps, Models 3010A and 3500	Smiths Medical International Ltd	Advice has been provided by the manufacturer regarding a device modification
Oxoid ready-poured plate, Mueller Hinton agar, 4mm depth (PO0152A)	ThermoFisher Scientific	Advice has been provided by the manufacturer regarding a device removal
Meteor Scooter	Invacare	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use
ZOLL R series Defibrillator/Pacemaker/Monitor	ZOLL Medical	Advice has been provided by the manufacturer regarding the use of the device
Protégé® EverFlex Biliary Stent System	ev3 Inc	Advice has been provided by the manufacturer regarding a device removal
CryoCath Arctic Front Cryoablation system	Medtronic CryoCath	Advice has been provided by the manufacturer regarding the use of the device
Panta Support Device	Newdeal SAS	Advice has been provided by the manufacturer regarding a device removal
Low Mix Dual Infusion Set with Gravity IV Valve, model: 6604	Mediplus Limited	Advice has been provided by the manufacturer regarding a device removal
ON-Q® ONDEMAND™	I-flow Corporation	Advice has been provided by the manufacturer regarding the use of the device
Sesamoid Plasty Workstation Power Cord	Zimmer	Advice has been provided by the manufacturer regarding a device modification
V60 Ventilator	Respironics California Inc	Advice has been provided by the manufacturer regarding a device modification
Morcellator Cutting Tubes	Richard Wolf GmbH	Advice has been provided by the manufacturer regarding a device removal