



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

Product	Manufacturer	Type
ARCHITECT HCV Ag	Abbott Japan Co., LTD	Advice has been provided by the manufacturer regarding the use of the device
Luminos Rf Classic	Siemens	Advice has been provided by the manufacturer regarding a device modification
Universal Cables for use with ConMed Linvatec Surgical Power Tools	ConMed Linvatec	Advice has been provided by the manufacturer regarding a device removal
Ceralas / Megabeam Bare Fiber	CeramOptec GmbH	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use
Tergumed	Proxomed Medizintechnik GmbH	Advice has been provided by the manufacturer regarding the use of the device
Mammomat Inspiration Biopsy Unit	Siemens Healthcare	Advice has been provided by the manufacturer regarding a software upgrade
Bard® MAGNUM® Disposable Biopsy Core Needles 16 Gauge	Bard Limited	Advice has been provided by the manufacturer regarding a device removal
Varian Oncology Systems	Clinac C-series and Novalis Tx with electron beams	Advice has been provided by the manufacturer regarding a device modification
Tryptone soya broth	Thermo Fisher Scientific	Advice has been provided by the manufacturer regarding a device removal
Tecnis™ 1-Piece Intraocular Lens (IOL)	AMO	Advice has been provided by the manufacturer regarding a device removal
AED 10 and MRL Jumpstart ( 150j and 200j)	Welch Allyn	Advice has been provided by the manufacturer regarding the use of the device
Exafit Stem	Zimmer GmbH	Advice has been provided by the manufacturer regarding the use of the device
Powerheart and CardioVive Automated External Defibrillators	Cardiac Science	Advice has been provided by the manufacturer regarding a software upgrade
Uni-Gold Urinary Antigen	Trinity Biotech	Advice has been provided by the manufacturer regarding a device removal
Elements Gutta Percha Cartridge Kit and Elements RealSeal Cartridge Kit	SybronEndo Europe	Advice has been provided by the manufacturer regarding a device removal
Anti-Co(b)	Immucor Gamma	Advice has been provided by the manufacturer regarding a device removal

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070 Neuron Delivery Catheter	Penumbra Inc	Advice has been provided by the manufacturer regarding a device removal
A High Res SSP Unitray®	Invitrogen	Advice has been provided by the manufacturer regarding a device removal
Planmed Nuance and Planmed Nuance Excel DigiGuide	Planmed Oy	Advice has been provided by the manufacturer regarding a software upgrade
TriniCHECK Control Level 3	Trinity Biotech	Advice has been provided by the manufacturer regarding a device modification
TriniLIZE PAI-1 Activity Kit -	Trinity Biotech	Advice has been provided by the manufacturer regarding a device modification
Total Iron Serum Reagent Set	Pointe Scientific Inc.	Advice has been provided by the manufacturer regarding a device removal
Applix Smart Pump, Applix Vision Pump, Applix Pump Giving Sets	Fresenius Kabi	Advice has been provided by the manufacturer regarding the use of the device
Oxoid Ready Poured Plate, DCA (Hynes)	ThermoFisher Scientific	Advice has been provided by the manufacturer regarding a device removal
Stryker Stair-PRO Stair Chair 6251, 6252	Stryker Medical Kalamazoo	Advice has been provided by the manufacturer regarding a device modification
Millex® 33 Syringe Filter Unit	Millipore	Advice has been provided by the manufacturer regarding a device removal
Bile Acid Control Set	Trinity Biotech	Advice has been provided by the manufacturer regarding a device modification
Dimension Vista LOCI Reaction Vesels	Siemens Healthcare Diagnostics	Advice has been provided by the manufacturer regarding a device removal
Cognis CRT-Ds and Teligen ICDs	Boston Scientific	Advice has been provided by the manufacturer regarding the use of the device
Aycan Workstation OsiriX PRO	Aycan Digitalsysteme GmbH	Advice has been provided by the manufacturer regarding a software upgrade
Novo X/XSK 330, Novo X 333, Novo XS4, Top X/XSK 330 and Novo X 550 Dialyse-Bed-Chair	Likamed GmbH	Advice has been provided by the manufacturer regarding a device modification
SureSigns Patient Monitors, Vital Signs Monitors and Vital Signs Viewers	Philips Healthcare	Advice has been provided by the manufacturer regarding a device modification
Mölnlycke Procedure Pak® -	Mölnlycke	Advice has been provided by the manufacturer regarding a device removal

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Galileo Echo	Immucor Gamma	Advice has been provided by the manufacturer regarding the use of the device
TriniCHECK Control Level 1 & 2	Trinity Biotech	Advice has been provided by the manufacturer regarding a device modification
Epicor UltraWand LP	St. Jude Medical	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use
Pureflux-210L	Nipro Europe	Advice has been provided by the manufacturer regarding a device removal
Agilia Volumat Set VL ON 70	Fresenius Kabi	Advice has been provided by the manufacturer regarding a device removal
Oxoid Ready Poured Plate, F.A.A. + Nalidixic acid + Tween ( H.P.A)	ThermoFisher Scientific	Advice has been provided by the manufacturer regarding a device removal
kVue Couchtop	WFR-Aquaplast/Q-Fix Systems	Advice has been provided by the manufacturer regarding a device modification
Corin Ltd.	Uniglide Unicondylar Knee, Femoral Component	Advice has been provided by the manufacturer regarding a device removal
VNS Therapy Demipulse and Demipulse Duo Generators	Cyberonics	Advice has been provided by the manufacturer regarding the use of the device
Pronto Short Extraction Catheters	Vascular Solutions Inc	Advice has been provided by the manufacturer regarding a device removal
CARTO 3 System	Biosense Webster Ltd	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use
Eclipse Client versions 7.3 , 8.0, 8.1, and 8.5	Varian	Advice has been provided by the manufacturer regarding a software upgrade
CHROMOPHARE surgical lights and lighting systems and CHROMOVIEW camera, monitor and appliance carrier arms	Berchtold GmbH	Advice has been provided by the manufacturer regarding a device modification
METS Femoral Shaft	Stanmore Implants Worldwide	Advice has been provided by the manufacturer regarding a device removal
Elucigene CF30	Tepnel Diagnostics	Advice has been provided by the manufacturer regarding the use of the device
Quo-Test A1c test	Quotient Diagnostics	Advice has been provided by the manufacturer regarding a device removal

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MAC800	GE Medical Systems Information Technologies	Advice has been provided by the manufacturer regarding a software upgrade
MD-JADE 2	MeVis Medical Solutions AG	Advice has been provided by the manufacturer regarding a software upgrade
A3402 curved, A3404 45o, A3405 60o, A3406 90o Coaxial Handpieces	Altomed Ltd.	Advice has been provided by the manufacturer regarding a device removal
BHR Streamline Introducer	Smith & Nephew	Advice has been provided by the manufacturer regarding a device removal
ENT registration Headset used with the OEC® IT3000; IT2500 (EnTrak); IT2500 Plus (Entrak Plus); IT3500 (InstaTrak); IT3500 Plus (InstaTrak Plus); ConneCTstat; ConneCTstat Plus Systems	GE Healthcare	Advice has been provided by the manufacturer regarding the use of the device
SeQual Eclipse Oxygen System, Model 1000	SeQual Technologies Inc.	Advice has been provided by the manufacturer regarding a device modification
Cepheid LightCycler HSV 1/2 Qual Kit	Roche Diagnostics GmbH	Advice has been provided by the manufacturer regarding a device removal
Pathfinder and InCompass T-Handle Driver	Abbott Spine	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use
Stainless Steel BiPolar Head and Stainless Steel Physiological Head	Joint Replacement Instrumentation Ltd	Advice has been provided by the manufacturer regarding the use of the device
DRBI *04 Locus High Res SSP UniTray / DRBI*04 Locus High Res Allset Gold SSP	Invitrogen	Advice has been provided by the manufacturer regarding the use of the device
B&H Surgical Instrument Makers	Single use monopolar / bayonet bipolar forceps	Advice has been provided by the manufacturer regarding a device removal
Orthopilot Active Transmitter Hip FS605	B Braun Aesculap AG	Advice has been provided by the manufacturer regarding the use of the device
Reusable Delivery Module of the VIDION ANV Therapy System	NeoVista Inc	Advice has been provided by the manufacturer regarding the use of the device
T-piece Resuscitation Circuits for Panda & Giraffe Resuscitation Systems	GE Healthcare	Advice has been provided by the manufacturer regarding a device removal
IVORY® long necks (WMEL) together with Neck Forceps	Memometal Technologies	Advice has been provided by the manufacturer regarding a device removal

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Accu-Check Inform II	Roche Diagnostics	Advice has been provided by the manufacturer regarding a device removal
Glucose Biosensors	Siemens Healthcare Diagnostics Inc.	Advice has been provided by the manufacturer regarding a device removal
Oxoid Brain Heart Infusion	ThermoFisher Scientific	Advice has been provided by the manufacturer regarding a device removal
T2 Ankle Arthrodesis Nail	Stryker Osteosynthesis	Advice has been provided by the manufacturer regarding a device removal
Bakare Kleerside Adjustable Nursing Bed	Bakare Beds Ltd	Advice has been provided by the manufacturer regarding the use of the device
UniCel DxH 800 Coulter Cellular Analysis System	Beckman Coulter	Advice has been provided by the manufacturer regarding a software upgrade
CYSTODRAIN Supra-pubic drainage kit with silicone balloon catheter	Coloplast A/S	Advice has been provided by the manufacturer regarding a device removal
GENOS MC/MT MINI Internal Distractors	Gebruder MARTIN GmbH & Co. KG	Advice has been provided by the manufacturer regarding a device removal
Vanguard Lock-On Femoral Impactor	Biomet UK Ltd.	Advice has been provided by the manufacturer regarding a device removal
HeartStart Vehicle Wall Mount (Model M5528A) and DC Power Module (Model M5529A)	Philips Healthcare	Advice has been provided by the manufacturer regarding the use of the device
Nexgen ® MIS procedures TM tibial tray Size 8	Zimmer GmbH	Advice has been provided by the manufacturer regarding a device removal
Dimension® IBCT Flex® Reagent Cartridge	Siemens Healthcare Diagnostics Inc.	Advice has been provided by the manufacturer regarding the use of the device
Dade Hepzyme	Siemens Healthcare Diagnostics Product GmbH	Advice has been provided by the manufacturer regarding a device removal
ARCHITECT HIV Ag/Ab Combo Calibrator	Abbott Laboratories	Advice has been provided by the manufacturer regarding the use of the device
Oasys Screwdriver	Weber Instrumente GmbH & Co. KG	Advice has been provided by the manufacturer regarding a device removal
Philips X Ray Systems with SCP Generators and Tube Grid switch funct	Philips Healthcare	Advice has been provided by the manufacturer regarding the use of the device
VIDAS TPSA	BioMérieux	Advice has been provided by the manufacturer regarding the use of the device
chromID Salmonella Agar	BioMérieux	Advice has been provided by the manufacturer regarding a device removal

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TiniCHECK D-Dimer High & Low	Trinity Biotech	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use
Access Immunoassay Systems Enhanced AccuTnl Reagent Kit	Beckman Coulter	Advice has been provided by the manufacturer regarding the use of the device
INNEX tibia insert FIXSC M/15, S/15 and M/12.5	Zimmer GmbH	Advice has been provided by the manufacturer regarding a device removal
Mamoray HDR-C Plus DLF1 - 37780023	Agfa Healthcare	Advice has been provided by the manufacturer regarding the use of the device