



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

Product	Manufacturer	Type
Eleganza Standard, Smart and Deluxe Bedframes	Linet UK	Advice has been provided by the manufacturer regarding a device modification
ENDOPATH ETS-Flex 45 Endoscopic, Articulating Linear Cutter	Ethicon Endo-Surgery Inc.	Advice has been provided by the manufacturer regarding a device removal
Cancellous Bone Screws & Gap Plate Screws Restoration Modular Components & Adaptor Sleeves	Stryker Ireland Ltd	Advice has been provided by the manufacturer regarding a device removal
Alaris® GP volumetric pump and Alaris® GP Guardrails® volumetric pump	Cardinal Health	Advice has been provided by the manufacturer regarding a device modification
Flow Class I (FL1PC) & Class II (FL2PC) Positive Control Serum	Lambda One Inc.	Advice has been provided by the manufacturer regarding a device removal
MPO QuickCard	Bio-Diagnostics Ltd.	Advice has been provided by the manufacturer regarding a device removal
LiNA Grey Shark and LiNA White Shark	LiNA Medical ApS	Advice has been provided by the manufacturer regarding a device removal
Dental Application on the Extended Brilliance Workspace	Philips	Advice has been provided by the manufacturer regarding a software upgrade
Bradshaw Bariatric Bed	Sidhil Ltd	Advice has been provided by the manufacturer regarding a device removal
Clearview Troponin I	Unipath Ltd	Advice has been provided by the manufacturer regarding a device removal
iUni Unicondylar Knee Repair System	ConforMIS	Advice has been provided by the manufacturer regarding a device removal
Delta Ceramic Ball Heads	Stryker Ireland Limited	Advice has been provided by the manufacturer regarding a device removal
Clinical Chemistry Total Bilirubin	Abbott Diagnostics	Advice has been provided by the manufacturer regarding the use of the device
Aidapt VB539 and VB535 Solo Deluxe Shower Seat and Solo Deluxe Shower Seat with pads	Aidapt Bathrooms Ltd.	Advice has been provided by the manufacturer regarding a device modification
BHM/Medi-Man Combi Sling	Arjo Huntleigh Healthcare	Advice has been provided by the manufacturer regarding the use of the device

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ITST Tapered Reamer	Zimmer Inc.	Advice has been provided by the manufacturer regarding a device removal
Dynesys Top-Loading Spacer Cutter	Zimmer Spine	Advice has been provided by the manufacturer regarding the use of the device
Microm STP 420D Tissue Processor	ThermoFisher	Advice has been provided by the manufacturer regarding the use of the device
Trident Acetabular System Surgical Protocol	Stryker Osteonics Corporation	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use
Broselow/Hinkle Intraosseus Needle	Vital Signs Ltd.	Advice has been provided by the manufacturer regarding a device removal
CoaguChek XS; CoaguChek XS Plus	Roche Diagnostics	Advice has been provided by the manufacturer regarding the use of the device
GE Centricity PACS RA1000 Workstation, software versions 2.1.x and 3.0.x	GE Healthcare	Advice has been provided by the manufacturer regarding a software upgrade
GE Centricity PACS, software versions 1.0.x and 2.0.x	GE Healthcare	Advice has been provided by the manufacturer regarding a software upgrade
REA Azalea Base Wheelchair	Invacare Ireland Limited	Advice has been provided by the manufacturer regarding a device modification
Pump Hoses XD 2020	Ulrich GmbH & Co. KG	Advice has been provided by the manufacturer regarding a device removal
Acuson S2000 Ultrasound System	Siemens Healthcare	Advice has been provided by the manufacturer regarding a software upgrade
AquaJoy Premier Plus and Junior Plus bathlifts	AquaJoy Bathlifts Ltd.	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use
Neonatal/Paediatric 96 Hour I.V. Filter	Vygon (UK) Ltd.	Advice has been provided by the manufacturer regarding a device removal
RF Ablation System Foot Switch used with EPT-1000 Cardiac Ablation systems	Boston Scientific	Advice has been provided by the manufacturer regarding a device removal
Compostop CS, the C5L, S5L and the C5LT apheresis disposables	Fresenius Kabi	Advice has been provided by the manufacturer regarding a device removal
Hilite Oxygenators	MEDOS Medizintechnik AG and Chalice Medical	Advice has been provided by the manufacturer regarding the use of the device
Bemis Quick-Fit Liner System	Bemis Limited	Advice has been provided by the manufacturer regarding the use of the device
Neuron Delivery Catheter 0.053	Penumbra Inc.	Advice has been provided by the manufacturer regarding a device removal

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Posey Waist and Wrist Restraints	Posey Company	Advice has been provided by the manufacturer regarding a device removal
ACT3020 Drills	BIOMET 3i	Advice has been provided by the manufacturer regarding a device removal
Quick-set® infusion sets	Medtronic Diabetes	Advice has been provided by the manufacturer regarding a device removal
Wellcolex Colour Salmonella	ThermoFisher Scientific	Advice has been provided by the manufacturer regarding a device removal
Oxidase Identification Sticks	ThermoFisher Scientific	Advice has been provided by the manufacturer regarding a device removal
CMT Plates	Immucor Gamma	Advice has been provided by the manufacturer regarding the use of the device
CASA Beds	Days Healthcare	Advice has been provided by the manufacturer regarding a device modification
BrightView Gamma Camera	Philips Healthcare	Advice has been provided by the manufacturer regarding a device modification
Infant Radiant Infant Warmers labeled as Hill-Rom Stabilet	Draeger Medical Inc.	Advice has been provided by the manufacturer regarding a device removal
INNOTEST hPLAP	Innogenetics	Advice has been provided by the manufacturer regarding a device removal
Neptune and Aquila Bath Lifts	Mountway Ltd.	Advice has been provided by the manufacturer regarding a device removal
PO0171A Brilliant Green Agar (Modified)	ThermoFisher Scientific	Advice has been provided by the manufacturer regarding a device removal
Newdeal Large QWIX Measurer Reference 119150	Integra Life Sciences	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use
15 x 100mm Kii Optical Access System, non-threaded	Applied Medical Resources Corporation	Advice has been provided by the manufacturer regarding a device removal
ACCESS Heavy Duty wheelchair	Remploy Healthcare	Advice has been provided by the manufacturer regarding a device modification
University Bath Hoist and University Bath Hoist Transporter	Unihoist Ltd	Advice has been provided by the manufacturer regarding a device modification
Columbia Agar with Sheep Blood 'Plus' PB5039A	ThermoFisher Scientific	Advice has been provided by the manufacturer regarding the use of the device
Chocolate Agar with Vitox PO5090A	ThermoFisher Scientific	Advice has been provided by the manufacturer regarding a device removal

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Cetrimide Agar PO51076A	ThermoFisher Scientific	Advice has been provided by the manufacturer regarding a device removal
Sorbitol-MacConkey-Agar with MUG; 125e	Heipha Dr. Müller GmbH	Advice has been provided by the manufacturer regarding a device removal
Oral / Enteral Syringes supplied by Medicina Ltd.	Maxter Catheters	Advice has been provided by the manufacturer regarding the use of the device
Trulife Aluminium Double Adjustable Elbow Crutches	Trulife Limited	Advice has been provided by the manufacturer regarding a device removal