



IRISH MEDICINES BOARD  
FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- JULY 2010

Product	Manufacturer	Type	Link to FSN
PK7300 Wash Solution	Beckman Coulter	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
CellSearch Circulating Tumor Cell Kit	Veridex LLC	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Power cords supplied with affected SleepStyle™	Fisher & Paykel Healthcare Limited	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Galaxy Ultra Operating Theatre Lights incorporating Ondal AC2000 Spring Arms	Brandon Medical	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
Vitreia 5.1, Vitreia fX 3.0, Vitreia Enterprise Suite 1.2	Vital Images	Advice has been provided by the manufacturer regarding a software upgrade	<a href="#">Manufacturer's FSN</a> <a href="#">Manufacturer's FSN</a>
Orchestra Base Primea Infusion system	Fresenius Kabis	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
FemSoft® Urethral Inserts	Rochester Medical	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Gyrus One Piece Electrode	DePuy Mitek	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Ionized Calcium and Ionized Magnesium Sensors	Nova Biomedical	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
AMPLILINK Software version 3.2	Roche Diagnostics	Advice has been provided by the manufacturer regarding a software upgrade	<a href="#">Manufacturer's FSN</a>
Leica Peloris Rapid Tissue Processor	Leica Microsystems	Advice has been provided by the manufacturer regarding a software upgrade	<a href="#">Manufacturer's FSN</a>
Dimension Vista 500 System; ECREA method	Siemens	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Dimension Vista 1500 System; ECREA, TP, ACTM & PHOS methods	Siemens	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Fibula Rod, Lot # W65318, Lot # W64072, Lot # W65319	Acumed	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Acumed 3.5mm x 25.0 mm Cortical Screw	Acumed	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Millennium, Stellaris and MVE	Bausch + Lomb	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
Fresenius Medical Care 5008 Dialysis Machines	Fresenius Medical Care	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	<a href="#">Manufacturer's FSN</a>

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NBP Cuff NEO	Draeger	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Levo C3	Levo	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
Contasure Needleless	DIMA	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	<a href="#">Manufacturer's FSN</a>
Nephrostomy Puncture Set, REF RC-401140, lot 10-0420	Urotech	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Orthofix Spinal Implants Modular Non-Cannulated Bone Tap	Orthofix Spinal Implants	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Tyvek Self-Seal Pouch with STERRAD Chemical Indicator	Advanced Sterilization Products (ASP)	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Xio	Elekta	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Bausch + Lomb ReNu® Multi-Purpose Solution and ReNu® MultiPlus solution	Bausch + Lomb	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Merit Laureate Hydrophilic Guide Wire	Merit Medical	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Integra Neuroballoon™ Catheter	Integra NeuroSciences Implants	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Volcano pcFM Software Kit	Volcano Corporation	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Navigation Orthopedic Dovetail Clamp	Medtronic	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	<a href="#">Manufacturer's FSN</a>
Pointe Scientific Liquid Creatinine Reagent	Pointe Scientific Inc	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Karl Storz carts 29003xxx	Karl Storz Endoscopy (UK) Ltd	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
ADVIA Centaur HBc Total	Siemens Healthcare Diagnostics Inc	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
microTargeting™ Guideline 4000 ver.1.4	FHC	Advice has been provided by the manufacturer regarding a software upgrade	<a href="#">Manufacturer's FSN</a>
ADVANCE® Medial Pivot Tibial Inserts	Wright Medical	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
BD Beaver™ Arthro-Lok™ Pointed Tip 4mm Blade	BD Ophthalmic Systems	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Mallory Head Calcar	Biomet Orthopedics	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
NycoCard U-Albumin	Axis-Shield PoC AS	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>

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Stryker® EPIC®, EPIC II®, and EPIC II ®+ Critical Care Bed Models 2030 and 2031 and Zoom® II Critical Care Bed Model 2040	Stryker Medical Kalamazoo	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
Synchron Systems Rheumatoid Factor (RF) Reagent	Beckman Coulter	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Exeter Femoral Head 26mm dia. Standard neck	Stryker Caen	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
QuickCat™ Extraction Catheter	Spectranetics	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
TruCore II / TruCore II URO Biopsy Instruments	Medical Device Technologies Inc. dba Angiotech	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
DePuy P.F.C. Sigma® Modular Tibial Tray SZ-4 N-8	DePuy	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Impaction Bur Guard	Stryker Instruments Kalamazoo	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Carpal button screw	SBI International	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Pulse*Spray 5F 90cm with 20cm Slit Pattern	AngioDynamics	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Benephit Infusion Systems	AngioDynamics	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Chirana sterile hypodermic syringe for single use	Chirana T. Injecta	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
CS300 Intra-aortic Baloon Pump and CS100 Intra-aortic Baloon Pump	Maquet	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
19506C Kolibri Navigation Station 2.0 (with mobile camera stand 2.0)	BrainLab	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
BINDAZYME Human C1q binding Circulating Immune Complex EIA Kit	INOVA Diagnostics, Inc	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Focal4D	CMS Software	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Ophthalmic Irrigation/Aspiration Coaxial Handpieces/Bimanual Handles	Sterimedix/Altomed	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Boots All In One Solution 120ml	Boots	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Synchron System(s) Immunoglobulin A (IgA) Reagent	Beckman Coulter Inc	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
UniCel Dxl 600 and Dxl 800 Access Immunoassay Systems	Beckman Coulter Inc	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Tonometer Measuring Prisms	Haag-Streit International	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	<a href="#">Manufacturer's FSN</a>

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PEGA® TUBE (REF 10255)	Venner Medical GmbH	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Liaison VZV IgG & Liaison VZV IgM	DiaSorin Spa	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
SA9085 Atlas Skull Traction Unit	ArjoHuntleigh	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Mobility scooters and powerchairs using battery packs / boxes manufactured prior to July 2010	Roma Medical Aids Limited	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
SpineJack Preparation Kit	VEXIM SAS	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Destination™ Carotid Guiding Sheath	Terumo Medical Corporation	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Vein Hooks/Phlebectomy Hook - S090, S106, S134 and S135	Single Use Surgical	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
PACE 203H/300 and Model 3085	Osypka Medical	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
AXIOM Luminos	Siemens	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
Promerix Operating Table	Merivaara	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
ADVIA Centaur HIV Ag/Ab Combo (CHIV) Assay	Siemens Healthcare Diagnostics Inc	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
SMS Pipeline Hose	SMS Technologies	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
ACUSON and SONOLINE Antares ultrasound systems	Siemens	Advice has been provided by the manufacturer regarding a software upgrade	<a href="#">Manufacturer's FSN</a>
Respironics V60 Ventilator	Philips Healthcare	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
Access Thyroglobulin Antibody II Reagent	Beckman Coulter	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Stryker ® Model 6100 M1 Ambulance Cot	Stryker Medical Kalamazoo	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
COBE Spectra White Blood Cell Set / COBE Spectra White Blood Cell Set - Functionally Closed	Caridian BCT	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
C series Clinacs	Varian	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Mercury M36 3-Wheel Scooter	Drive Medical Limited	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
HeartStart FRx, HeartStart HIS and HeartStart Home AEDs	Philips Healthcare	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>

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Brahms fßhCG Kryptor	Brahms GmbH	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Ultimate Endo Retrieval Pouch	Cory Bros and Purple Surgical	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	<a href="#">Manufacturer's FSN</a>
TracheoFlex and LaryngoFlex Sets	Teleflex Medical GmbH	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Disposable Scope Warmer	Stryker Endoscopy	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
BBL Staphyloslide Latex Test Kit	BD Diagnostics Systems	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
7500 Fast Dx Real-Time PCR Instrument with SDS v1.4 Software	Applied Biosystems	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Suprasorb CNP P1 pump unit	Lohmann & Rauscher GmbH & Co.KG	Advice has been provided by the manufacturer regarding a software upgrade	<a href="#">Manufacturer's FSN</a>
Ultraflex™ Esophageal NG Stent System, Ultraflex™ Tracheobronchial Stent System and Ultraflex™ Precision Colonic Stent System	Boston Scientific	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
CONTAK RENEWAL® 3 / 3 RF / 4 / 4 RF and VITALITY® HE implantable defibrillators	Boston Scientific	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
KaVo Estetica E70 and E80	KaVo	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
Essenta DR Compact	Philips Healthcare	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
Estrone RIA kit	Beckman Coulter UK Ltd	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
COMPLETE® Multi-Purpose Solution and Total Care® (1) Contact Lens Solution	Abbott Medical Optics (AMO)	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
PTS Panels CHOL+HDL+GLU	Polymer Technology Systems, Inc	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Trabecular Metal Femoral Cone	Zimmer	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
ScanBeta Cot	Scan Mobility	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
PSD Gel packaged with: Peri-Strips Dry Staple Line Reinforcement with Apex Processing, Peri-Strips Dry with Veritas Collagen Matrix Staple line Reinforcement Replacement Gel 3-packs	Synovis Surgical Innovations	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
VIDAS RUB IGG II	BioMérieux	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>

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Novabel	Merz Pharmaceuticals GmbH	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
DSL I-PTH ELISA and IRMA KIT	Beckman Coulter	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Permobil Wheelchair	Permobil Limited	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
NovaFlex Delivery System	Edwards Lifesciences LLC	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Paramedic CU-ER1, Paramedic CU-ER2, Paramedic CU-ER3, and Paramedic CU-ER5	CU Medical Systems, Inc.	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	<a href="#">Manufacturer's FSN</a>
PALAMIX uno 1x80 Vacuum mixing system, PALAMIX duo 2x80, PALAMIX Hip Set	Heraeus	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
NEWDEAL® Forefoot cannulated Drill - sterile	Newdeal	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Eleganza 3 Bedframe Fitted With Split Siderails	Linet Spol s.r.o.	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
HeartStart OnSite (model M5066A) and HeartStart Home (model M5068A)	Philips Healthcare	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	<a href="#">Manufacturer's FSN</a>
ABC Screw Driver F/Selflocking Screws	Aesculap AG	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Comfort 4 Therapy Chair	Digiterm Medical Equipment	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Corgi Sprint Size 3 Wheelchair	Activate	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>