



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

Product	Manufacturer	Type	Link to FSN
1 Day Acuvue TruEye (narafilecon A) Brand Contact Lenses	Johnson & Johnson Vision Care	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
TotalCare® Duo®2 Therapy System	Hill-Rom	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN
Implant Holder for SynFix-LR	Synthes GmbH	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
GAMMA3 Long Nail Kit R2.0, Ti, Right 11x360mm x 125° 32250360S	Stryker Osteosynthesis	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
ACUSON X300 and X300 PE Diagnostic ultrasound systems	Siemens Medical Solutions	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Omxix Pressure Regulator	Ethicon	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN
Octopus Nuvo Tissue Stabilizer Model TSMICS1	Medtronic Limited	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
R57420 Rocket® Uterine Sounds	Rocket Medical	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Accu-Chek® Multiclix lancing device	Roche Diagnostics	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN
Mountway Smart Battery Chargers (supplied with Mountway bath and toilet lifts)	Mountway Ltd.	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
enFlow™ Disposable IV Cartridge	GE Healthcare	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
BrightSpeed Excel/Edge/Elite Select and BrightSpeed Elite Computed Tomography X-ray System	GE Healthcare	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Seven Plus Continuous Glucose Monitoring System	Dexcom	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN

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CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 and CYTO-5STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5	Beckman Coulter Inc.	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Oxford Voyager Fixed Ceiling Hoist X-Y layouts fitted with Gate System	Joerns Healthcare	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN
VITROS 5600 Integrated System / VITROS 5,1FS Chemistry System	Ortho-Clinical Diagnostics	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Quirosa Sterile Umbilical Clamp	Quirosa, S.A.	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
IMTEC-ANA-LIA	Human GmbH	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
EverFlow Dolphin Protect Hemodialysis catheter	Gambro	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
XiO	Elekta	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Relactagel	Kora Healthcare	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Orbiter patient transfer system	Trumpf	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Paraffine Heater PT15	Heuser Apparatebau GmbH	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN
Oncor Impression Plus	Siemens	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Model 8731SC Intrathecal Catheter Kit, Model 8598A Spinal Segment Revision Kit	Medtronic	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
4Z1c matrix array transducers on the ACUSON SC2000™ volume imaging ultrasound system	Siemens Medical Solutions	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
CADD-Legacy Duodopa Pump	Smiths Medical	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Power cord, Europe, 4.5m. Product nos. 3113.3659 and 0223.2824	Maquet	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN

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Cholestech LDX Multi-Analyte Controls, Lipid Controls, and Calibration Verification Material	Alere San Diego Inc.	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Helping Hand Slings	The Helping Hand Company	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN
Endopath XCEL with Optiview Technology	Ethicon Endo-Surgery (Europe) GmbH	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
All Procedure Packs that contain ENDOPATH® XCEL™ with OPTIVIEW™ Technology	Ethicon Endo-Surgery (Europe) GmbH	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
HemoCue Glucose 201 DM and HemoCue Glucose Hb 201 DM Analyzers	HemoCue	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
coDiagnostiX	Straumann	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Access / Access 2 Systems, SYNCHRON LXi 725 and UniCel DxC 600i Integrated Systems	Beckman Coulter Inc.	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Ortivus Clinical Workstation version 3.1	Ortivus AB	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Disposable Coring Trephine and Disposable Dowel Harvest Tube	Biomet Sports Medicine Inc.	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
IAB-05800 Series IAB with SuperArrowFlex (Wire-reinforced) Sheath	Teleflex Medical	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
RELEASE* Non-Adherent Absorbent Dressing	Systagenix	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Panocell 20	Immucor Inc.	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Model 5388 Dual-Chamber External Temporary Pulse Generator Medical Device Correction	Medtronic	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Peristeen Anal Irrigation System	Coloplast	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Signa OpenSpeed, 0.7T and Signa Ovation, 0.35T MR System Patient Tables	GE Healthcare	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Mac 3 HEINE Laryngoscope Blades	HEINE Optotechnik	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN

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EnRhythm Pacemaker	Medtronic	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Awl 2.5 mm with Trocar Tip	Synthes GmbH	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN
Symbiq One-Channel and Two-Channel Infusers	Hospira	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Foundation Knee Revision BasePlate	DJO Surgical	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Paramedic CU-ER1, CU-ER2, CU-ER3 and CU-ER5	CU Medical Systems	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN
Synchron Systems LX20 & UniCel DxC Systems Cartridge Glucose Reagent	Beckman Coulter Inc.	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
LoTrach Traheostomy Tube	Venner Medical (Singapore) Pte. Limited	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN
Xpert® MRSA/SA BC (Blood Culture)	Cepheid	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
BeneHeart D6	Mindray	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Alaris PC Unit	CareFusion	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
UroBeam	Dornier Medilas	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
CELL-DYN 1700/1700CS	Abbott Laboratories	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Universal Flat Panel Yoke	Stryker Communications	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Suction catheter TT03-14-T34-N	GBUK Healthcare	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Vital Signs Monitor, Model 93300 - élance	Spacelabs Medical	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
OEC 9800 C-arm and 9900 C-arm	GE Healthcare	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN

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Molina Pin Driver ref. No. 51-600-85	Gebr. Martin GmbH & Co. KG	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
E-COM DROC software	E-COM Technology Limited	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Arrow Walrus	Arrow International	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
AIA-PACK B12	Tosoh Biosciences	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN
UniCel DxH 800 Coulter Cellular Analysis System, UniCel DxH 800 Floor Cabinet	Beckman Coulter Inc.	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Synchron CX4/5/7 CE, CX4/5/7 Delta and CX9 ALX Clinical Systems	Beckman Coulter Inc.	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Habib Bipolar Resection Device	AngioDynamics	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
UniCel DxC and Synchron LX Clinical Systems	Beckman Coulter Inc.	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Scorpio AP Sizing Guides	Stryker	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Access Immunoassay Systems Thyroglobulin	Beckman Coulter Inc.	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Philips M1567A & M1568A Single and Dual Disposable Pressure Transducer Kits	Philips Medizin Systeme Böblingen GmbH	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
PleuraSeal Lung Sealant System	Covidien	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
EXaCT Targeting Couch and Exact Couch.	Varian	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN(a)
			Manufacturer's FSN(b)
Level 1 Normothermic I.V. Fluid Administration Sets, Product Codes D-60 HL and DI-60HL	Smiths Medical	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Kirton DBO patient chair	Kirton	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN

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C5L	Fresenius Kabi	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
TLS3 Thermal Ligating Shears	Starion	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Vision Alpha High Frequency Oscillator Ventilators	Novalung	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
AMPLATZER® Cardiac Plug.	AGA Medical Corporation	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
PT2XV, Velocity™ Injection Port and Applier, B D2XV, SAGB Quick Close Swedish Adjustable Gastric Band including Velocity™ Injection Port and Applier, B D3XV, SAGB VC Swedish Adjustable Gastric Band including Velocity™ Injection Port and Applier	Obtech Medical Sarl	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Universal IVF Medium Ref. No. 10301010, 10X10ml, with expiry date 14 Jan 2011 lot numbers 10290035 and 10290155	Origio	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
RTX/MyMedic 3370 and 3371 Power Adaptors	Tunstall Healthcare (UK) Limited	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Laparoscopic Gastric Banding Packs: LGB10, LGB12, LGB13, LGB15, LGB16, LGB17, LGB18, LGB19, LGB22, LGB23, LGB24, LGB25, LGB26	Ethicon Endo Surgery	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
CT Drainage Set, Direct puncture set with pigtail catheter, 12F (4.0mm)x25cm	Optimed	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Static Mattresses	Park House Healthcare	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN
TruLink Pre-wired Neonate ECG Electrodes PN: 685-0037-00	Spacelabs Healthcare	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Ciaglia Blue Rhino / Blue Dolphin Percutaneous Tracheostomy Introducer	Cook Medical	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Interspinous implant Le U	Arca Medica	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Bucky Diagnost Ceiling System	Philips	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN

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TeCorp implants (corpectomy implants) Borrows 13mm (Fuchsia)	Scient'x	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
CeSpace Peek Implant 5° 16x7mm Anatomic; FJ427P	Aesculap AG	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Stryker Femoral Sponges	Stryker Instruments	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN