



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

Product	Manufacturer	Type	Link to FSN
TSKgel G8 Variant HSi	Tosoh Corporation	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
ARTISTE™ digital linear accelerator with syngo® RT Therapist version 4.1 connected to LANTIS™	Siemens	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Pacemaker Millennium *VD, Millennium *D	MEDICO	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Affinity® Four Birthing Bed	Hill-Rom	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Alaris Gateway Workstation (AGW) – Pole Clamp	CareFusion	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
AvantGuard Li800A0, LI801A0, LI802A0	Hill-Rom	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
SDC HD (Digital Image Capture System)	Stryker Endoscopy	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
SDC Pro 2 (Digital Image Capture System)	Stryker Endoscopy	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Cardiac Blankets for use with Warm Air Thermal Regulating Units labeled “sterile”	Cincinnati Sub-Zero Products Inc	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
TempPad Cold Therapy Pad	Cincinnati Sub-Zero Products Inc.	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
TriniCLOT Lupus Screen and TriniCLOT Lupus Confirm	Trinity Biotech plc	Advice has been provided by the manufacturer regarding changes/updates made to	Manufacturer's FSN
DRB1*03/08/14/16 SSP UniTray, DRB1*08/16 SSP UniTray with Taq, All Set Gold	Invitrogen	Advice has been provided by the manufacturer regarding changes/updates made to	Manufacturer's FSN
Oxoid Bottled Media, Brain Heart Infusion Broth, BO0366M	ThermoFisher Scientific	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Thermoflect Hypothermia Prevention Products	Encompass Group	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
DOSI-FLOW	Leventon SAU	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
RELI SSO HLA-B Typing Kit	Invitrogen	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
DRB3,4,5 SSP UniTray, DRB4 AllSet Gold SSP and DRB345 AllSet Gold SSP	Invitrogen	Advice has been provided by the manufacturer regarding changes/updates made to	Manufacturer's FSN
Cw High Resolution SSP Unitray and Cw AllSet Gold SSP kit	Invitrogen	Advice has been provided by the manufacturer regarding changes/updates made to	Manufacturer's FSN
TorqVue Delivery Systems	AGA Medical Corporation	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN

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Various Breathing Systems that contain a 22F, 22M, 22M/15F T-piece	Intersurgical Ltd	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Compat Go Pump, Compat Go Plus Pump	Nestle Healthcare Nutrition	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
ARCHITECT Reaction Vessels	Abbott Laboratories	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
NexGen® Complete Knee Solution Legacy Knee-Posterior Stabilized LPS-Flex Gender Solutions	Zimmer	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Ext Tandem Connector 40mm and 60mm	Biedermann Motech GmbH	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
BD™ CD103 PE and BD CD103 FITC	BD Biosciences Europe	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Mistique Infusion Catheter	Merit Medical Systems, Inc.	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Atrisept II ASD & PFO Devices	Cardia Inc	Advice has been provided by the manufacturer regarding changes/updates made to	Manufacturer's FSN
Embolectomy Catheter Ref # 337100	Teleflex Medical	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Xia Precision Jam Shidi Needles	Stryker Spine	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Rotary Microtome HM 340E /HM 355S	Thermofisher Scientific	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
OPERA, PRECISION RXi, MERATEL, BRT-20, CLINODIGIT, COMPACT, FUTURA 2000, ARKITON	Medical Merate S.p.A.	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Monoplus Violet and Monsyn Violet	Aesculap AG	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Probe 3 PN and Probe 3 PS Intraparenchymal Probes	Spiegelberg GmbH	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Defibrillators CardioLife TEC-7621K, TEC-7631K, TEC-7721K and TEC-7731K	Nihon Kohden	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Access Immunoassay Systems Free T3 Calibrators	Beckman Coulter	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Oxoid Ready Poured Plate, Iso-Sensitest Agar + 5% Blood + 20mg/L N.A.D., 4mm depth, PB0378A	Thermofisher Scientific	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
CELL-DYN 4000 Vent Head Spring Assembly	Abbott Laboratories	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
UniCel® DxC 600 / 600 PRO / 600i / 800 / 800 PRO / 880i / 860i / 680i / 660i	Beckman Coulter	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Brain Heart Infusion Broth TV5010D	ThermoFisher Scientific	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
C-Series Ximatron	Varian	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN

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Oxoid Ready Poured Plate, Iso-Sensitest Agar + Horse Blood; 4mm depth, PB0146A	Thermofisher Scientific	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Syngo® RT Therapist	Siemens	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Diathermy Cables 3405M and 3508M	Unomedical Ltd	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
0055 ArcoTable NT	Arcoma	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Captia Measles IgM Kit-	Trinity Biotech plc	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
VACS II and VACS III Valvuloplasty Catheters	OSYPKA	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Disposable Pads H315 used for defibrillators cardioLife TEC-5521K, TEC-5531K, TEC-7621K,	Nihon Kohden	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Oxoid Ready Poured Plate, Pseudomonas CFC Selective Agar, PO0291A	ThermoFisher Scientific	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
CyberKnife MultiPlan Treatment Planning System Version 3.5	Accuray	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
AMPLICOR Swab Packet	Roche Molecular Diagnostics	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Mölnlycke ProcedurePak®	Mölnlycke Healthcare	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
PLAC Test Reagent Kit (immuno-turbidimetric method)	diaDexus	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN