



IRISH MEDICINES BOARD

FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- JANUARY 2011

Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Is the Irish market affected?
IMPAX Image Viewer	Agfa Healthcare	Advice regarding a software upgrade	13 December 2010	Yes
ArcRoyal Custom Procedure Trays	ArcRoyal Limited	Advice regarding a device removal	14 December 2010	Yes
BD FACS 7-Color Setup Beads	Becton Dickinson Biosciences	Advice regarding a device removal	17 January 2011	Yes
LATITUDE Patient Management System	Boston Scientific Limited	Advice regarding a software upgrade	10 January 2011	Yes
Codman® Disposable Drill Kits	Codman & Shurtleff Inc.	Advice regarding a device removal	03 January 2011	Yes
Codman® Disposable Twist Drill	Codman & Shurtleff Inc.	Advice regarding a device removal	03 January 2011	Yes
PROSTAFLOW™ Prostatectomy Catheter P.V.C. Latex	Coloplast	Advice regarding a device removal	24 November 2010	Yes
FOLYSIL® X-Tra Catheter	Coloplast	Advice regarding a device removal	01 January 2011	Yes
System 2450® Electrosurgical Generator	ConMed Electrosurgery	Advice regarding a device modification	04 January 2011	Yes
Nellcor Durasensor® (DS-100A) sensors	Covidien	Advice regarding a device removal	12 December 2010	Yes
S-ROM Noiles Distal Femoral Cutting Guide	DePuy Orthopaedics Inc.	Advice regarding changes/updates made to instructions for use	31 October 2010	Yes
XVI	Elekta	Advice regarding the use of the device	05 January 2011	Yes
XiO, all Models with Software Release Number 4.50.00 and above	Elekta	Advice regarding the use of the device	13 December 2010	Yes
Ethilon Suture, Ethibond and Mersilene Polyester Fiber Sutures and Mersilk Sutures	Ethicon	Advice regarding a device removal	13 January 2011	Yes
Xeleris Workstation 1.0, 1.1, 2.0, 2.1, 3.0	GE Healthcare	Advice regarding a software upgrade	20 January 2011	Yes
SafeSheath® Sealing Adapter, CPS SafeSheath® Sealing Adapter	GE Healthcare	Advice regarding a device removal	24 January 2011	Yes
All powered wheelchairs (including Spectra Plus, Harrier Plus/HD/XHD, Apollo, Mirage)	Invacare	Advice regarding the use of the device	04 January 2011	Yes
Invacare Typhoon II Power Wheelchair with Stability Lock	Invacare	Advice regarding a device modification	09 December 2010	Yes
Rad-8™ Pulse Oximeter	Masimo Corporation	Advice regarding a software upgrade	04 January 2011	Yes
Pronto-7 Rainbow 4D Reusable Sensor	Masimo Corporation	Advice regarding the use of the device	21 December 2010	Yes
SynchroMed® II and SynchroMed EL Implantable Drug Pumps	Medtronic	Advice regarding the use of the device	13 January 2011	Yes
Micrus Endovascular Microcoil System	Micrus Endovascular	Advice regarding a device removal	27 December 2011	Yes
Intellivue Information Center	Philips Healthcare	Advice regarding a device modification	26 January 2011	Yes
Precedence and SKYLIGHT SPECT Systems	Philips Healthcare	Advice regarding a device modification	01 January 2011	yes

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Sireskop SX, Axiom sireskop SD and Axiom Luminos TF	Siemens	Advice regarding a device modification	23 December 2011	Yes
iNtellec Cranial Navigation / Planning Version 1.0 and 1.1, SpineMap® 3D Version 1.0 Products and OrthoMap® 3D Version 1.0 Products	Stryker Navigation	Advice regarding a software upgrade	31 January 2010	Yes
iNtellec Cranial Navigation / Planning Version 1.0 and 1.1, SpineMap® 3D Version 1.0 Products and OrthoMap® 3D Version 1.0 Products	Stryker Navigation	Advice regarding a software upgrade	31 January 2010	Yes
5800 Series FibreOptix™ and Ultra 8® Catheters CC IAB Catheters	Teleflex Medical	Advice regarding a device removal	07 January 2011	Yes
Unomedical Sterile Urine Drainage Bags	Unomedical	Advice regarding a device removal	26 November 2010	Yes
4D Integrated Treatment Console	Varian	Advice regarding the use of the device	04 January 2011	Yes