



IRISH MEDICINES BOARD

FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- AUGUST 2012

Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Is the Irish market affected?
Armada 35 and Armada 35 LL Percutaneous Transluminal Angioplasty (PTA) Catheter	Abbott Laboratories Vascular Enterprises Ltd.	Advice regarding a device removal	20 August 2012	Yes
IMPAX Image Viewer	Agfa Healthcare	Advice regarding a software upgrade	05 November 2010	Yes
Halo Energy Generators	BARRX Medical	Advice regarding the use of the device	13 August 2012	Yes
Clever Chek Talking Blood Glucose Meter and Test Strips	BBI Healthcare	Advice regarding the use of the device	27 July 2012	Yes
BVI CustomEyes Ophthalmic Procedure Kits	Beaver Visitec	Advice regarding a device removal	08 August 2012	Yes
OSSEOTITE NT™ CERTAIN IMPLANT 5MM x 10MM	Biomet 3i	Advice regarding a device removal	29 August 2012	Yes
BULKAMID® Urethroscope	Contura International A/S	Advice regarding a device modification	07 February 2012	Yes
High Power single-use grounding pads and Cool-tip RFA Electrode Kits	Covidien	Advice regarding a device removal	13 August 2012	Yes
DUET TRS	Covidien	Advice regarding a device removal	22 August 2012	Yes
XVI R4.5 to XVI R4.5.1 (Upgrade)	Elekta Limited	Advice regarding a software upgrade	04 May 2012	Yes
Digital linear accelerators of type Precise, Synergy Platform, Synergy, Synergy S, Infinity, Axesse	Elekta Limited	Advice regarding the use of the device	01 August 2012	Yes
XVI	Elekta Limited	Advice regarding a software upgrade	24 January 2012	Yes
PROXIMATE PPH Set (PPH03 / PPH01)	Ethicon Endo-surgery	Advice regarding a device removal	02 August 2012	Yes
SURGIFLO® Hemostatic Matrix Kit & SURGIFLO® Hemostatic Matrix Kit with Thrombin	Ethicon Inc.	Advice regarding a device removal	22 August 2012	Yes
LIP W11182 LEGIONELLA MEDIUM + BCYE + GVPN	Fannin Limited LIP	Advice regarding a device removal	24 August 2012	Yes
Optima XR220amx / Optima XR200amx / Brivo XR285amx	GE Healthcare	Advice regarding changes/updates made to instructions for use	08 August 2012	Yes
Innova 2121IQ and Innova 3131IQ	GE Healthcare	Advice regarding a software upgrade	08 August 2012	Yes
Giraffe and Panda Warmer T-Piece Resuscitation System	GE Healthcare	Advice regarding a device removal	08 August 2012	Yes
LIFECODES PAK12G	Gen-Probe	Advice regarding a device removal	13 August 2012	Yes
Channel separator LFC-S-05 used with Fibrocleaners, Poka Yoke, Ed FLOW	Getinge	Advice regarding a device modification	05 July 2012	Yes
Perimeter OCTOPUS 101	Haag-Streit International	Advice regarding the use of the device	17 August 2012	Yes
Minivator Bath Bliss Reclining Bathlift 311	Handicare Limited	Advice regarding a device modification	17 August 2012	Yes
SOPIRA Carpule Needles	Heraeus Kulzer GmbH	Advice regarding a device removal	08 September 2010	Yes
Affinity® Four Birthing Beds	Hill-Rom	Advice regarding a device modification	22 May 2012	Yes

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FreeSpan Traverse and FreeSpan UltraTwin Traverse	Hill-Rom	Advice regarding changes/updates made to instructions for use	10 July 2012	Yes
ABX PENTRA ML	Horiba Medical	Advice regarding a software upgrade	10 August 2012	Yes
Pentax Ultrasound Video Gastroscope, EG-3870UTK	Hoya Corporation, Pentax Life Care Division	Advice regarding changes/updates made to instructions for use	27 April 2012	Yes
Capture-R Ready Indicator Red cells	Immucor	Advice regarding a device removal	27 August 2012	Yes
EndoWrist Hot Shears Tip Cover Accessory	Intuitive Surgical	Advice regarding a device removal	31 May 2012	Yes
OXFORD Easytrack 2, 3, & 4 Post Systems	Joerns Healthcare	Advice regarding a device modification	08 April 2011	Yes
Symplicity® Catheters Model RDN006	Medtronic	Advice regarding a device removal	02 August 2012	Yes
Shepard Grommet without wire	Network Medical Products Ltd	Advice regarding a device removal	19 July 2012	Yes
Cardiolife TEC-8300K series Defibrillator	Nihon Kohden Corp	Advice regarding a device modification	06 August 2012	Yes
Micro-Pace 4580, Dual Chamber External Pacemaker	PACE Medical Inc.	Advice regarding a device removal	28 June 2012	Yes
PS2682-265LPC; PS2683-268LPC; PS2684-272LPC	Randox	Advice regarding changes/updates made to instructions for use	29 May 2012	Yes
COBAS TaqMan and COBAS TaqMan 48	Roche Diagnostics	Advice regarding the use of the device	05 July 2012	Yes
LightCycler 1.2 and 2.0	Roche Diagnostics	Advice regarding the use of the device	05 July 2012	Yes
Cobas 8000 Analyser	Roche Diagnostics	Advice regarding the use of the device	05 July 2012	Yes
Digital linear accelerators of type ARTISTE, ONCOR and PRIMUS with syngo RT Therapist version 4.2	Siemens AG Healthcare	Advice regarding the use of the device	11 July 2012	Yes
ADVIA Centaur HIV 1/O/2 Enhanced (EHIV) Assay	Siemens Healthcare Diagnostics	Advice regarding the use of the device	02 August 2012	Yes
ADVIA Centaur Muti-Diluent 1	Siemens Healthcare Diagnostics	Advice regarding the use of the device	31 July 2012	Yes
ADVIA Centaur / Centaur XP FSH Assay	Siemens Healthcare Diagnostics	Advice regarding a device removal	08 August 2012	Yes
ADVIA Centaur Prolactin Assay	Siemens Healthcare Diagnostics	Advice regarding a device removal	08 August 2012	Yes
ADVIA Centaur / ADVIA Centaur XP	Siemens Healthcare Diagnostics	Advice regarding the use of the device	01 August 2012	Yes
Endoscopy metal and peek suture anchors	Smith and Nephew	Advice regarding a device removal	01 August 2012	Yes
OptimaXL, Sirius, XLED, Xenon, Orion, Laryn handles	Timesco	Advice regarding a device modification	09 August 2012	Yes
AIA-PACK TgAb CALIBRATOR SET	Tosoh Corporation	Advice regarding a device removal	02 August 2012	Yes
Eclipse Treatment Planning System	Varian	Advice regarding a software upgrade	10 August 2012	Yes
Volcano s5/s5i Family Software Version 3.2.1/3.2.2	Volcano	Advice regarding a software upgrade	30 August 2012	Yes
KleenSpec Disposable Vaginal Specula	Welch Allyn	Advice regarding a device removal	08 August 2012	Yes