



## IRISH MEDICINES BOARD

## FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- JUNE 2012

Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Is the Irish market affected?
Alere Cholestech LDX	Alere San Diego Inc.	Advice regarding a software upgrade	24 February 2012	Yes
Zitzi Clozitt Commode	Anatomic SITT AB	Advice regarding a device modification	30 May 2011	Yes
Minstrel, Minerva, Excelsior, Gemini Patient Lifts	ArjoHuntleigh (manufactured by Medibo Medical Products NV)	Advice regarding changes/updates made to instructions for use	31 May 2012	Yes
Xevonta Hi 20, Article Code 7204665	B Braun	Advice regarding a device removal	14 June 2012	Yes
iPlan RT Dose version 4.1 only (v. 4.1.0, 4.1.1 and 4.1.2)	Brainlab AG	Advice regarding a software upgrade	01 June 2012	Yes
Carestream DRX-1 System Battery	Carestream Health Inc.	Advice regarding a device removal	18 June 2012	Yes
SpeediCath Complete	Coloplast	Advice regarding a device removal	05 June 2012	Yes
Rotulator Single Use Stapler	Covidien USA	Advice regarding a device removal	13 June 2012	Yes
Vital Signs enFlow IV Fluid Warmer Model 100 - updated FSN	GE Healthcare	Advice regarding the use of the device	05 June 2012	Yes
Zimma Walking Frames	Invacare	Advice regarding a device modification	25 May 2012	Yes
Jenx Ltd Headrest Brackets	Jenx Limited	Advice regarding a device modification	19 April 2012	Yes
Stents Introducer for Biliary endoscopic application, Diameter 7 Fr, for SHS stent range	M.I. Tech	Advice regarding a device removal	23 May 2012	Yes
Maquet QUADROX-I Oxygenators.	Maquet Cardiopulmonary AG	Advice regarding the use of the device	25 May 2012	Yes
Horizon Medical Imaging (HMI) versions 11.5, 11.5.1, 11.5.2, 11.6, 11.7 and 11.8.	McKesson	Advice regarding a software upgrade	13 June 2011	Yes
Horizon Medical Imaging (HMI) versions 11.5, 11.5.1, 11.5.2, 11.6, and 11.7 or customers who have been upgraded from these versions	McKesson	Advice regarding a software upgrade	29 May 2012	Yes
Hintegra tibial alignment rod, ref. 309615	Newdeal SAS	Advice regarding a device removal	25 May 2012	Yes
VITROS 5, 1FS System Software & VITROS 5600 / 4600 System Software	Ortho Clinical Diagnostics	Advice regarding the use of the device	22 May 2012	Yes
VITROS 5, 1FS System Software & VITROS 5600 / 4600 System Software - Addendum	Ortho Clinical Diagnostics	Advice regarding the use of the device	22 June 2012	Yes
Xcelera Connect R2.1L1 SP2	Philips	Advice regarding a software upgrade	31 May 2012	Yes
MultiDiagnost Eleva: Productcode: 708034 / 708032 / 708036 / 708037 with optional cable swivel	Philips	Advice regarding a device modification	21 May 2012	Yes
ABL80 FLEX and ABL80 FLEX CO-OX Analyzers	Radiometer	Advice regarding changes/updates made to instructions for use	08 June 2012	Yes
AXIOM Aristos MX	Siemens	Advice regarding a device modification	03 May 2012	Yes

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Data Station AMPLILINK	Siemens Diagnostics	Advice regarding the use of the device	25 June 2012	Yes
Magnetom Essenza 1.5T Systems	Siemens Healthcare	Advice regarding changes/updates made to instructions for use	22 March 2012	Yes
IMMULITE 2000, IMMULITE 2000 Xpi & IMMULITE 2500 Rapid TSH	Siemens Healthcare Diagnostics	Advice regarding the use of the device	01 June 2012	Yes
DreamMaster Light Mattress Elevator DM300	SmitCare	Advice regarding a device modification	21 May 2012	Yes
Metal Liner Components of the R3 Acetabular System	Smith & Nephew	Advice regarding a device removal	01 June 2012	Yes
Spacelabs Healthcare Pathfinder SL	Spacelabs Healthcare Ltd.	Advice regarding a software upgrade	11 May 2012	Yes
Alumina Femoral Ceramic Head- V40 Taper +0.0mm	Stryker	Advice regarding a device removal	07 June 2012	Yes
CS-2x00i	Sysmex Corporation	Advice regarding a software upgrade	13 June 2012	Yes
TECOVIT 200 and TECOTHERM TS med 200 Total Body Cooling System	TEC COM GmbH	Advice regarding the use of the device	30 June 2012	Yes
Sarns™ High-flow Aortic Arch Cannula - Sarns™ Flexible Arterial Cannula	Terumo	Advice regarding a device removal	06 June 2012	Yes
MULTIGENT Hemoglobin A1c Reagent	ThermoFisher Scientific	Advice regarding changes/updates made to instructions for use	31 May 2012	Yes
Oxoid Antimicrobial Susceptibility Testing Disc ATM30 (Aztreonam)	ThermoFisher Scientific	Advice regarding a device removal	16 May 2012	Yes
GH3 Trolley	V. Guldmann A/S	Advice regarding changes/updates made to instructions for use	13 February 2012	Yes
4D Integrated Treatment Console v10.2.3 and Bar-Code Conical Collimator (BCCV) v1.0	Varian Medical Systems	Advice regarding the use of the device	28 March 2012	Yes
Portable Intensive Care (PIC50)	Welch Allyn	Advice regarding the use of the device	22 October 2010	Yes