



## IRISH MEDICINES BOARD

## FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- APRIL 2012

Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Is the Irish market affected?
ARCHITECT STAT Troponin-I Reagent Kit	Abbott Diagnostics	Advice regarding a device removal	11 April 2012	Yes
i-STAT PT/INR cartridge	Abbott Point of Care	Advice regarding a software upgrade	03 April 2012	Yes
CE Infusor and Intermate	Baxter	Advice regarding the use of the device	16 March 2012	Yes
FLOSEAL Hemostatic Matrix	Baxter	Advice regarding the use of the device	27 April 2012	Yes
HomeChoice Disposable Sets and Maifold Sets	Baxter Healthcare	Advice regarding changes/updates made to instructions for use	20 April 2012	Yes
Access Immunoassay Systems Vitamin B12 Reagent Kit	Beckman Coulter Inc.	Advice regarding a device removal	23 March 2012	Yes
SQ RX Pulse Generator	Cameron Health	Advice regarding a software upgrade	23 April 2012	Yes
VeinViewer 1.1 GS	Christie Medical Holdings Inc.	Advice regarding a device modification	12 April 2012	Yes
FirstStep hCG Pregnancy Test	Concateno	Advice regarding the use of the device	23 March 2012	Yes
S.M.A.R.T.® & S.M.A.R.T.® Control®	Cordis	Advice regarding a device removal	09 April 2012	Yes
Legendair and Supportair Ventilators	Covidien	Advice regarding a device modification	02 April 2012	Yes
DePuy Cemented, Polished and Cobalt Chromium Alloy Hip Stems in combination with metal-on-metal (MoM) articulations	DePuy International Ltd	Advice regarding the use of the device	17 April 2012	Yes
MLCi and MLCi2 radiation heads	Elekta UK	Advice regarding the use of the device	19 April 2012	Yes
Hera II	Ergolet	Advice regarding a device modification	18 April 2012	Yes
HARMONIC® Hand Piece / HARMONIC® Blue Handpiece and Blue Test Tip	Ethicon Endo-Surgery, LLC	Advice regarding the use of the device	02 April 2012	Yes
Legionella Medium + BCYE Growth Supplement	Fannin LIP	Advice regarding a device removal	12 April 2012	Yes
OEC 9800, OEC FluoroTrak 9800 Plus, OEC 9800 Plus, OEC 9800MD	GE Healthcare	Advice regarding a device modification	26 March 2012	Yes
Discovery NM 630 & Discovery NM/CT 670	GE Medical Systems	Advice regarding a device modification	16 April 2012	Yes
LIFECODES PakPlus kit	Gen-Probe GTI Diagnostics Inc.	Advice regarding the review of patient results/patient recall/sample retesting is required	13 April 2012	Yes
GEMSTAR Bolus Cord	Hospira Inc.	Advice regarding the use of the device	22 March 2012	Yes
Micro-Pace Temporary Cardiac Pacemaker Ref 4580	PACE Medical Inc	Advice regarding a device modification	20 April 2012	Yes
Macrolane	Q-Med	Advice regarding the use of the device	17 April 2012	Yes
Fluido® Junior Disposable Sets (630000) & Fluido® Junior (640000)	Sewoon Medical Co. Limited	Advice regarding a device removal	22 March 2012	Yes

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ADVIA Centaur HCV	Siemens Healthcare Diagnostics	Advice regarding a device removal	25 April 2012	Yes
QuickSite® and QuickFlex® Left Ventricular CRT Leads	St. Jude Medical	Advice regarding the use of the device	03 April 2012	Yes
4D Integrated Treatment Console (4DITC)	Varian Medical Systems Inc	Advice regarding a software upgrade	09 April 2012	Yes