

Notice Information: Medical Devices - Warning 29 September 2006

Part 1. Product Information

- a) Title:
- b) Product Name/Type:
- c) Reference:
- d) Manufacturer/Supplier:

Part 2. Target Audience

- a) Target Audience:

Part 3. Problem/Issue

- a) Problem/Issue:

Part 4. Background Information

- a) Background Information: Pro-active market surveillance undertaken by the Irish Medicines Board (IMB) has revealed the practice of splitting / manufacture of diagnostic kits for self-testing by Celtic Integrated Network or www.testkitsdirect.com. This was being performed in an uncontrolled setting and involved non-CE marked devices. The company does not have a validated quality system and has not been subject to assessment by the relevant regulatory body.

Part 5. Action to be taken

- a) Action to be taken: Check to determine if you have purchased any of the above listed devices from www.testkitsdirect.com, Celtic Integrated Network or from internet auction sites. If you have purchased these affected devices, check the packaging to determine if a CE mark is present, that they are not relabelled and that they are in date. If you have concerns about your device do not use it and consult your doctor or pharmacist. Pharmacies who have purchased devices from Celtic Integrated Networks or www.testkitsdirect.com which do not bear a valid CE mark or are over-labelled should cease supply. If you have used an affected device and are concerned about your health please seek medical advice. Caution is recommended if purchasing any medical device from an internet site or from a non-conventional supplier. Always purchase medical devices with a CE mark and from reputable and recognised sources.

Part 6. Enquiries

- a) All enquiries should be made to: All adverse incidents relating to a medical device should be reported to the: Irish Medicines Board Medical Devices Department Kevin O'Malley House Earlsfort Centre Earlsfort Terrace Dublin 2. If you have any enquiries, you may contact the Medical Devices Department at: Telephone: +353-1-6343429 Fax: +353-1-6344033 Email: medicaldevices@imb.ie Website: www.imb.ie SN2006(07): Diagnostic Kits for Self-Testing

Part 7. Keywords

- a) Keywords: Diagnostic Kits for Self-Testing