

Notice Information: Medical Devices - Warning 01 February 2008

Part 1. Product Information

- a) Title: Baby Beets Fetal Doppler
- b) Product Name/Type: 'Baby Beets' Fetal Doppler
- c) Reference: SN2008(03)

Part 2. Target Audience

- a) Target Audience: Maternity Hospitals; General Practitioners; Pharmacists; Distributors; General Public

Part 3. Problem/Issue

- a) Problem/Issue: The Irish Medicines Board (IMB) have been alerted that the 'Baby Beets Fetal Doppler' is not officially CE marked and therefore may not reach the required standards of safety and quality, as required by the medical device legislation. This product may have been purchased through the internet.

Part 4. Background Information

- a) Background Information: A medical device cannot be marketed in Ireland and Europe without carrying a CE mark. A CE mark is applied by the manufacturer to denote that the device meets the relevant regulatory requirements, is safe to use and performs as intended. The 'Baby Beets Fetal Doppler' incorrectly claims to be CE marked and incorrectly claims that its European representative is Lloyds Pharmacy, United Kingdom. There is no evidence that the safety and performance of this product meets the requirements of the medical device legislation. This product could pose a risk to the mother and / or baby. This product is not connected to the Baby Beets fetal doppler (spelt with an 'ea' rather than 'ee').

Part 5. Action to be taken

a) Action to be taken:

Check if you have a Baby Beets Fetal Doppler in your possession. If you have determined that you have this product, you should discontinue use immediately. If you have any health concerns, please consult your doctor (General Practitioner, Gynaecologist or Obstetrician) for their advice. If you are selling this product, stop, quarantine the product and contact the IMB immediately.

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: +353-1-6764971 Fax: +353-1-6344033 Email: vigilance@imb.ie Website: www.imb.ie SN2008(03): IMB Safety Notice - Baby Beets Fetal Doppler

Part 7. Keywords

a) Keywords:

SN2008(03): Baby Beets Fetal Doppler