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NOTICE**

AidFast, 1st Aid & Powerplast Digital Thermometers

IMB Safety Notice: SN2009(03)
Circulation Date: 22nd April 2009

MANUFACTURER/SUPPLIER

Unknown

TARGET GROUPS

General public
Pharmacies
Retailers

ISSUE

Non-compliant and inaccurate (up to 0.5°C) Aid Fast, 1st Aid and Powerplast digital thermometers have been provided to discount outlets in Ireland. These digital thermometers are not appropriately CE marked. These thermometers may be marketed under a variety of brands and the packaging may vary.

BACKGROUND

The IMB has become aware that non-compliant and inaccurate (up to 0.5°C) Aid Fast, 1st Aid and Powerplast digital thermometers have been provided to retail outlets in Ireland.

An investigation that was carried out by the Competent Authority for medical devices in the United Kingdom, the MHRA, found that several brands of digital thermometers, Aid Fast, 1st Aid and Powerplast, are giving inaccurate readings of up to 0.5°C.

These digital thermometers are not in compliance with the medical device legislation as they have inadequate instructions for use, inadequate warnings and precautions and inadequate advice on cleaning for re-use. Additionally, the packaging does not supply information on the manufacturer or the batch or serial number. These products are not appropriately CE marked. These thermometers may be marketed under a variety of brands and the packaging may vary.

These thermometers are available on the Irish market and may also be available for sale on the Internet.

The IMB will continue to monitor this issue closely along with our colleagues in the United Kingdom.

S A F E T Y

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ACTION OR RECOMMENDATIONS

Advice for Pharmacies, Retailers and Wholesalers

Pharmacies, retailers and wholesalers should examine their stock to determine if they have any medical devices branded Aid Fast, 1st Aid or Powerplast digital thermometers.

If you find that you have these products cease sale of these products immediately and quarantine all stock. Contact the IMB immediately to obtain further instruction and guidance.

Also, should you discover any other similar brands of digital thermometers that do not clearly identify the manufacturers name and address on the packaging, please advise the IMB.

Advice for Consumers

Consumers should check their digital thermometer to determine if their device is branded Aid Fast, 1st Aid or Powerplast.

If you find that you have one of these devices, discontinue use immediately and seek an alternative. Consumers with health concerns should consult with their general practitioner.

ENQUIRIES

All adverse incidents relating to a medical device should be reported to the:

Human Products Safety Monitoring Department
Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2.

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: vigilance@imb.ie
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SAMPLES OF THE DIGITAL THERMOMETERS – PACKAGING MAY VARY

