

# Information Notice

## Medical Devices

### Caution When Purchasing Thermometers



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#### ISSUE

Thermometers (contact or non-contact) are used to measure the temperature of an individual. Examples include digital thermometers placed under your tongue, ear thermometers or non-contact forehead thermometers. Thermometers are considered to be medical devices as they have a medical purpose, medical devices are regulated by the HPRA.

It has recently come to the attention of the HPRA that a number of thermometers placed on the Irish market do not meet regulatory requirements for medical devices. Such devices may not perform as intended and instances of inaccurate temperature readings have been reported to the HPRA.

The HPRA would like to emphasise that **those purchasing thermometers used to measure the temperature of an individual take appropriate precautions**

- Purchase from a reputable source
- Ensure the medical device has a CE mark accompanied by a four-digit number
- Ensure labelling and information provided with the device is in the English language

A medical device is a healthcare product or piece of equipment that a person uses for a medical purpose. Medical devices placed on the Irish market **must bear a CE mark**. Thermometers are considered Class IIa medical devices as per Rule 10 of Annex IX of the medical device directive 93/42/EEC. Class IIa medical devices are required to undergo notified body assessment prior to CE marking. Therefore, thermometers should have a four-digit number displayed alongside their CE mark. This four-digit number represents the number of the notified body who has certified the product as being compliant with European medical devices legislation.

If the manufacturer is located outside of the EU, then the name and address of an Authorised Representative within the EU must be printed on the device labelling and instructions for use.

For further advice on how to determine if a device conforms with the medical device directive, please see below.

## RECOMMENDATIONS

The HPRA advises the following in relation to the purchase of thermometers:

### For stakeholders (distributors / retailers):

- Ensure that the **CE mark**, accompanied by a four-digit notified body number, is visible on the device / packaging and the instructions for use
- Ensure correct proportion of the letters as outlined below:



- Check the **manufacturer contact details** are available on device / packaging and instructions for use
- Where the manufacturer is located outside of the EU, check the **name and address of a European based point of contact, known as the authorised representative**, is visible on the device / packaging and instructions for use
- Check device information is provided in the English language
- Purchase medical devices from reputable sources. Try to buy directly from the manufacturer or an authorised distributor
- Retailers of thermometers should request a copy of the **Declaration of Conformity** and **Notified Body Certificate** from the manufacturer. These documents should be in the name of the manufacturer and reference the medical device directive 93/42/EEC
- **If you are considering purchasing or have purchased a thermometer for retail and have any concerns, please contact the HPRA.** We can advise if the thermometer meets regulatory requirements
- Report any incidents relating to the use of a medical device to the HPRA

### Members of the public:

- Purchase from a reputable source
- Ensure a **CE mark**, accompanied by a four-digit notified body number, is visible on the device / packaging and the instructions for use
- Check device information is provided in the English language
- If in doubt, report any suspected non-compliant devices to the HPRA and incidents relating to the use of a medical device to the HPRA

## HPRA CONTACT INFORMATION

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