

What should I do if a customer contacts me about an issue or incident related to the use of a device?

If a customer contacts you about an incident or problem related to the use of a medical device and if they suspect that the device poses a risk to their health and safety, you should advise them to stop using it where possible. They should report the problem to their healthcare provider, the HPRA and the manufacturer of the device. Any unexpected problem or malfunction that may affect health, that causes or contributes to an injury, or that leads to incorrect follow-up / treatment should be reported to the manufacturer for investigation.

Members of the public and healthcare professionals can report incidents to the HPRA by filling in our online user report form on www.hpra.ie. They can also request printed copies of the form from the HPRA.

Further information

If you have any questions about the regulation of medical devices, or queries about any particular products, please e-mail devices@hpra.ie

This is one in a series of information leaflets that you can get from the HPRA and from our website: www.hpra.ie.

The Health Products Regulatory Authority (HPRA)

Our role is to protect and enhance public and animal health by regulating medicines, medical devices and other health products.

What does the HPRA do?

As the regulatory authority, we monitor the safety of all medical devices available in Ireland. Our aim is to make sure that these products do not compromise the health and safety of the patient or the person using them. We also work to ensure that medical device manufacturers comply with all safety regulations.



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A GUIDE FOR RETAILERS

Selling Medical Devices in Ireland

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I sell medical devices, why should I read this leaflet?

Medical devices are available in a wide range of retail outlets from specialist suppliers to pharmacies, supermarkets and discount stores. The Health Products Regulatory Authority (HPRA) has developed this leaflet to highlight the important role retailers can play in ensuring that medical devices sold in Ireland are safe and comply with relevant laws.

What is a medical device?

A medical device is a healthcare product or piece of equipment that a person uses for a medical purpose. It is not a medicine or drug. Medical devices can diagnose, monitor or treat disease and help people with physical impairments become more independent.

Examples of medical devices include plasters and bandages, thermometers, contact lenses, pregnancy tests, wheelchairs and crutches, blood pressure meters, blood glucose meters, and more complex equipment like cardiac defibrillators and HIV testing kits.

As a retailer, what should I look out for when sourcing medical devices?

- That the text on the label is in English.
- That the device has a CE mark on the label, packaging or the device itself. As well as the CE mark, some devices must also show a four digit number to confirm that they meet important safety and design standards. These include devices that measure something (for example a thermometer) and those that are supplied in a sterile state (for example some bandages or plasters).
- A European address on a CE marked device. This is a legal requirement.
- That the expiry date, where this is relevant to the product, has not passed.
- That you are buying your stock directly from a manufacturer, an authorised dealer or from a reputable supplier.
- The presence of elaborate or unexpected claims about a medical device. Be wary in these cases as it is unlikely such claims are true.

A valid medical device bears a CE mark, which indicates that it meets the basic requirements for safety and effectiveness under European law.

If you have concerns that a medical device does not comply with the legal requirements, some of which are listed above, you can request further information and documentation from the manufacturer. For example, ask to see both the declaration of conformity and the CE certificate.

CE These documents confirm that the product meets the legal requirements that are in place.

What records do I need to keep?

It is recommended that retailers keep records of all their suppliers of medical devices as well as details including the names of products and the quantities received. These records will be important in the event that an unsafe product is placed on the Irish market and a retailer is requested to cooperate with their supplier and with the HPRA in recalling the product from the market.

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