

How to report an incident to the HPRA

If a medical device poses a risk to your health and safety, stop using it where possible and report the problem to your healthcare provider, the HPRA and the manufacturer of the device. You should report any unexpected problem or malfunction that may affect your health or cause or contribute to an injury, for example a blood glucose meter giving an incorrect blood glucose reading, leading to incorrect treatment.

You can report incidents to the HPRA by filling in our online user report form on www.hpra.ie. If you would prefer to fill out a printed copy of the form, you can download it from our website or request a copy by phone or e-mail.

More information

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.

(The HPRA cannot provide advice on which medical devices you should buy.)



Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
Phone: (01) 676 4971
Fax: (01) 634 4033
E-mail: devices@hpra.ie

www.hpra.ie



MEDICAL DEVICES

Buying medical devices for personal use



Our advice

OUR ADVICE ON

Buying medical devices for personal use

More and more people now buy or lease medical devices for use at home.

This leaflet highlights some key points to consider for using medical devices effectively and safely at home or on holiday.

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 wheelchairs, contact lenses and solutions, blood pressure meters, blood glucose meters and pregnancy test kits and complex equipment like infusion pumps, hip implants, coronary pacemakers and artificial heart valves.

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

Buying a medical device

People usually buy a medical device for personal or home use after specific advice from a doctor or other healthcare professional. If you are buying a medical device without specific medical recommendations, it is very important to understand what benefit, if any, the device will have, as all medical devices carry some risk. You should only buy medical devices from recognised suppliers, distributors or manufacturers. A healthcare professional should be able to advise you about this. If you buy a medical device on the internet, there is a greater risk that it may not meet basic safety requirements.

All valid medical devices must bear a CE mark for the specific medical purpose claimed.

What can the device do?

People using medical devices should know what the device can and can't do.

Some products may not deliver the health benefits they claim and may, in fact, pose a safety risk to users. People shopping for medical devices should be wary of products that claim to have a number of health benefits or are capable of diagnosing or treating many different medical conditions. These products may be bogus and might have no evidence to support their claims.

First of all, check if the device has a CE mark. Check with your GP or another healthcare professional if you are unsure of a product's use and how suitable it is for you.

Safety tips

Before buying a device, it's important to make sure that it will perform safely and effectively.

- Make sure the device is suitable for your medical condition.
- Get a demonstration of how to use the device – especially if it's a complicated device or procedure.
- Make sure you understand any instruction booklet provided by the manufacturer.
- Register the device and fill in any warranty or guarantee cards. It is important that you can be contacted if there has been any manufacturing fault or other safety issues arise.
- Keep the device in good condition by following instructions about service and maintenance. Keep a record of the service history.
- Store the device according to the manufacturer's instructions. Incorrect storage conditions, for instance the wrong temperature or humidity, could affect how the device works or give you incorrect results.
- Make sure you have everything you need. For instance, find out if the device needs anything else to make it work such as test strips, batteries and so on.
- Contact the distributor or manufacturer to arrange for repairs if your device breaks down. If you think the breakdown might have affected your health, you should report this to the HPRA.
- If you are concerned about a result given by a medical device, seek medical advice.