HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Information Notice

Medical Devices

Caution when Purchasing Medical Devices

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ISSUE

It has come to the attention of the HPRA that medical devices which may not meet the necessary construction, performance and safety requirements are being purchased for use in Ireland. The HPRA would like to emphasise that those purchasing medical devices take appropriate precautions.

A medical device is a healthcare product or piece of equipment that a person uses for a medical purpose. Medical devices can diagnose, monitor or treat disease and all medical devices placed on the Irish market must bear a CE mark. Higher risk medical devices will have a four digit number displayed alongside the CE mark. This four digit number represents the number of the notified body who has certified the product as being compliant with the relevant legal requirements. Devices which are not appropriately CE marked may not be placed on the Irish market.

The HPRA is aware a number of medical devices that are not compliant with medical devices legislation are available for purchase, in particular online. Examples include (but are not limited to); HIV test kits, dermal fillers (hyaluronic acid), condoms, pregnancy tests, syringes, needles etc.

The HPRA would recommend to take precautions when purchasing medical devices, in particular when purchasing on-line, and purchase from a reputable source. Devices should be appropriately CE marked to avoid potential harm to patients and / or users.

For further information please refer to a dedicated medical device brochure relating to 'Buying medical devices online', which is available for download from www.hpra.ie

RECOMMENDATIONS

The HPRA advises that users:

1. Purchase medical devices from reputable sources. Try to buy directly from the manufacturer or an authorised distributor.

2. Ensure that devices bear a CE mark, and where appropriate also have a notified body number affixed.

3. Check the required information is available on device labelling, including:
   - Manufacturer contact details
   - European authorised representative details, if the manufacturer is located outside of Europe
   - Relevant symbols (for example the sterile symbol should be present for devices supplied in a sterile condition, the do not reuse symbol should be present for single use devices, expiry date etc)

4. Check device information is provided in the English language.

5. If in doubt, request further documentation from the supplier (for example the declaration of conformity and EC certification).

6. Report any suspected non-compliant devices to the HPRA.

7. Report any incidents relating to the use of a medical device to the HPRA.

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