HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Information Notice

Medical Devices

Caution when Purchasing Dental Devices Online

CE

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ISSUE

It has come to the attention of the HPRA that medical devices which may not meet the required performance and safety standards are being purchased over the internet for use in dental practices. The HPRA would like to emphasise that medical devices should be purchased from a reputable source.

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 online. Examples include (but are not limited to); contra angle dental hand-pieces, dental intra oral cameras, dental implants (fixation screws), x-ray units etc.

The HPRA has been informed that non-CE marked portable dental x-ray units were purchased for use in Irish dental practises, which when tested were shown to lack sufficient shielding in the x-ray tube. This could give rise to high patient / operator radiation doses. It was also found that such x-ray units did not meet the expected standards of construction and electrical safety.

The HPRA would recommend that dentists, and others in the dental profession, take precautions when purchasing dental devices. 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 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, etc)

4 Check device information is provided in the English language.

5 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.

HPRA CONTACT INFORMATION

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