BDIA

Importing Dental Products FAQs

About Us

The British Dental Industry Association (BDIA) is the UK' s trade association representing manufacturers and suppliers of dental product, services and technologies. With over a century of experience, the BDIA plays a key role in shaping the dental industry through its strong regulatory input and close collaboration with government bodies, regulators, and stakeholders.

Q. Can I import medical devices from outside of Great Britain?

A. The importation and supply of medical devices in Great Britain is strictly regulated.

Direct personal importation of medical devices from outside of Great Britain may fail to comply with the Medical Devices Regulations 2002 (UK MDR).

Medical devices imported in this way may not meet the requirements of the UK MDR 2002 and these devices may not be registered with the Medicines and Healthcare Products Regulatory Agency (MHRA).

Q. What are the requirements for an importer of medical devices?

A. Importing a medical device from outside of Great Britain comes with a set of legal requirements and obligations.

Any importer of a medical device, including a member of the dental team, must inform the relevant manufacturer or that manufacturer's UK Responsible Person (UKRP) of their intention to import a device. The manufacturer or their UKRP must then provide the Medicines and Healthcare Products Regulatory Agency (MHRA) with the importer's details.

This process ensures that the regulator knows what products are being placed on the market in Great Britain and how they are entering the country.

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Q. The product I want to purchase is CE marked, does that mean I can import it?

A. A product bearing a CE mark does not necessarily mean it can be legally placed on the Great Britain market.

All medical devices must be registered with the MHRA before being placed on the Great Britain market. Registration can only be completed by the manufacturer of the medical device where the manufacturer is based in the UK, or their UK Responsible Person if they are based outside of the UK.

If a medical device has not been registered with the MHRA it cannot be lawfully placed on the Great Britain market.

In addition, products may have the CE mark applied in relation to a wide range of EU requirements, such as the Low Voltage Directive, and so the presence of the CE mark does not necessarily mean that a product is compliant with the legal requirements for a medical device.

Members of the dental team should also be aware of the risks associated with counterfeit dental devices, which may fraudulently apply the CE mark. For more information see our FAQ document on counterfeit and non-compliant devices and other resources as part of our Counterfeit, Substandard Instruments and Devices Initiative (CSIDI) campaign.

Q. If I am only importing medical devices for use within my own dental practice, do these requirements still apply?

A. Yes. Any medical device products imported for use in a dental practice must be registered with the MHRA, and their importer must inform the manufacturer or their UK Responsible Person of their intention to import the device.

If a medical device has not been registered with the MHRA it cannot be lawfully placed on the Great Britain market.

Registered dental professionals have an obligation to identify and follow these regulations under the GDC's Standard for the Dental Team (Standard 1.0: You must find out about laws and regulations that affect your work and follow them).

Q. Can I import medical devices for sale or supply to others?

A. No, not without taking on the legal status of an importer and informing the relevant manufacturer or their UK Responsible Person. All medical devices being supplied on the Great Britain market must be registered with the MHRA by the manufacturer or their UK Responsible Person.

If a medical device has not been registered with the MHRA it cannot be lawfully placed on the Great Britain market.

Registered dental professionals have an obligation to identify and follow these regulations under the GDC's Standard for the Dental Team (Standard 1.9.1: You must find out about laws and regulations that affect your work and follow them).

Q. How are these requirements enforced?

A. The importation, sale and supply of medical devices in the United Kingdom is governed by the Medical Devices Regulations (UK MDR), the General Product Safety Regulations 2005 (GSPR) and Medicines and Medical Devices Act 2021 (MMD Act).

Schedule 3 of the MMD Act also makes provision for a criminal offence for breaching a provision of the UK MDR. That criminal offence has not yet come into force, and until it is, section 12 of the Consumer Protection Act 1987 will continue to apply to breaches of the UK MDR, so that such breaches will continue to be a criminal offence.

The MHRA's enforcement powers allow it to exercise the investigatory powers, including powers of entry.

The General Product Safety Regulations 2005 might apply to consumer products that are also medical devices, where these products are not covered by the UK MDR. Therefore, if you are involved in the supply of medical devices that are intended to be used by a consumer, you need to understand your obligations under these regulations.

In addition, registered dental professionals have an obligation to identify and follow these regulations under the GDC's Standard for the Dental Team (Standard 1.0: You must find out about laws and regulations that affect your work and follow them).

Helpful Links and Resources

Check whether a manufacturer is registered with the MHRA
https://pard.mhra.gov.uk/manufacturer-search/

Guidance: Regulating medical devices in the UK
https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk