

Regulation of Medical Devices FAQs



About Us

The British Dental Industry Association plays an active role in supporting the regulation of dental and medical devices across the UK. We work closely with Government departments, the MHRA, and other key stakeholders, and our members are bound by our Code of Practice meaning that in choosing to do business with any of them you can have confidence that everything you buy is of guaranteed quality and provenance.

Q. What is a medical device?

A. 'Medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings.

In your dental practice, this can range from dental hand instruments to impression materials, composites, implants, handpieces, intra-oral scanners, x-ray units and more.

Q. How are medical devices classified?

A. Medical devices are categorised according to their risk classification, with devices in higher classifications being subject to additional regulatory requirements.

Some examples of risk classification include:

- Class I – intraoral camera, prophylaxis powder, operating light
- Class I reusable – probe, elevator, excavator
- Class IIa – handpieces, treatment unit, impression materials
- Class IIb – implants and abutments, x-ray devices
- Class III – devices with medicinal substances

Q. Who regulates medical devices?

A. Medical devices in the United Kingdom are regulated by the Medicines and Healthcare products Regulatory Agency (MHRA).

Manufacturers must register with the MHRA before placing their devices on the market. The MHRA has a range of investigatory and enforcement powers in relation to the regulation of medical devices.

Q. What is a Notified/Approved Body and what do they do?

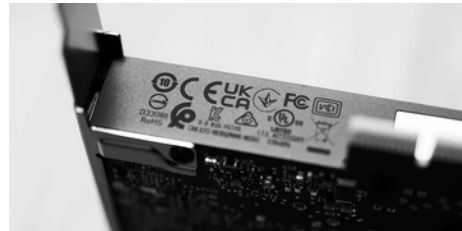
A. Manufacturers wishing to place a Class I medical device on the market are able to self-certify against the regulatory requirements. For all other device classifications (including Class I devices that are sterile, reusable or have a measuring function) the involvement of a conformity assessment body is required. In the EU, these are known as Notified Bodies while in the United Kingdom they are known as Approved Bodies.

These bodies are independent organisations that assess medical devices against the regulations before they are placed on the market.

Where a device displays the CE mark, a four digit number will identify the body that has carried out the conformity assessment for that device.

CE
0086

CE 0123



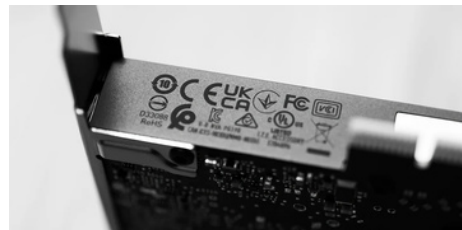
Q. What should appear on the label of a medical device?

A. Medical devices placed on the market in Great Britain must have a UKCA or CE marking, depending on which legislation the device has been certified under. Where relevant, this must also be accompanied by the number of the Notified/Approved Body that carried out the conformity assessment.

The label will identify the manufacturer of the device, and where a manufacturer based outside of the UK has placed a device on the market with the UKCA mark, the label must also show the details of their UK Responsible Person – their regulatory point of contact in the UK.

CE
0086

CE 0123



Q. What are my responsibilities as a dental professional in relation to medical device regulation?

A. registered dental professionals have an obligation to identify and follow relevant 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).

Ensuring that the medical devices in use at your practice are compliant with the regulations helps to protect the safety of your patients.

The use of counterfeit or non-compliant devices may jeopardise your professional registration, and could lead to a fitness to practise investigation by the General Dental Council.

You may also have additional responsibilities if you are manufacturing custom-made medical devices or if you are considering importing medical devices. Please see our FAQ documents on [chairside manufacturing](#) and [medical device importation](#).

Helpful Links and Resources

Regulating medical devices in the UK

<https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market>

EU Notified Bodies for medical devices

<https://webgate.ec.europa.eu/single-market-compliance-space/notified-bodies/notified-body-list?filter=legislationId:34,notificationStatusId:1>

UK Approved Bodies for medical devices

<https://www.gov.uk/government/publications/approved-bodies-for-medical-devices/approved-bodies-for-medical-devices>