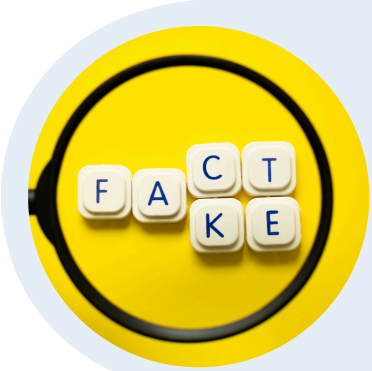
BDIA

Counterfeit and non-compliant devices FAQs



About Us

The British Dental Industry Association is committed to protecting the dental industry and patients from the risks posed by counterfeit and non-compliant dental devices. We work closely with regulators and enforcement bodies to raise awareness and promote compliance. BDIA members are bound by of 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 meant by a non-compliant device?

A. A medical device is non-compliant if it has been placed on the market in Great Britain despite not meeting the requirements of the Medical Devices Regulations 2002 (UK MDR).

Examples of non-compliance include:

- Devices that have not been registered with the Medicines and Healthcare products Regulatory Agency (MHRA).
- Devices that have not received appropriate CE or UKCA certification.
- Devices that have received CE or UKCA certification relating to other product legislation (such as electrical requirements) but not for medical devices.
- Devices where CE or UKCA certification has expired.
- Counterfeit devices.

The supply of non-compliant devices is illegal. Purchasing and using these devices could put your patients and your professional registration at risk.

01494 782873 bdia.org.uk info@bdia.org.uk

Q. What is meant by a counterfeit device?

A. A counterfeit device is one that is fraudulently imitating another manufacturer's product and intellectual property. These products are intended to trick buyers and users into thinking that they are using a device from a reputable manufacturer by using their design and branding.

While counterfeit devices may appear superficially similar to the genuine products, they are not manufactured in accordance with legal requirements and will not have the same quality, safety or performance.

All counterfeit devices are non-compliant, but not all non-compliant devices are counterfeit.

Q. How can I tell whether a device listed for sale is counterfeit or non-compliant?

A. Before purchasing a device, make sure that you are undertaking appropriate checks and precautions:

- Only purchase from reputable suppliers, such as BDIA members
- Consider the price – if it looks too good to be true, it probably is
- Is the manufacturer registered with the MHRA? Try checking the MHRA's registration database.
- Ask the manufacturer or supplier whether they can provide details of the device's certification.

Q. How can I tell whether a device I have purchased is counterfeit or non-compliant?

A. If you already have any equipment that you suspect might be substandard or fake, there are a couple of questions to ask yourself:

- Did you pay a price that was drastically out of line with the normal price for the product?
- Did you buy it through an Internet dealer or supplier that you didn't know?
- Now compare it with a similar product you know to be genuine
- Check the weight – copies made with cheap alloy are often much lighter
- Finish – look for rough edges or poor quality laser etching
- Has the item failed in use? Some substandard hand instruments have bent or even broken when put under some pressure
- Has the item been supplied with a UK charging/power plug? If not, it is non-compliant
- Look at the CE mark – there usually is one, but are you sure it is genuine, or even the correct one?
- The paperwork – are the labelling and instructions for use in English?
- Is the manufacturer registered with the MHRA? Try checking the MHRA's registration database.

Q. I suspect that a medical device is counterfeit or non-compliant. What should I do?

A. If you encounter a device that you suspect could be counterfeit or non-compliant:

- Do not use the device – doing so could put your patients and your professional registration at risk.
- Report the device to the MHRA using the Yellow Card reporting scheme.

Q. What are the risks of using counterfeit or non-compliant devices?

A. Counterfeit or non-compliant devices put you and your patients at risk through poor quality, safety and performance. The risks associated with their use include:

- Safety – counterfeit or non-compliant devices failing while in use risk injuring patients, and could contain harmful substances
- Professional registration – 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. Registered dental professionals have an obligation to identify and follow medical device 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).
- Poor reliability – counterfeit or non-compliant devices risk being of poor quality and may break or wear out prematurely.
- Service and repair – counterfeit and non-compliant devices may have poor after-sales support and may not be able to be repaired should something go wrong.
- Liability – using counterfeit or non-compliant devices may put you at risk by invalidating your professional indemnity insurance.

Helpful Links and Resources

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

Report a suspected counterfeit or non compliant device
https://yellowcard.mhra.gov.uk/