

# Devices Regulation - Background

The number and range of medical devices is vast and includes most healthcare products, other than medicines, used for the diagnosis, prevention, monitoring and treatment of disease, injury, or disability. Medical devices cover everything from artificial hips to wound dressings, incubators to infusion pumps and MRI scanners to scalpels.

In this document we refer to two types of medical devices, these are:

- a. **General medical devices** - used for the diagnosis, prevention, monitoring and treatment of disease, injury, or disability (see glossary for full definition). This includes active implantable medical devices
- b. ***in vitro* diagnostic medical devices (IVDs)** – used for the *in vitro* (outside of a living organism) examination of specimens from the human body (see glossary for full definition)

Where we have used the term 'medical device' or 'device' it can be assumed that we are referring to both types of medical device.

Under the current regulations, a medical device cannot be marketed in Great Britain without carrying a UKCA or a CE marking (with some exceptions - e.g. custom-made devices). A medical device cannot be marketed in Northern Ireland without a CE mark and EU rules applying to medical devices need to be met (also with some exceptions, e.g. for custom-made devices).

A CE marking indicates that the medical device meets the requirements of applicable European Union (EU) legislation. The MHRA will accept the CE marking for medical devices placed on the Great Britain market until 30 June 2023. You can read more about this [here](#). A UKCA marking is applied by the manufacturer and means that the medical device meets the requirements of the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations) and, when used as intended, works properly and is acceptably safe.

For all but the lowest risk medical devices, such as unmedicated bandages, conformity to the required standards must be verified by an independent certification body, called an Approved Body, before the UKCA marking can be affixed. The MHRA is responsible for designating Approved Bodies and audits them to ensure that they perform to high standards.

Manufacturers must be able to support their performance claims for the medical device. In many cases, including for higher risk medical devices, this information will come from a clinical investigation (for general medical devices) or performance study (for IVDs) of the medical device.

Once a medical device is on the market, the manufacturer must continue to assess the safety and performance of that medical device. This is known as 'post-market surveillance'. The manufacturer should also report certain incidents involving the medical device to the MHRA. This is known as 'vigilance'.

You can read more about existing requirements for placing a medical device on the UK market in MHRA guidance [here](#).

This consultation covers all parts of medical device regulation from pre-market approval of medical devices, supply of medical devices to the market and post-market monitoring of medical devices. Some parts of the consultation are technical in nature.

The MHRA welcomes all feedback it receives regarding this consultation. Respondents are able to comment on particular sections that are of interest – they are not required to review and respond to the entire consultation document.