Regulation stage

General medical device and active implantable medical devices guide

General medical device and active implantable medical devices

If your product is a general medical device, or an active implantable device, you need to determine which class your device is in. Guidance is available from the MHRA.

Examples include:

Class I: Low risk (examination lights, bandages, syringes without needles).

Class IIa: Medium risk (standard hearing aids, suture needles and short-term corrective lenses). Includes software which provides information that may be used to make a diagnosis, clinical decision or for therapeutic purposes.

Class IIb: Medium risk (apnoea monitors, ventilators, surgical lasers). Software classification is similar to Class IIa, but includes software which informs clinical decisions that might result in serious harm or require a surgical intervention.

Class III: Higher risk (pacemakers, total hip joint replacement system, breast implants, contraceptive IUDs, devices containing medicinal substances). Includes software, which informs clinical decisions that could lead to irreversible deterioration of a health condition or death.

If your product is a general medical device or an active implantable device and it is in Class IIa, IIb, III, or is a Class I device that is sterile or has a measuring function, then you will need to contact a UK approved body or EU notified body. They can carry out the necessary assessments to ensure your device meets the regulatory requirements for its intended use.

UK approved bodies can certify devices for England, Wales and Scotland through UKCA mark certification. The UKCA mark is a UK product marking (introduced in January 2021) for goods placed on the market in Great Britain. The UKCA mark covers most goods which previously required the CE marking. The UKCA mark is not recognised by the EU market. To certify a device for both UK and EU markets you will need to use an EU notified body. Find out more about using the UKCA marking. CE marks for medical devices are currently valid in the UK until at least 2028, after which a UKCA mark will be required.

In Northern Ireland, medical devices must have either a UKNI mark or a CE mark.

UK approved bodies are designated by the MHRA to ensure that manufacturers comply with the regulations set out in UK MDR 2002. If the device meets the regulatory requirements, then the UK approved body has the authority to issue an UKCA certificate. The manufacturer should add the UKCA mark to their device when certification has been provided and register the device with the MHRA. The device can then be placed on the market in England, Wales and Scotland.

If you have a Class I general medical device that is not sterile and does not have a measuring function, you can self-certify your device for the UKCA as outlined below:

- confirm that your products are Class I medical devices as described in Part II of the UK MDR 2002, Annex IX (as modified by Part II of Schedule 2A to the UK MDR 2002)
- check that your products meet the relevant essential requirements of Part II of the UK MDR 2002, Annex I (as modified by Part II of Schedule 2A to the UK MDR 2002)
- carry out a clinical evaluation as described in Part II of the UK MDR 2002, Annex X (as modified by Part II of Schedule 2A to the UK MDR 2002)
- notify the MHRA of any proposals to carry out a clinical investigation to demonstrate safety and performance
- prepare technical documentation
- draw up the declaration of conformity
- put the UKCA mark on your device as described in Regulation 10 of the UK MDR 2002
- register the device with the MHRA
- implement and maintain corrective action and vigilance procedures including a systematic procedure to review experience gained in the post-production phase
- provide relevant documentation if requested by the MHRA

You will need strong quality management and risk management systems for successful certification of medical devices. The requirements for these systems in UKCA-marked medical devices are harmonised with international standards ISO 13485 and ISO 14971 respectively.