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Find out how to enable JavaScript for Windows, or how to enable JavaScript for Mac.

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Regulation stage

General medical device and active implantable medical devices guide

General medical device and active implantable medical devices

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:

- Class I - generally regarded as low risk
- Class Ila - generally regarded as medium risk
- Class llb - generally regarded as medium risk
- Class Ill - generally regarded as high risk

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.

UK approved bodies can certify devices for the UK market by issuing an UKCA certificate. This is an 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.

The 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 and register the device with the MHRA. The device can then be placed on the Great Britain market.

If you have a class I general medical device that is not sterile and does not have a measuring function, then 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

Support links

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