Developers guidance

UKCA marking requirements for medical devices

This is required guidance

It is legally required and it is an essential activity.

This Guide covers:

- Great Britain (England, Scotland, Wales)

From:

- Medicines and Healthcare products Regulatory Agency (MHRA)

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To place a medical device on the market in England, Wales or Scotland you must show it meets certain regulations.

Why you need a UKCA mark

The UK Conformity Assessed (CA) mark shows your device meets the requirements of the UK Medical Device Regulations 2002 (UK MDR 2002). If you do not know whether your technology is a medical device, read determining if a technology is a medical device.

You should get a UKCA or relevant CE mark before placing a medical device on the market in England, Wales or Scotland. This is required by law. Different legislation is in place for medical devices in Northern Ireland – see GOV.UK for regulation of medical devices in Northern Ireland.

If you do not comply with the UK MDR 2002, the Medicines and Healthcare products Regulatory Agency (MHRA) has enforcement powers to hold you accountable. Serious non-compliance can result in criminal prosecution and civil sanctions against you. The MHRA also has powers to remove unsafe devices from the market.

Getting a UKCA mark

To get a UKCA mark for your medical device you should:

- work out the risk classification for your device
- read all the relevant legislation that applies to your class of device
- generate evidence and documentation, and
- prove you've met the requirements

If you do not know the risk class for your device, see determining if a technology is a medical device.

Identifying which requirements are relevant to your device

To get a UKCA mark you must meet the essential requirements relevant to your device in the UK MDR 2002. You should identify which regulations apply to the intended use of your device.

The 3 main types of medical devices and their requirements are:

- General medical devices – see Part 2 of the UK MDR 2002
- Active implantable medical devices – see Part 3 of the UK MDR 2002
- In vitro diagnostics medical devices – see Part 4 of the UK MDR 2002

Proving you've met the requirements

You must prove your medical device meets the relevant requirements. You do this by providing a declaration of conformity. You can self-assess for a Class 1 device. But higher-risk class devices must have a conformity assessment done by an approved body.

Having a conformity assessment

The type of conformity assessment depends on the risk class for your device.

Use the conformity assessment routes guide on GOV.UK to find the route to conformity assessment for your class of device. For the purposes of this guide, read:

- 'CE marking' as 'UKCA marking'
- 'Competent Authority' as 'MHRA'
- 'Notified body' as 'approved body'

There are several approved bodies in the UK that you can choose from. Make sure your chosen body is qualified and experienced in certifying devices of your class. You can search the register of UK conformity assessment bodies to find an appropriate body.

Preparing for the conformity assessment

You must create documentation that references each requirement and how you've met it. You can create most of this documentation from your Quality Management System (QMS) processes. If you've not set up your QMS, do it before or in parallel with the device documentation. This makes sure you use systematic approaches.

You must show evidence of:

- Processes
- Risk management systems
- Device design
- Device development
- Clinical evaluation

You must follow the regulations before placing your device on the market.

After passing your conformity assessment

Once you've passed your conformity assessment, you'll receive a certificate from your approved body.

After you get your certificate, you should:

- place the UKCA mark on your device
- place the identification number of the approved body on your device, and
- register yourself and your device with the MHRA

If your device changes after it's been placed on the market, you must reassess to make sure you're still meeting the requirements.

This information is not intended to replace formal statutory guidance regarding legal requirements. For an authoritative view of what regulations require beyond this digest, please see the relevant gov.uk web pages pertaining to the MHRA.

