Developers guidance

Understanding UK MDR 2002 regulations 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)

To place a medical device on the market, there are certain requirements you need to meet.

Medical devices: Complying with UK law (UK MDR 2002)

UK law specifies requirements that legal manufacturers of medical devices must meet to legally place a device on the market.

These requirements are set out in the UK Medical Device Regulations 2002 (UK MDR 2002). They apply to all digital technologies meeting the definition of a medical device in the UK.

The regulations make sure that medical devices placed on the UK market are safe and effective for patients, the public, and health and care professionals.

Understanding these regulations will help you to plan the development of your medical device more effectively and avoid wasting time and resources.

Medical devices that comply with the law encourage public trust. This has a positive effect on adoption rates and investment in innovation.

Non-compliance can lead to:

- prosecution
- removal of your device from the market
- delays in development and adoption of your device
- damage to your reputation

How to make sure you conform with the UK MDR 2002

You should start thinking about the UK MDR 2002 during the conceptualisation stage of your device. This will help you plan for compliance, engineering and evidence generation. If your digital technology is considered to be a medical device ('in scope') the requirements of the legislation apply throughout its entire lifecycle.

Step 1: what parts of the UK MDR 2002 apply

Determine which parts of the legislation in the UK MDR 2002 applies to your device when defining its intended purpose.

This could be:

- Medical Devices
- Active Implantable Medical Devices, or
- In Vitro Diagnostic Devices

Step 2: medical device documentation

Think about how to show that your device conforms with the essential requirements of the relevant legislation. This is done by creating and maintaining documentation and processes based on the risk classification of the device and the conformity route that you choose.

Step 3: medical device assessment

Consider how your device will be assessed. For low-risk devices (Class 1), you will be able to self-certify. Higher-risk devices (Class 2a, 2b and 3) and class 1 devices with additional considerations (such as a measuring function) are assessed by an approved body. These approved bodies are governed by the same legislation and overseen by the Medicines and Healthcare products Regulatory Agency (MHRA).

Successful assessment will allow you to assign a UKCA mark to your device. You will declare that to the best of your knowledge its benefits outweigh the risks, which have been minimised.

Is your digital technology a medical device?

Think about how close your technology is to being a medical device, even if it does not currently meet the criteria. Your technology may become a medical device if functionality is added over time. An example would be added functionality in response to changes in user requirements if used in a slightly different population. Be aware of this possibility and plan for it in your technology development strategy.

Resources:

Stay up to date with the MHRA's latest guidance on regulating medical devices in the UK.

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.