The UK Medical Devices Regulation 2002, (SI 2002 No 618, as amended) (UK MDR 2002)

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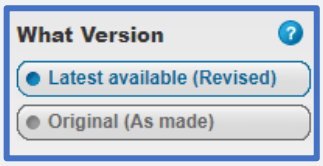
UKCA marking

The requirements for UKCA (UK Conformity Assessed) marking of medical devices are described in the UK MDR. UKCA marking is currently one of the routes to market that manufacturers can use to place their products on the market of Great Britain (England, Wales and Scotland). It applies to most goods that previously required CE marking. The marking is currently only recognised in Great Britain.

UK MDR

The UK MDR describes the conformity assessment requirements for medical devices. The website has the original version, as made, and the latest revised version. This can be selected on the left panel:



It is worth noting that this legislation is regularly updated and it is important to go back to the source in the link above to stay up to date with requirements.

The requirements are currently founded on the European Directives transposed into UK law through this Statutory Instrument (SI No 618):

- Medical Device Directive 93/42/EEC (MDD)
- Active Implantable Medical Devices Directive 90/385/EEC (AIMD)
- In vitro diagnostic medical devices Directive 98/79/EC (IVDD).

It is worth noting that the links above are to the UK government copies of these documents.

Part I of the UK MDR is an introduction to the SI, including interpretation and scope. There is also a section on translational provision, covering the implementation of the requirements.

The UK MDR describes how the MDD, AIMD and IVDD are implemented in the UK in parts II, III and IV, respectively. Further content is described in Schedule 2A at the end of the document.

Part V describes the requirements for Approved Bodies and part VI includes fees. For manufacturers, these include fees for clinical investigation notices and medicinal consultations. Part VII describes enforcement and other requirements.

In addition, there are schedules at the end of the document, including association agreements, and mutual recognition agreements.

MHRA publications

The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK competent authority responsible for regulation of medicines, medical devices and blood components for transfusion.
MHRA has produced guidance on regulating medical devices in the UK, including implementation of the future regulations (see below).
Some guidance is relevant for specific manufacturers, for example, virtual manufacturing. Within these guidance documents are specific requirements, such as labelling, that manufacturers must meet.

Declaration of conformity

The publications by the UK Government state the conformity requirements for medical devices being placed on the market of Great Britain. The manufacturer is responsible for checking conformity and making a declaration of conformity to these requirements. Where the medical device is higher risk, third party conformity assessment by a UK approved body is required.

Designated Standards

The British government has designated a number of medical device related international standards for consideration in UKCA regulatory approval procedures. A list of the current designated standards is available here. By complying with a designated standard, a manufacturer can evidence that its products or services comply with the technical requirements of the UK legislation and, if necessary, claim the so-called presumption of conformity. It should be noted that the designated standards for UKCA may differ from those harmonised for CE marking under the European regulations.

Application of the UK MDR to products placed on the market under CE marking

The UK MDR currently allows medical devices with CE marking to be placed on the market of Great Britain. However, there are additional requirements to CE conformity assessment that the manufacturer must meet. These requirements include:

- Registration with MHRA
- For manufacturers outside of Great Britain, the appointment of a UK Responsible Person (UKRP)
- Labelling requirements
- Updating of the manufacturer's QMS to include reporting to MHRA and post market surveillance and vigilance in the UK.

It is also recommended that the manufacturer consider the UK state of the art. The UK state of the art is the benchmark used by the National Institute for Health and Care Excellence (NICE) in their technology appraisal. The technology appraisal evaluates methods and processes to provide recommendations, in the form of NICE guidance, on the use of new and existing medicines, products and treatments in the UK National Health Service (NHS). This assessment is important for devices that are intended to be used by the NHS.

The Future Regulations

The government intends to reform the regulatory framework for medical devices in the UK. They consulted on the future framework for medical devices regulation in 2021 and their response to the feedback received was published in June 2022. This response gives some insight into what the future regulations may look like.

A statutory instrument (SI) bringing in enhanced post market surveillance requirements has been laid in October 2024 and will come into force 6 months later in 2025.

The new future core regulations are then expected to be introduced through 2 separate SIs. It's anticipated that information about what will be covered in the first of these will be made available in 2025, with the SI coming into force thereafter. The second SI will then follow and is expected in 2026.

Should you have any questions, please do not hesitate to ask us using our enquiries email box dqs-uk@dqs.de

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