Developers guidance

Determining if a technology is a medical device

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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It's your responsibility as a developer to determine whether your digital healthcare technology is a medical device.

Definition of a medical device

To decide if your digital healthcare technology is a medical device, you'll first have to compare it against the full legal definition of a medical device in the UK Medical Device Regulations 2002 (UK MDR 2002).

In summary, a medical device is any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application, which is intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy or of a physiological process, or control of conception

A medical device does not achieve its main intended action by pharmacological, immunological or metabolic means although it can be assisted by these.

A medical device may be intended to administer a medicinal product or incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device.

If your technology is a software app, check GOV.UK's guidance on medical devices software applications. This gives information on how to decide whether your app is a medical device.

Understanding medical device risk classifications

The law classifies a medical device based on the level of risk associated with it. The higher the risk, the stricter the controls on its use will be.

These are the risk classifications for general software medical devices:

Class 1 – generally regarded as low risk

Class 2a - generally regarded as medium risk

Class 2b - generally regarded as medium risk

Class 3 - generally regarded as high risk

The risk classification applies to the device for its given intended purpose by following the classification rules and implementation aspects of the legislation. It must be stated in all labelling and registration activities.

The risk class of your device informs:

- what regulatory processes you should follow
- the evidence you need to generate over the device's lifecycle
- whether your device needs to be assessed by an approved body or you can self-assess that it meets legislative requirements, and
- the routes of conformity through the UK MDR 2002, which are only available to certain risk classes of medical devices.

Determining the risk classification for your medical device

When you decide your technology is a medical device, you have to determine its risk classification. This is the process of:

- reviewing and implementing the classification rules of the UK MDR 2002 against the intended purpose, and
- determining the appropriate risk classification of the medical device

To do this, you should:

- review the classification annex of the relevant legislation under the UK MDR 2002 to
  - locate the rules
  - determine which rules are applicable
- review the applicable rules against the intended purpose statement and relevant definitions, and
- follow the implementation rules within the classification annex

Misclassification of device risk may lead to compliance actions against your organisation. This could delay or stop you placing the medical device on the market, which may cost money and cause reputational damage.

For more information to help you determine the risk class of your medical device, see:

- the Medicines and Healthcare products Regulatory Agency's guidance on borderlines with medical devices
- the International Medical Device Regulators Forum
- our information on technical standards

Changes to your medical device

Changes to your medical device may affect its risk classification. These include changes to the technology's intended use, functionality or the use-environment. So, you should review these and reassess your technology regularly.

Note that even if you decide your technology is not a medical device, future changes could turn it into a medical device.

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.

