Adopters guidance

Thinking about whether a medical device will meet your needs

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This is best practice guidance

Although not legally required, it's an essential activity.

This Guide covers:

- Great Britain (England, Scotland, Wales)

From:

- AI and Digital Regulations Service

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You need to think about whether the medical device is fit for purpose and likely to meet your needs before deciding whether to adopt it.

Getting information about the device

You can ask the developer to provide information that helps you decide whether the device is right for you. The developer should have documents describing the device's functionality, limitations and risks. These will have helped it show compliance with the UK Medical Device Regulations 2002 (UK MDR 2002). The developer does not have to share these documents with you. But if it is open and transparent with this information, you may have greater trust in the developer and the device.

Understanding the intended purpose

You should make sure you understand the 'intended purpose' of the device; that is, what exactly it can be used for and the exact conditions under which it can be used. The developer should have written an intended purpose statement for the device. You can ask the developer for a copy of the statement. Sometimes you can find it in the regulatory certification documents or the instructions for use.

Understanding the intended purpose helps you decide whether the device is the right solution to a problem you are trying to solve. Be aware that using the device beyond its regulated intended purpose may have liability implications for your organisation and staff.

Understanding the medical device risk class

The developer should have used its intended purpose statement to help determine the medical device's risk class. These are Class 1, Class 2a, Class 2b or Class 3 (the higher the number, the higher the risk to patients).

A higher-risk device may have stricter controls on its use than a lower-risk device. If you are concerned that the risk class for the device is too low for its intended purpose or there is not enough evidence of safety, you can report this to the Medicines and Healthcare products Regulatory Agency (MHRA). See reporting safety issues about medical devices to the MHRA for more information.

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Understanding UKCA and CE marks

The UK Conformity Assessment (UKCA) mark shows the device meets the requirements of the UK MDR 2002. It helps you know the device is safe, performs as intended and that the benefits outweigh the risks.

To get the UKCA mark, the developer will have gone through a conformity assessment. The developer does this assessment itself for lowest risk (class 1) devices. Higher-risk devices are assessed by an approved body. There are several approved bodies in the UK and the developer should have chosen a suitable one to assess the specific type of medical device.

A developer based in Great Britain should have obtained the UKCA mark before placing the medical device on the market. This is a legal requirement. But developers in the European Union go through a similar process and get a European conformity (CE) mark. A CE mark for medical devices is currently recognised in Great Britain, so the device you are considering may have this instead of a UKCA mark. But there are limitations on recognition of CE marks based on the risk class and the specific legislation that applies to the device. If the device you are considering has a CE mark, not a UKCA mark, check our what's new page regularly for updates.

Checking MHRA registration

To place a medical device on the market the developer (or their UK Responsible Person) and the device must both be registered with the MHRA. You can check this on the MHRA's Public Access Registration Database.

Further reading

See the MHRA's guidance on regulating medical devices in the UK and implementation of medical devices future regime.

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