Developers guidance

Registering medical devices with the MHRA

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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Before you place medical devices on the market, you should register each device with the MHRA. Here's how.

Registering medical devices: why developers should do it

Registering your medical device with the MHRA is a legal requirement of the UK Medical Device Regulations (UK MDR 2002). Registering proves that medical devices comply with relevant regulation. You should register with the MHRA for each device you place on the market. If you are not in the UK, you should appoint a UK Responsible Person to do it for you.

Compliant devices encourage public trust, which 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 register medical devices with the MHRA

Register your medical device with the MHRA here. You should do this before placing your device on the market. You will have to pay a fee and may also apply to make amendments.

Registering medical devices if you are outside the UK

If you're a developer based outside the UK and wish to place a device on the Great Britain market, you should appoint a single UK Responsible Person who will take responsibility for the device in Great Britain. This applies only to developers in England, Scotland and Wales.

Doing this shows you are compliant with medical device regulations. You should do this before placing your device on the market.

Get further detail on the UK Responsible Person here.

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 gov.uk for information on the MHRA's enforcement duties.

