Developers guidance

What it means to place medical devices on the UK market

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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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Entry into the UK health and social care market can be challenging for developers of digital technologies driven by data and AI. What does ‘placing a technology on the market’ mean in relation to medical devices?

In the context of medical devices, placing a product on the market means making it available for use in the context of its intended purpose. its intended way. This includes devices provided for free.

To place medical devices on the market, you may need to advertise them directly to consumers and adopters. These could be local and/or national commissioners.

Once medical devices are placed on the market, they are subject to UK legislation relating to post-market surveillance and monitoring. Additionally, medical devices placed on the UK market are required to register with the MHRA.

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.

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