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[Skip to main content](#)

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Innovation Service

Menu

Q  
Search

Search on the Innovation Service

Q

X

Search

Close search

X

Close menu

- Menu
- [Home](#) >

- [Get support](#)



#### Further information on innovator support

- [Innovation Service](#)

Get personalised support

- [Innovation guide](#)

The key stages from creation to adoption

- [Funding your innovation](#)

Find potential funding opportunities

- [News](#) >
- [Case studies](#) >
- [About the Service](#) >
- [Sign in to the Innovation Service](#) >

1. [Home](#)
2. [Your guide to innovation in the NHS](#)
3. [Regulation](#)

[Back to Regulation](#)

Regulation stage

Medical devices guide

Downloaded on May 2nd, 2024

# Medical devices

## Medical devices

This guidance is specific to the provisions in Great Britain (England, Wales and Scotland). For information on how to comply with the legal requirements in Northern Ireland, please see the [MHRA guidance for Northern Ireland](#).

Medical devices are products or equipment that are used for medical purposes, but work differently to a medicine or a drug.

The clinical data required by regulators to demonstrate that a medical technology product performs as intended and is safe to use is dependent on the class of technology. Higher risk products require more extensive clinical evaluation and evidence standards before they can be launched onto the market.

There are three main types of medical devices:

- [general medical devices](#)
- [active implantable medical devices](#)
- [in vitro diagnostics \(IVDs\)](#)

Check if your innovation is a medical device, and which of the three main types it is. Further guidance is available:

- [medical device stand-alone software including apps](#)
- [borderline products- how to tell if your product is a medical device](#)

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