

Regulation stage

Medical devices guide

Downloaded on April 3rd, 2025

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 used for medical purposes but work differently to a medicine or 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 \(IVDs\)](#)

Technologies and products whose primary purpose is not medical may not be considered a medical device. For example, breast pumps, toothbrushes and insect repellents are not typically considered medical devices. However, a similar product may be considered a medical device if it is primarily intended for medical purposes. For example, a breast pump which is designed for the treatment of inverted nipples.

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](#)