NHS
Innovation Service

Regulation stage

Medical devices guide

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