Regulation stage

Registering your medical device with MHRA guide

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Medical devices, including IVDs and custom-made devices, need to be registered with the MHRA after they have been certified by an UK approved body, an EU notified body, or where they have been self-certified, and prior to being put onto the UK market. The MHRA performs market surveillance of medical devices in the UK.

There is a fee of £240 for each registration application. You will need to provide detailed information about the manufacturer and device when registering.

Manufacturer details:

- legal entity name and address as it appears on the device labelling or packaging
- company type (for example, limited company or sole trader)
- administrative contact, you can have up to 15 people with access
- a letter of designation for a UK Responsible Person (where applicable)

The letter of designation must be a legal contract, stating that you are the exclusive UK Responsible Person acting for the manufacturer and the mandatory tasks you are contracted to undertake on behalf of the manufacturer. The mandatory tasks that must appear in the designation contract can be found in regulatory guidance for UK Responsible Persons.

Device details when registering a device with the MHRA:

- which regulations apply
- the class of device you are registering
- Global Medical Devices Nomenclature (GMDN) code and term to describe your device
- basic unique device identification- device identifier (UDI-DI) (if applicable)
- medical device name (brand, trade, or proprietary name)
- model or version detail
- catalogue or reference number
- UK approved body (or EU notified body) where applicable
- attributes (such as sterility, contains latex, MRI compatible)

- copies of any applicable conformity assessments

Find out more about how to register your device with the MHRA.