Your guide to innovation in the NHS

Regulation stage

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Regulation

There are regulatory requirements that must be met before an innovation can enter the UK market. The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for ensuring that medicines and medical devices are effective and safe. All medical devices, including software, must be registered with the MHRA before they can be sold in the UK.

Medical devices are assigned one of four different classes, ranging from low risk (Class I) to high risk (Class III). Depending on the classification of your innovation, there will be different levels of evaluation required for the necessary regulatory approval.

Examples of medical device classification:

Class I: Low risk (examination lights, bandages, syringes without needles).

Class IIa: Medium risk (standard hearing aids, suture needles and short-term corrective lenses). Includes software which provides information that may be used to make a diagnosis, clinical decision or for therapeutic purposes.

Class IIb: Medium risk (apnoea monitors, ventilators, surgical lasers). Software classification is similar to Class IIa, but includes software which informs clinical decisions that might result in serious harm or require a surgical intervention.

Class III: Higher risk (pacemakers, total hip joint replacement system, breast implants, contraceptive IUDs, devices containing medicinal substances). Includes software which informs clinical decisions that could lead to irreversible deterioration of a health condition or death.

Digital health tools that may be medical devices include:

- patient-facing apps that enable self-management or remote monitoring of medical conditions such as diabetes or depression
- symptom checkers that offer medical advice based on information entered by a patient
- online digital tools to assist in diagnosis, e.g. a cloud-based software programme that identifies melanomas from dermatoscope images
- an app that advises on insulin dose based on a diabetic patient's blood glucose level and dietary input
- medical calculators and algorithms

If you would like to understand what regulations apply to digital health technologies (DHTs), and how to meet them, visit the AI and Digital Regulations Service. You can learn more about what regulations to follow and how to evaluate effectiveness. The website is aimed at both developers of AI and digital technology, or adopters who will buy or use DHTs in health and social care.

You can access support from the AI and Digital Regulations Service through the NHS Innovation Service.

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

General medical device and active implantable medical devices

If your product is a general medical device, or an active implantable device, you need to determine which class your device is in. Guidance is available from the MHRA.

Examples include:

Class I: Low risk (examination lights, bandages, syringes without needles).

Class IIa: Medium risk (standard hearing aids, suture needles and short-term corrective lenses). Includes software which provides information that may be used to make a diagnosis, clinical decision or for therapeutic purposes.

Class IIb: Medium risk (apnoea monitors, ventilators, surgical lasers). Software classification is similar to Class IIa, but includes software which informs clinical decisions that might result in serious harm or require a surgical intervention.

Class III: Higher risk (pacemakers, total hip joint replacement system, breast implants, contraceptive IUDs, devices containing medicinal substances). Includes software, which informs clinical decisions that could lead to irreversible deterioration of a health condition or death.

If your product is a general medical device or an active implantable device and it is in Class IIa, IIb, III, or is a Class I device that is sterile or has a measuring function, then you will need to contact a UK approved body or EU notified body. They can carry out the necessary assessments to ensure your device meets the regulatory requirements for its intended use.

UK approved bodies can certify devices for England, Wales and Scotland through UKCA mark certification. The UKCA mark is a UK product marking (introduced in January 2021) for goods placed on the market in Great Britain. The UKCA mark covers most goods which previously required the CE marking. The UKCA mark is not recognised by the EU market. To certify a device for both UK and EU markets you will need to use an EU notified body. Find out more about using the UKCA marking. CE marks for medical devices are currently valid in the UK until at least 2028, after which a UKCA mark will be required.

In Northern Ireland, medical devices must have either a UKNI mark or a CE mark.

UK approved bodies are designated by the MHRA to ensure that manufacturers comply with the regulations set out in UK MDR 2002. If the device meets the regulatory requirements, then the UK approved body has the authority to issue an UKCA certificate. The manufacturer should add the UKCA mark to their device when certification has been provided and register the device with the MHRA. The device can then be placed on the market in England, Wales and Scotland.

If you have a Class I general medical device that is not sterile and does not have a measuring function, you can self-certify your device for the UKCA as outlined below:

- confirm that your products are Class I medical devices as described in Part II of the UK MDR 2002, Annex IX (as modified by Part II of Schedule 2A to the UK MDR 2002)
- check that your products meet the relevant essential requirements of Part II of the UK MDR 2002, Annex I (as modified by Part II of Schedule 2A to the UK MDR 2002)
- carry out a clinical evaluation as described in Part II of the UK MDR 2002, Annex X (as modified by Part II of Schedule 2A to the UK MDR 2002)
- notify the MHRA of any proposals to carry out a clinical investigation to demonstrate safety and performance
- prepare technical documentation
- draw up the declaration of conformity
- put the UKCA mark on your device as described in Regulation 10 of the UK MDR 2002
- register the device with the MHRA
- implement and maintain corrective action and vigilance procedures including a systematic procedure to review experience gained in the post-production phase
- provide relevant documentation if requested by the MHRA

You will need strong quality management and risk management systems for successful certification of medical devices. The requirements for these systems in UKCA-marked medical devices are harmonised with international standards ISO 13485 and ISO 14971 respectively.

In vitro diagnostic medical devices

In vitro diagnostic (IVD) medical devices are usually a reagent, calibrator, apparatus, equipment or system used in vitro to examine specimens such as blood, tissue and urine for a clinical purpose. Examples include:

- pregnancy tests
- blood glucose monitors
- HIV test kits
- certain blood collection tubes
- immunoassays

IVDs include specimen receptacles, and products specifically designed for use in IVD examination, but not products which are for general laboratory use.

IVDs are regulated by Part IV of the UK MDR 2002 and all IVDs must be registered with the MHRA. There are four categories of IVDs, listed in order of perceived risk:

- general IVDs. This can include hormone tests and clinical chemistry tests
- IVDs for self-testing which are intended to be used by people in a home environment, excluding those that fall into the two categories below
- IVDs in the classifications stated in Part IV of the UK MDR 2002, Annex II List B (as modified by Part Ill of Schedule 2A to the UK MDR 2002). This includes reagents for measuring blood sugar and products for rubella, toxoplasmosis and phenylketonuria
- IVDs in the classifications stated in Part IV of the UK MDR 2002, Annex II List A (as modified by Part Ill of Schedule 2A to the UK MDR 2002). This includes reagents and products for HIV I and II, hepatitis B, C and D, and reagent products for determining ABO systems and anti-Kell, including those used to test donated blood, plus tests for screening

General IVDs can be self-certified, but all other IVDs need approval from a UK approved body or EU notified body before they can be registered with the MHRA and placed on the UK market. Find out more about the IVD directive and what regulatory approval your IVD needs to go through. CE mark certification for IVDs is valid until 2030, after which a UKCA mark will be required.

Further guidance is provided by the MHRA.

Registering your medical device with MHRA

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.

Medicinal product

Get in touch with the MHRA as soon as possible if your innovation is a medicinal product. You can access support from MHRA through the NHS Innovation Service. You should also register new medicines with UK Pharmascan. This supports the uptake of new medicines into the NHS. They will help you understand what is required from the marketing authorisation process and how to comply with the Human Medicines Regulations 2012.

Marketing authorisation is the process of reviewing and assessing the supporting evidence for a medicinal product in relation to its marketing. The process is finalised by the granting of a licence to be sold. The marketing authorisation process has a number of routes to follow and takes 6 to 12 months. The MHRA provides guidance on your application for a licence, which includes:

- MHRA fee and proof of payment
- Summary of Product Characteristics (SmPC) and label and leaflet
- Reference Medicinal Product
- Pharmacovigilance System Summary
- Risk Management Plan
- Active Substance Master File (ASMF)

If your application is for a new active substance, a pre-submission meeting with the MHRA 90 days before your intended submission is recommended. You can arrange this by emailing presubmission@mhra.gov.uk.

The Innovative Licensing and Access Pathway (ILAP) aims to accelerate the time to market, facilitating patient access to medicines. These medicines include new chemical entities, biological medicines, new indications and repurposed medicines. The ILAP works with UK-based and global developers of medicines (both commercial and non-commercial). The entry point into ILAP is the innovation passport application. This is open to medicines at the pre-clinical trial stage through to the mid-development programme point.

Surgical or invasive procedure

This applies to a new surgical technique or interventional procedure.

A new procedure must be a:

- surgical procedure (making a cut or a hole to gain access to the inside of a patient's body)
- procedure accessing the body cavity without cutting
- procedure using electromagnetic radiation, such as x-rays or lasers

It must also:

- be available within the NHS or independent sector, or be about to be used for the first time outside of formal research
- not yet be considered standard clinical practice

NICE publishes guidance on the use of interventional procedures in the UK. This guidance assesses the safety and efficacy of new techniques and procedures. Notify NICE about a new procedure or find out more about surgical innovations and advancing surgical care from the Royal College of Surgeons England.

Digital healthcare technologies

Digital healthcare technologies (DHTs) are apps, software, artificial intelligence (AI) and digital platforms or services used for health or social care. Some DHTs are considered to be medical devices.

Software is likely to be a medical device if:

- it results in a diagnosis or prognosis
- influences treatment and decision making, including calculating risk
- is linked to a medical device or medicine (potentially as an accessory)

Digital technology assessment criteria

The digital technology assessment criteria (DTAC) are the NHSE recommended criteria for NHS organisations to use when introducing new digital technologies. Companies demonstrating that they have met the requirements of DTAC are showing that they have met the minimum standards for:

- clinical safety
- data protection
- technical assurance
- interoperability
- usability and accessibility

Technical security requirements:

- cyber essentials certificate
- penetration testing
- custom code review
- multi-factor authentication
- logging and reporting

DTAC is available as a document which details the questions which developers must answer and guidance on how to do so. Further guidance on good practice in developing digital healthcare technologies is provided by the DHSC.

Artificial intelligence technology development standards

The international standard ISO/IEC 42001 was introduced as best practice for artificial intelligence management systems in December 2023 for organisations which are developing and using AI-based technologies, including in healthcare. ISO/IEC 42001 details the steps which companies should take as they establish, implement, maintain and improve these AI technologies, to provide confidence that their AI technologies are being developed in an open, ethical and transparent manner while managing any risks.

The key aims of ISO/IEC 42001 are:

- determination of organisational objectives, involvement of interested parties and organisational policy
- management of risks and opportunities
- ensuring suitable processes for the management of concerns related to the trustworthiness of AI systems, such as security, safety, fairness, transparency, data quality and quality of AI systems throughout their life cycle
- ensuring suitable processes for the management of suppliers, partners and third parties that provide or develop AI systems for the organisation

Adherence to ISO/IEC 42001 demonstrates to NHS organisations that your AI technology has been responsibly developed, implemented and maintained in compliance with legal and ethical regulatory standards, and that AI-specific risks are being managed effectively.

To understand what regulations apply to digital technologies and how to meet them, see the AI and Digital Regulations Service. This explains what regulations you need to follow, how to evaluate effectiveness, and how to generate evidence for the NHS organisations who will buy or use your technology.

If you are unsure about your innovation category

If you are unsure which category your innovation falls under, read the MHRA guidance on:

- how to tell if your product is a medicine
- how to tell if your product is a medical device