Obtain United Kingdom Conformity Assessed (UKCA) Mark via one of these pathways.

OR

Obtain European Union (EU) Conformité Européene (CE) Mark via one of these pathways.

Manufacturer performs a self-certification to demonstrate device conformity assessment in line with UK Medical Devices Regulations (MDR) 2002.

Class: I

Clinical evidence evaluation is required.

OR

UK-approved Notified Body conducts the formal UKCA Mark conformity assessment in line with UK Medical Devices Regulations (MDR) 2002.

Class: IIa, IIb, III

Clinical investigation may be required.

Manufacturer self-attests to technical and QMS requirements prior to 26 May 2021 via the EU Medical Devices Directive (**EU MDD**).

Class: I

(valid until 30 June 2028)

Clinical evidence evaluation may be required.

OR

Valid declaration and CE marking via the EU Medical Devices Directive (**EU MDD**)

Class: IIa, IIb, III

(valid until 30 June 2028)

Clinical investigation may be required.

OR

Manufacturer self-attests to technical and QMS requirements via the EU Medical Devices Regulation (**EU MDR**).

Class: I

(valid until 30 June 2030)

Clinical evidence evaluation is required.

OR

Engage with a qualified EU Notified Body to obtain CE Mark via the EU Medical Devices Regulation (**EU MDR**).

Class: IIa, IIb, III

(valid until 30 June 2030)

Clinical evidence evaluation is required, in addition to ***clinical investigation*** if manufacturer cannot demonstrate equivalence or MDR conformity.

Register with the European Database on Medical Devices (EUDAMED).

Appoint a single UK Responsible Person if based outside the UK.

Class: I, IIa, IIb, III

Register product with the Medicines and Healthcare products Regulatory Agency (MHRA).

Class: I, IIa, IIb, III

If appropriate, engage with England's National Institute for Health and Care Excellence (NICE) via one of these tools or pathways for DHT clinical and cost-effectiveness assessment.

Class: I, IIa, IIb, III

Engage with the National Health Service (NHS) for guidance on product commissioning.

Class: I, IIa, IIb, III

Tool:
Evidence Standards Framework (ESF) for DHTs

Note: Meeting ESF standard does not imply DHT has been assessed or endorsed by NICE.

Class: I, IIa, IIb, III

Clinical investigation may be required based on product risk.

Standard pathways:
Types of NICE guidance and advice include: diagnostics guidance, highly specialized technologies guidance, medical technologies guidance, technology appraisal guidance, and NICE guidelines.

Class: I, IIa, IIb, III

Clinical investigation may be required based on product risk.

Selective pathway:
Medical Technologies Evaluation Programme

Register first with the NHS Innovation Service.

Guidance for NICE priority areas
Class: I, IIa, IIb, III

Clinical investigation may be required based on product risk.

Selective pathway:
Early Value Assessment

NICE generates evidence plans for NHS priority areas and makes recommendations following data generation.

Class: I, IIa, IIb, III

Clinical investigation relying on real-world data is required.

Tool:
Digital Technology Assessment Criteria for Health and Social Care (DTAC)

Common baseline criteria for DHTs that can be used in new procurement processes or contract renewals

Class: all products

Clinical investigation may be required based on product risk.

Pilot (with MHRA & NICE): Innovative Device Access pathway (IDAP)

Limited number of select technologies receive tailored support on regulatory and access pathways.

Class: I, IIa, IIb, III

Clinical investigation is required.

Selective pathway:
Artificial Intelligence (AI) Award accelerates the testing and evaluation of AI technologies from initial feasibility to evaluation within the NHS.

Class: I, IIa, IIb, III

Clinical investigation may be required.

Program:
NHS Innovation Service

Service to connect technology innovators to several public sector organizations within the UK health care system

Class: I, IIa, IIb, III

Clinical investigation is not required to engage.

Note: The reimbursement route for a device or diagnostic depends on who the commissioner/provider of services for the target patient population is. This process may be done at national, regional, or organizational level depending on the product. There is no automatic funding direction associated with a NICE evaluation. Some devices associated with specialized services are reimbursed by NHS England at a national level with a funding mandate for specialized commissioners.

Pricing and reimbursement routes include:

Note: The vast majority of medical devices are locally commissioned.

Direct engagement during the appropriate phases of product development through launch with **local** entities such as:
- Health Innovation Networks (HINs)
- Integrated Care Systems (ICSs)
- NHS Trusts
- Primary Care Networks (PCNs)

Patient access options include:

Health Innovation Networks (HINs), formerly known as Academic Health Science Networks (AHSNs), are placed to identify and spread health innovation at pace and scale, driving the adoption and spread of innovative ideas and technologies across large populations.

OR

An innovation business partner, which aligns the business objectives of a start-up/technology company with the key health priorities of an NHS Trust.

OR

NHS England's Health Systems Support Framework (HSSF) that provides access for NHS and its partners to an extensive network of accredited third-party suppliers with expertise in essential support services. The scope of the HSSF is limited to non-clinical services and those that do not involve the direct provision of patient care.

OR

All suppliers of cloud services can apply to sell on the G-Cloud framework. A framework is an agreement between suppliers and government. All suppliers agree to the same terms when they apply.

Key

Step that applies to a **national** process

Step that applies to a **local** or **regional** level

Details regarding clinical data:

Clinical evidence evaluation *refers to the review of published data.*

Clinical investigation *refers to a systematic investigation or study undertaken to verify the safety and performance of a device.*

NO **national** pathways for DHTs