*For medical devices

Regulatory Requirements	Applicable	Source (UK MDR 2002)	Comment and Guidelines
Regulatory authority	Y	Medicines and Healthcare products Regulatory Agency (MHRA)	
Regulatory representative	Y	Part II (7A)	U.K. Responsible Preson (UKRP)
Device classification system	Y	Part II (7)	Class I (SC), Im, Is, IIa, IIb and III
Device regulatory pathway	Y	Part II (13) Schedule 2A (Part 2 - Annex II to VI)	Full or partial QMS, product verification, type examination
Device regulatory file	Y	Part II (Annex II, II or VII)	Technical Documentation needs to be drawn-up for every device
Labeling, UDI	Y	Schedule 2A (Part 2 - Annex I)	UKCA/Approved Body number or CE/Notified Body number, UKRP name and address. No UDI requirements in GB **for now**.
Clinical requirements	Y	Schedule 2A (Part 2 - Annex X)	A CER is required per MEDDEV 2.7/1 rev.4, with clinical investigations when no sufficient clinical evidence is available for the subject/equivalent devices
Local tests/clinical investigation (CI)	N	-	No need of local tests or local CI
Manufacturer and device registration	Y	Part II (7A)	Manufacturer and device registrations required with the MHRA before the device to be on the GB market
Quality management system (QMS)	Y	Schedule 2A (Part 2 - Annexes II, V, VI)	Full or partial QMS is required depending on the classification and regulatory pathway selected
Audit / inspection Device / QMS certificate renewals	Y	Schedule 2A (Part 2 - Annexes II to VI)	UKAB premarket & annual surveillance audits are required for the conformity assessment procedure (except for class I SC devices). MHRA monitors the UK market with inspections.
Reporting of significant changes	Y	Schedule 2A (Part 2 - Annexes II to VI)	Significant changes require to be reported to UKAB per the conformity assessment procedure
Reporting of vigilance & FSCA	Y	Guidance on vigilance	Within 2, 10 or 30 days via the MORE portal; FSCA needs to be reported before or at the initiation
Post-market surveillance	Y	MD (PMSR) (GB) Regulations 2024	Aligned with EU MDR with specific timeline for class I (3 years) - applicable from 16-June-2025
Retention policy	Y	Schedule 2A (Part 2 - Annexes II to VI)	5 years / 15 years (implantable devices)

*For medical devices

Type	Reference	Description
Regulation	UK MDR 2002	Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)
Regulation	*UK MDR 2019*	*The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019*
Regulation	*UK MDR 2020*	*The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020*
Regulation	*UK MDR 2023*	*The Medical Devices (Amendment) (Great Britain) Regulations 2023*
Regulation	*UK MDR 2024*	*The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024*
Guidance	Implementation of the Future Regulations	
Guidance	Regulating Medical Devices in the UK	
Guidance	Register medical devices to place on the market	
Guidance	Guidance on registration of certain medical devices which are reusable Class I devices, upclassified Class I devices, and/or reliant on expired/expiring CE certificates	
Template	EU MDR Article 120 extension confirmation	
Guidance	Medical devices: guidance for manufacturers on vigilance	
Guidance	Guidance on Class I medical devices	
Guidance	MORE Submissions - user reference guide	
Guidance	Effective field safety notices (FSNs): guidance for manufacturers of medical devices	
Template	Field Safety Corrective Action - FSCA	
Guidance	Medical devices: the regulations and how we enforce them	

*For medical devices

Scope of UKCA marking
UKCA marking is the regulatory process to place medical devices (MD) on the Great Britain (England, Wales, Scotland) market. The UKCA mark is not recognized on the Northern Ireland requiring a CE mark or UKNI mark.

UK Approved Body
UK approved bodies (AB) are similar to notified bodies (NB) in EU and are designated by the MHRA for the certification of MD in GB (except for class I self-certified devices)

Transition period
Currently, MD with a valid CE marking can be placed on the GB market until (the sooner is retained):

- 31 December 2027 or until the expiry of the (AI)MDD certificate for Class III or Class IIb implantable MD
- 30 June 2028 or until the expiry of the (AI)MDD certificate for other MDs (including class IIb non-implantable, IIa, Im, Is MD and class I MD upclassified under MDR)
- 30 June 2030 or until the expiry of the MDR certificate for MD and class I self-certified MD

MHRA published an infographic that summarizes the timelines applied in UK during the transition period.
MHRA also published a guidance document that describes the transitional rules for devices marketed in EU that are reusable Class I devices, upclassified Class I devices, and/or reliant on expired/expiring CE certificates. Any manufacturer with devices in scope of this guidance document needs to issue a letter for extension confirmation.

Conformity assessment
See the Conformity Assessment flowchart published by the MHRA. The regulatory pathways are similar to those in EU under Medical Devices Directive (93/42/EEC) taking into account the amendments brought with the Schedule 2A of the UK MDR 2002.

Manufacturer and supply chain registration
Medical device manufacturers, producers of system or procedure pack, and other, need to be registered in UK for the devices that will be placed on the GB market. In addition, non-UK manufacturers needs to appoint a UK Responsible Person (UKRP) to register the devices on behalf of the manufacturer. The following details need to be provided:

- legal entity name and address
- company type
- administrative contact
- a letter of designation for UK Responsible Persons (where applicable).

Distributors and suppliers are not required to be registered with the MHRA. However, if the GB importer is not the UKRP, it must inform the manufacturer (or UKRP) of the intention to import a device in GB so that they provide the MHRA with the importer details, including their place of business in Great Britain.

Registration of devices
All medical devices, including custom-made devices and systems or procedure packs, must be registered with the MHRA before they can be placed on the market in GB. The MHRA will only accept registration of devices from UK manufacturers or UKRP. The fees for new or change to an existing registration is £100 per application.
The following details need to be provided:

- applicable legislation
- the class of device
- Global Medical Devices Nomenclature (GMDN) Code and Term to describe your device
- Basic UDI-DI (if applicable)
- medical device name (brand/trade/proprietary name)
- model or version detail
- catalogue/reference number
- UDI-DI (if applicable)
- UK Approved Body (or EU Notified Body) where applicable
- attributes such as sterility, contains latex, MRI compatible. The full list of attributes is available in the following Excel Spreadsheet.

All conformity assessment certificates or self-certification conformity declarations will be submitted to the MHRA.

Registrations need to be performed via the Device Online Registration System (DORS) and will be accessible in the Public Access Registration Database (PARD). The first renewal date is 1 yr after account request was completed, and then at least every 2 yrs.

*For medical devices

UK Reponsible Person

Manufacturers not located in UK must appoint a UKRP that will register the devices with the MHRA and act on their behalf as described in the guidance "Regulating medical devices in the UK". The obligations include but are not limited to:

- ensure that the declaration of conformity and technical documentation have been drawn up,
- keep available a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate,
- cooperate with the MHRA on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices, etc.

Labeling

Medical devices placed on the GB market must have a UKCA marking or a CE marking. The labeling requirements are described in the Annex I of the applicable EU directive as amended by the Schedule 2A of the UK MDR 2022. In addition, where relevant, the number of the Approved Body or Notified Body must appear on the label; and, where applicable, the name with the address of the UKRP needs to be included on product labelling or the outer packaging, or the instructions for use in cases where the UKCA marking has been affixed (including when devices are both, CE and UKCA marked).

Vigilance and FSCA

Currently, no PMS requirements such as PMS plan/PMS report/PSUR, are required in GB.

Once a medical device has been placed on the GB market, the manufacturer is required to submit vigilance reports to the MHRA when complaints are received for incidents that meet the reporting requirements in UK. Any event which meets all three reporting criteria below is considered an adverse incident and must be reported to the MHRA:

- an event has occurred. This includes situations where testing performed on the device, examination of the information supplied with the device, or any scientific information indicates some factors that could lead, or has led, to an event
- the manufacturer's device is suspected to be a contributory cause of the incident
- the event resulted in, or might have resulted, in death or a serious deterioration in state of health of a patient, user or other person

Not all adverse incidents result in death or a serious deterioration in health. These may have been prevented because of other circumstances, or because of intervention. Therefore, manufacturers must still send to the MHRA a report if:

- an incident associated with a device happened, AND
- if it occurred again, it might lead to death or serious deterioration in health

Vigilance reports need to be submitted via the MORE portal per the MORE submission guide. Submission via the MHRA mailbox is no longer accepted since August 31, 2023.
Timelines for reporting an event are 2 calendar days (serious public health threat), 10 calendar days (death or unanticipated serious deterioration in state of health) or 30 days (in all other situations)

Manufacturers must also take appropriate safety action when required for devices marketed in GB to reduce the risk of death or serious deterioration in health. FSCAs need be communicated to all affected users/patients via a Field Safety Notice (FSN) per the MHRA's published guidance on effective field safety notices.
Manufacturers need to notify the MHRA of FSCAs using the FSCA Report Form of the EU Commission via the MORE portal.
Notification should be made before or when the FSCA action is implemented in the UK.

Post-Market Surveillance (PMS)

PMS is generally aligned with EU requirements. However, manufacturers must take into account specificities applicable in GB, such as sales volumes, population size, estimated usage, complaint trends, incidents, serious incidents, or recalls originating from GB.
Key differences between GB and EU requirements include the following:

- While the EU does not specify a mandatory timeframe for issuing PMS reports for Class I devices, in GB, these reports must be issued at least every three years.
- The principles of device bundling are more clearly defined in GB. In particular, bundling is permitted when:
  - devices are covered by the same Clinical Evaluation Report (CER) or Performance Evaluation Report (PER), or
  - the devices are considered similar and the manufacturer can justify that their similarity supports the preparation of a single Periodic Safety Update Report (PSUR).