BHTA / BIVDA / PAGB Guide
UK Medical Device Registration and CE / UKCA / UKNI Marking

Contents

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Mk8 Aug-23

British Healthcare Trades Association
'Better health, better care, better value'

BIVDA
British In Vitro Diagnostics Association

PAGB The Consumer Healthcare Association

1. UK Medical Device Law – Current Picture

Medical devices are regulated under the Medical Devices Regulations 2002 (SI 2002 No. 618, or **UK MDR**)[1]. This secondary legislation translated into UK law the 1990 EU Active Implantable Medical Devices Directive (**EU AIMDD**), 1993 EU Medical Device Directive (**EU MDD**), and 1998 EU In Vitro Diagnostic medical device Directive (**EU IVDD**). Following Brexit, UK MDR has gone through a series of amendments.

EU MDD and EU AIMDD were superseded by the 2017 EU Medical Device Regulation 2017/745, or **EU MDR**, while EU IVDD was superseded by the 2017 EU In Vitro Diagnostic medical device Regulation 2017/746, or **EU IVDR**. As EU MDR and EU IVDR post-dated the Brexit transition period, it was not automatically retained by the EU (Withdrawal) Act 2018 and does not/will not apply in GB (per the Medicines Healthcare products Regulatory Agency, or MHRA). *NB: EU MDR and EU IVDR are still relevant to the UK*; market access for UK medical devices (Section 2 below) is governed by its application. Since 26-May-21, EU MDR has applied in the EU and Northern Ireland (NI), while EU IVDR has applied in the EU and NI since 26-May-22.

2. UK Market Access for Medical Devices – CE[2], UKCA[3] and UKNI[4] Marks

CE Marking: Post-Brexit, the UK has allowed CE-marked medical devices to remain on the UK market. In GB this is for a transitional period (see below and Section 4), and under the NI Protocol (updated by the Windsor Framework), CE marking will be required for medical devices being sold in NI. Under European requirements, medical devices are required to demonstrate compliance by display a CE mark to be sold legally in the EU (and for as long as the CE mark continues to be accepted in the UK). See MHRA: Medical devices: EU regulations for MDR and IVDR (Northern Ireland) for CE requirements to place products on the NI market, including importer and registration obligations.

UKCA Marking: Where a medical device is placed on the GB market, by demonstrating compliance with the UK MDR 2002 (as amended) UKCA mark should be displayed. UKCA marking is not currently mandatory for medical devices placed on the GB market, but will become so on expiry of the transitional periods introduced by MHRA's Spring 2023 Statutory Instrument (SI)[5] (see Section 4 for full detail. Under the new UK regulatory regime, planned to be introduced from 1 Jul-25, similar requirements to those introduced by EU MDR/EU IVDR will apply, and medical devices in the UK will require a UKCA mark. (NB, current UK law (SI 2020 No. 1478) stated that the UKCA mark was required from 01-Jul-23 – but MHRA laid an SI in Spring 2023 removing this 01-Jul-23 date and stated in its Implementation of Future Regulations Guidance that the planned inception date of the new UK regime is 01-Jul-25.)

UKNI Marking: Under the terms of the NI Protocol from 01-Jan-21, the rules for placing medical devices on the NI market will differ from those applicable to GB. As a result, the EU MDR and EU IVDR **already applies in NI** from 26-May-21, and 26-May-22 respectively, in line with the EU's implementation timeline. To apply a CE mark, high-risk medical devices and IVDs require review from an EU Notified Body. However, where a UK assessment body has provided an assessment in line with EU MDR or EU IVDR, a UKNI mark must be applied also; MHRA guidance states:

"UK Notified Bodies can apply to be designated under the relevant EU legislation for the purposes of conducting conformity assessments for the Northern Ireland market. Please note that there are currently no UK Notified Bodies designated to undertake such assessments under the EU MDR or the EU IVDR. This section outlines the criteria for affixing a UKNI marking to devices should any UK Notified Bodies be designated in future. In addition to the CE marking, device manufacturers will also need to apply the UKNI indication if they choose to use a UK Notified Body (should any be designated in future) for mandatory third-party conformity assessment. Device manufacturers must never apply the UKNI indication on its own - it must always accompany a CE marking."

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[1] Pre-Brexit, this gives/gave effect in UK law to: Directive 90/385/EEC on active implantable medical devices (EU AIMDD); Directive 93/42/EEC on medical devices (EU MDD); Directive 98/79/EC on in vitro diagnostic medical devices (EU IVDD).

[2] Conformité Européene.

[3] UK Conformity Assessed.

[4] UK Northern Ireland.

[5] UK Statutory Instrument, 2023 No. 627, The Medical Devices (Amendment) (Great Britain) Regulations 2023, Part 4.

Transitional arrangements (Section 4 below) mean, however, that the CE mark will continue to be accepted to place medical devices on the UK market for the immediate future (in some cases until as late as June 2030).

Medical devices fall into the following five groups across three Classes:

- **Class I** (low risk, e.g. mouth ulcer film, headlice treatment, eyeglass frames, wheelchairs, stethoscopes)
- **Class I Special Function** (low risk that are Sterile; Perform Measurement; or Reusable Surgical Instruments)
- **Class IIa** (medium risk, e.g. dental fillings, cooling gels, paraffin dressings, short-term contact lenses, hearing aids)
- **Class IIb** (medium-to-high risk, e.g. condoms, insulin pens, eye drops. lung ventilators)
- **Class III** (high risk, e.g. medicated condoms, transdermal medication patch, pacemakers, breast implants, cerebral stimulators)

IVDs vary hugely from medical devices (despite being a sub-category of medical device) and therefore, these products have a different classification structure.

Under the UK MDR 2002 (as amended), IVDs fall into the following four groups across three classes:

- **General IVD** (low risk, e.g. tests for hormones, cardiac markers, clinical chemistry tests)
- **Self-test IVD** (medium risk, e.g. pregnancy test, cholesterol home tests)
- **Devices included in Annex II List B** (medium-to-high risk, e.g. detection of rubella, self-test for blood glucose)
- **Devices included in Annex II List A** (high risk, e.g. detection of HIV, detection of hepatitis, ABO blood grouping)

Class I devices and general IVDs are "self-certified"; a manufacturer is responsible for assembling and maintaining technical files and other compliance documents in line with the regulations, and then makes a Declaration of Conformity (per product). The Declaration is lodged with the relevant national regulatory authority (MHRA in the UK), which may ask to examine technical files. A Declaration lasts for as long a product remains "substantially unchanged" in design, purpose, or application. As of 2022/23, the costs for placing a Class I device or general IVD on the UK market (*exclusive* of companies' own regulatory/compliance staff overheads) can be estimated as follows:

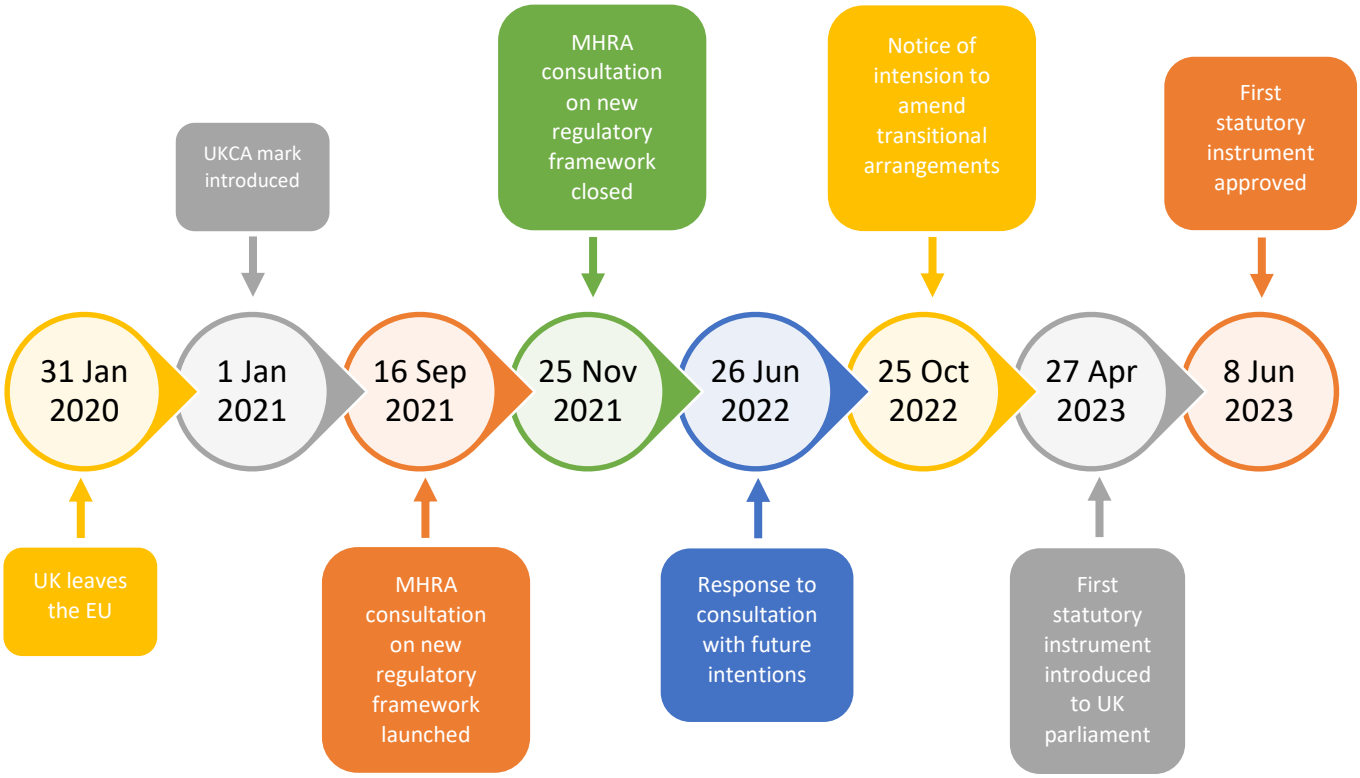
- **£1000s – Product Development:** These vary highly company-to-company and product-to-product; they are sunk costs, irrecoverable until/unless a product reaches the market and achieves success (up-front/one-off)
- **£240 – MHRA Registration Fee:** Payable for each registration application, a regulatory requirement before a product may be placed on the market (up-front/one-off; although similar fees apply for changes to registrations)
- **£1000s – Technical File & Compliance Audits:** Costs for periodic independent audits of companies' own documents, in line with compliance best-practice, typically charged at between £200-£500 per hour/per product (regular/ongoing)

Class I Special Function (measuring, sterile or reusable) , all Class II-and-above devices, self-test IVDs, IVDs included in Annex II list B, and IVDs included in Annex II list A are "3rd-party-assessed"; a manufacturer must obtain and maintain an EC or UKCA Certificate, through a a UK Approved Body (UK AB; designated by MHRA) or EU Notified Body (EU NB; designated by a European Member State) – independent companies appointed under law by a relevant national authority – to, which provide 3rd-party technical and compliance assessment. Provided a product remains "substantially unchanged" in design, purpose, or application, a certificate lasts for a set period of time (e.g. 3-5 years), after which 3rd-party re-certification must take place to verify continued conformity. As of 2022/23, the costs for placing a Class I Special Function, Class II-and-above device, self-test IVD, IVD included in Annex II list B, or IVD

included in Annex II list A on the UK market (*exclusive* of companies' own regulatory/compliance staff overheads) might be estimated as follows:

- **£1000s-to-£10000s – Product Development:** These vary highly from company-to-company and product-to-product; they are sunk costs, irrecoverable until/unless a product reaches the market and achieves success (up-front/one-off)
- **£240 – MHRA Registration Fee:** Payable for each registration application, a regulatory requirement before a product may be placed on the market (up-front/one-off; although similar fees apply for changes to registration details)
- **£1000s-to-£10000s – 3rd-Party Certification (Initial):** Costs for 3rd-party technical and compliance assessment to *obtain* an EC or UKCA Certificate, typically charged at between £200-£500 per hour/per product (up-front/one-off)
- **£1000s – 3rd-Party Re-Certification (Ongoing):** Costs for 3rd-party technical and compliance assessment to *renew* an EC or UKCA Certificate, typically charged at between £200-£500 per hour/per product (regular/ongoing)

3. UK Medical Device Law Evolution – Timeline



4. UK Medical Device Regulation – Transition Date Matrix

The guidance at **MHRA – Regulating Medical Devices in the UK** sets out MHRA's requirements (see Section 7 below for more details); as augmented by Apr-23 MHRA Implementation Guidance, press statements, and Statutory Instrument (including Explanatory Notes), it can be summarised as follows:

- Inception Date: "Core aspects" of the new UK medical device regime expected to come into effect 01-Jul-25
- Transitional Arrangements – Devices CE-Marked Under EU MDR or EU IVDR: Medical devices *CE-marked under EU MDR or EU IVDR* may stay on the GB market *until 01-Jul-30*
- Transitional Arrangements – Devices CE-Marked under EU MDD: Medical devices *CE-marked under EU MDD* may stay on the GB market until the sooner of current CE certificate expiry or for *3 years* after new regulations take effect (i.e. *until 01-Jul-28*)
- Transitional Arrangements – Devices CE-Marked under EU IVDD: Medical devices *CE-marked under EU IVDD* may stay on the GB market until the sooner of current CE certificate expiry or *until 1-Jul-30*
- CE-Marked Class I Medical Devices: Standard Class I medical devices *CE-marked under EU MDR* – i.e. those that do not/will not need 3rd-party assessment– will benefit from the EU MDR Transitional Arrangement above, and *may stay on the GB market until 01-Jul-30* (NB – the EU MDD-to-MDR transition period for Class I devices not requiring 3rd-party assessment has expired; ergo, only devices with Declaration of Conformity (DoC) to MDR should be placed on the GB market)

A **Transition Date Matrix** – showing transition dates based on Device Class and legislation under which a device is currently registered – is available on the next page. See also the Jun-23 **MHRA Infographic** of the timelines for placement of CE-marked medical devices on the GB market.

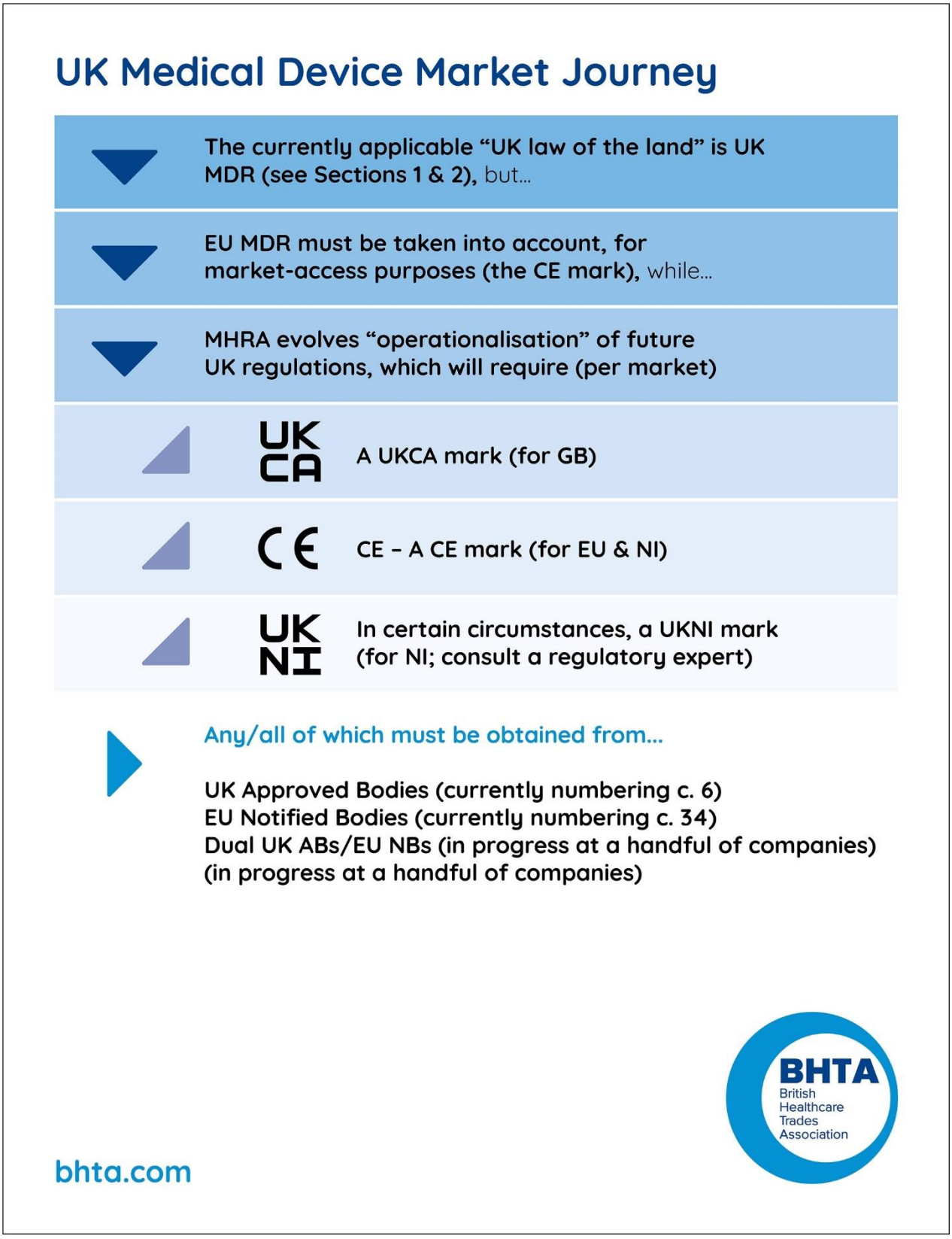
New UK Medical Device Regulation – Transition Date Matrix [as at Aug-23]

Device Class	**Law**	**NI Mkt Trans** (CE, MDD-MDR)	**GB Mkt Trans** (CE to UKCA)	**Conditions**
Class III; Class IIb implantables (not sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, connectors)	EU MDD	31-Dec-27	31-Dec-27	Certificate must have been valid on 26-May-21; expired certificates must be deemed valid by EU (MHRA requires "EU MDR Article 120 Letter" declaring key conditions for certificate extension are met); this will apply to system and procedure packs if they contain a device in these classes
Class IIb (non-implantable) and sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, connectors; **Class IIa; Class Is; Class Im**	EU MDD	31-Dec-28	30-Jun-28 (or Cert expiry, sooner of)	Certificate must have been valid on 26-May-21; expired certificates must be deemed valid by EU (MHRA requires "EU MDR Article 120 Letter" declaring key conditions for certificate extension are met); although certificate validity will be extended to 31-Dec-28 under EU MDR, these devices can only be placed on GB market until 30-Jun-28 (for devices for GB market, new expiry date should be entered as "30-Jun-28"); this will include system and procedure packs that contain such devices unless they also include a Class III or Class IIb implantable device (in which case the validity date will be 31-Dec-27 for NI, 30-Jun- 28 for GB)
Up-Classified Class I req. NB for EU MDR	EU MDD	31-Dec-28	30-Jun-28	Dates relate to validity of Declaration of Conformity
Class III, Class IIb, Class IIa	EU MDR	N/A	30-Jun-30	Technically, Mfrs may *already* apply a UKCA mark (for GB) to devices by working with UK ABs to obtain certification against UK MDR 2002
Class I	EU MDD	N/A	N/A	EU MDD-to-MDR transition period for Class I devices not requiring NB involvement has expired; ergo, only devices with DoC to MDR should be placed on the GB market
Class I	EU MDR	N/A	30-Jun-30	For Class I devices that are not up-classified and do not require NB involvement under EU MDR; technically, Mfrs may *already* apply a UKCA mark (for GB) to devices with DoC to UK MDR 2002
Device Class	**Law**	**NI Mkt Trans**	**GB Mkt Trans** (UKCA req'd)	**Conditions**
Class I-III medical devices	New UK MDR	N/A	TBC	Transition dates to the new regulatory regime are expected to be provided in an SI to be laid before 01-Jul-25 covering the balance of new medical device regulations; it is likely transition dates will be tied to the date this SI comes into force or the Inception Date of the new UK regime (expected 01-Jul-25)

New UK IVD Regulation – Transition Date Matrix [as at Aug-23]

IVD Class	**Law**	**NI Mkt Trans** (CE, IVD-IVDR)	**GB Mkt Trans** (CE to UKCA)	**Conditions**
Re-Classified to Class D	EU IVDD	26-May-25	26-May-25 (or Cert expiry, sooner of)	Certificate or declaration of conformity must have been valid on 26-May-22; transitional arrangements for EU IVDR are based on the product risk classification under the EU IVDR
Re-Classified to Class C	EU IVDD	26-May-26	26-May-26 (or Cert expiry, sooner of)	Certificate or declaration of conformity must have been valid on 26-May-22; transitional arrangements for EU IVDR are based on the product risk classification under the EU IVDR
Re-Classified to Class B or Class A (sterile)	EU IVDD	26-May-27	26-May-27 (or Cert expiry, sooner of)	Certificate or declaration of conformity must have been valid on 26-May-22; transitional arrangements for EU IVDR are based on the product risk classification under the EU IVDR
General IVDs (that do not require involvement of a NB under EU IVDR)	EU IVDD	N/A	30-Jun-30 (or Cert expiry, sooner of)	Declaration of conformity to IVDD requirements must have been made before 26-May-22
Class D **Class C** **Class B** **Class A (sterile)** **Class A**	EU IVDR	N/A	30-Jun-30	No conditions
IVD Class	**Law**	**NI Mkt Trans**	**GB Mkt Trans** (UKCA req'd)	**Conditions**
General IVDs, self-test IVDs, IVDs listed in Annex II list B, IVDs listed in Annex II list A	New UK MDR	N/A	TBC	Transition dates to the new regulatory regime are expected to be provided in an SI to be laid before 01-Jul-25 covering the balance of new medical device regulations; it is likely transition dates will be tied to the date this SI comes into force or the Inception Date of the new UK regime (expected 01-Jul-25)

5. UK Medical Device Market Journey – Infographic: Law / Regulation / Market Access



6. How to Determine If a Product Is a Medical Device[6]

Classification of Medical Device – EU Guidance Document: To determine if a product is a medical device and, if so, into which Class it fits (per Section 2 above), MHRA recommends this PDF Guidance Document from the original EU MDD legislation. On pp. 17-22 of the PDF, accessible via the "Download PDF rendition" link on the page, are flowcharts showing all device categories (Classes I-III) and definitions; pp. 23 ff. then list the rules governing each Class definition and gives examples of devices that fall into each category.

Borderline and Classification Issues for IVDs – EU Guidance Document: To determine if a product is an IVD and, if so, into which Class it fits.

MHRA – Borderlines with Medical Devices and Medicines: For more information on the distinction between medicines and medical device, see MHRA guidance Borderlines between medical devices and medicinal products.

MHRA – Borderline Products: Here MHRA set out how they make decisions on whether a product is a medical device for the purposes of UK legislation/regulation, and into which Class a medical device should fall, based on risk.

MHRA – Borderlines with Medical Devices and Other Products: MHRA guidance to assist in determining whether a product falls within the definition of a medical device for the purposes of UK legislation/regulation. See especially:

Section 5 – Assistive technology products (aids for daily living)

*Equipment intended for alleviation of, or compensation for a disability may or may not be considered medical devices. The determining factor will be whether or not there is a direct link between the corrective function of the equipment and the individual concerned and whether there is a stated medical purpose. The following products **are** considered to be medical devices as there is such a direct link:*

- *Baths with integral hoists*
- *External limb prostheses and accessories*
- *Hearing aids*
- *Mobility aids for the visually impaired*
- *Orthopaedic footwear*
- *Orthoses (lower/upper limb, spinal, abdominal, neck, head)*
- *Patient hoists*
- *Rehabilitation tricycles / mobility carts*
- *Walking / standing frames*
- *Walking sticks / crutches*
- *Wheelchairs*

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[6] UK law – Medical Devices Regulations 2002 (SI 2002 No. 618, as amended (UK MDR 2002)) – defines "medical device" as:
An instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which—
(a) is intended by the manufacturer to be used for human beings for the purpose of-
(i) diagnosis, prevention, monitoring, treatment or alleviation of disease,
(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
(iii) investigation, replacement or modification of the anatomy or of a physiological process, or
(iv) control of conception; and
(b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means,
and includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device.

*Other products, however, will be considered as 'general equipment' since it may be used 'by all' (rather than having a direct link with the individual concerned). Such products are usually considered as 'aids for daily living' and **are not** medical devices, for example:*

- *Acoustic signals at traffic lights*
- *Baths with doors*
- *Grab rails (at doorways, stairs etc.)*
- *Personal alarm systems / home alarm systems*
- *Portable ramps*
- *Special water taps*
- *Stair lifts*
- *Toilet equipment for the disabled / elderly (e.g. toilet seats, shower seats, commodes)*

Assistive Technology – Definition and Safe Use: MHRA further defines what it considers a medical device in the context of assistive technologies. In addition to the examples in the borderlines guidance above, see especially its definitions of:

*Assistive technology products that **are** medical devices:*

- *Communication aids*
- *Epilepsy / enuresis monitors*
- *Pressure management devices (pressure redistribution/relief cushions and mattresses)*
- *Posture management devices (from simple cushions to complex support systems)*
- *Slider boards*
- *Standing aids*
- *Sport-model wheelchairs*

*Aids to daily living products that **are not** medical devices:*

- *Bariatric chairs and stools*
- *Chair risers*
- *Fall alarms*
- *Wheelchair vehicle restraints*
- *Rise-and-recline chairs*
- *Shower chairs*

If – after reviewing the guidance above – clarification is still required as to whether a product is a medical device, or into which risk class a medical device falls, you may email Devices.Borderlines@mhra.gov.uk including full details of the product, its intended purpose and how it works.

7. How MHRA Regulates & Registers Medical Devices

The MHRA is the UK regulator for medical devices. It performs market surveillance of medical devices on the UK market and is able to take a decision over the marketing and supplying of a device in the UK. MHRA are also responsible for the designation and monitoring of UK conformity assessment bodies. For medical devices, these Approved Bodies (ABs) are organisations that have been designated by MHRA to assess whether manufacturers and their medical devices meet the requirements set out in relevant UK medical device regulations.

MHRA – Regulating Medical Devices in the UK: This guidance sets out what is required to place a medical device on the GB, NI, and EU markets, and what MHRA does within each of these processes. This is the best overview from which to understand the *medical device regulatory landscape*, with sub-sections on:

- Overview
- Legislation That Applies in Great Britain
- The Role of the MHRA
- Requirements for Those Manufacturing and Supplying Devices in Great Britain
- Registrations in Great Britain
- UK Responsible Person [UKRP]
- UKCA Mark and Conformity Assessment Bodies
- CE Marking and Notified Bodies
- Labelling Requirements
- Post-Market Surveillance and Vigilance
- Regulation of Medical Devices in Northern Ireland (see also stand-alone Guidance on Using UKNI Marking)
- Placing a Medical Device on the EU Market
- Contact MHRA at info@mhra.gov.uk or call 020 3080 6000

MHRA – Register Medical Devices to Place on the Market: This guidance sets out how to register medical devices with MHRA for markets in GB and NI; this is the best overview from which to understand the *medical device registration journey with MHRA*, with links to different parts of the process, including:

Who Must Register

Manufacturers (UK-based): If based in the UK, it is the responsibility of the manufacturer to register directly with MHRA each medical device prior to placing those devices on the market;

Manufacturers (non-UK-based) via UK Responsible Person (UKRP): If based outside the UK, it is the responsibility of the manufacturer to engage a UK-based UKRP to assume the responsibilities of the manufacturer in terms of registering medical devices with MHRA (see Section 10 below for more on UKRPs);

Suppliers & Distributors (UK-based): Suppliers and distributors are not required to register with MHRA, but they are responsible for ensuring that any medical devices they do supply or distribute have been properly registered, conformity-assessed, and labelled according to all applicable UK law and regulations. In addition, if a Supplier or Distributor acts as a UKRP, they must carry out all responsibilities of a UKRP;

Importers (UK-based): Importers are not required to register with MHRA, but in cases where an Importer is not acting as the UKRP for a device, the Importer must inform the relevant Manufacturer or UKRP of their intention to import a device, and the Manufacturer or UKRP must – in turn – provide MHRA with the Importer's details, including their UK place of business; in cases where an Importer acts as a UKRP, they must carry out all responsibilities of a UKRP.

When You Must Register

All medical devices – including IVDs, custom-made devices and systems or procedure packs – must be registered with MHRA ***before*** they can be placed on the Great Britain market.

NB – Procedure Packs: It is possible under UK and EU legislation[7] to combine medical devices together into a procedure pack. In the retail sector, this is most commonly seen in first aid kits, but it is not limited to this application. It is atypical to see the *kit/pack as a whole* CE/UKCA marked (indeed it is prohibited to do so except in some limited and rare circumstances), but any *individual medical device product* contained in the kit/pack should be CE/UKCA marked. It is therefore necessary to verify each individual component within a kit/pack for compliance; again, the CE/UKCA mark only applies to medical devices, and kits/packs may contain non-medical device products.

Information Required When Registering Your Devices With the MHRA

A full list of registration information – Organisation Details (mandatory); Importer Details (if applicable); General Device Details (mandatory); IVD Details (if applicable) – is available from MHRA as an Excel spreadsheet at Manufacturer and Device and Product and Importer Attributes.

For each *Manufacturer*, required details include:

- Legal entity name and address as it appears on the device labelling/packaging
- Company type (e.g. limited company, sole trader)
- Administrative contact (up to 15 people may have access)
- Where applicable, a letter of designation for UK Responsible Persons (UKRPs); this must be a legal contract, stating exclusive UKRP action on behalf of the manufacturer and specifying mandatory tasks the UKRP is contracted to undertake on behalf of the manufacturer (mandatory tasks that must appear in the UKRP designation contract can be found in MHRA's UK Responsible Person Guidance)

For each *Device*, required details include:

- Applicable legislation[8]
- Class of device being registered
- Global Medical Devices Nomenclature (GMDN) code and term to describe the device; if unsure of the GMDN code required, the relevant term may be selected from a drop-down list in MHRA's registration system; membership of the GMDN Agency is not required to find and select the appropriate GMDN term in MHRA's system
- 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 (if applicable)
- Device attributes (e.g. sterility, contains latex, MRI-compatible, etc.)
- A copy of any conformity assessment certificate or self-certification conformity declaration (as applicable)

[7] For full detail, see UK MDR Regulation 14, MDD Article 12 and EU MDR Article 22.

[8] See Section 1, Footnote 1 above for a list of applicable legislation.

IVDs Undergoing Performance Evaluation

Coronavirus Test Device Approval (CTDA) and Registering with MHRA

In particular, see MHRA Guidance for Industry and Manufacturers: COVID-19 Tests and Testing Kits and underlying legislation at The Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021 (No. 910).

Apply to Register on the Device Online Registration System (DORS)

A Manufacturer or UKRP must create an account on MHRA DORS before beginning to register medical devices with MHRA.

MHRA will email account applicants to confirm whether any account request has been accepted or rejected.

NB: *You will not be regarded as registered with MHRA until you have provided detailed information required at registration. Before placing devices on the market, you must ensure all information registered with MHRA is accurate and up to date; MHRA may request additional technical documentation from you to demonstrate your products conform to the relevant regulatory requirements before your registration is confirmed.*

To set up an account:

- Click on MHRA – Register Medical Devices to Place on the Market;
- Scroll approximately 2/3 of the way down the page, to a section headed **"Apply to register on the Device Online Registration System (DORS)"**;
- Click on the MHRA DORS link in this section; this will take you to a new MHRA window where you fill out a form to request an MHRA DORS account;
- Once you receive your account details from MHRA – which will follow via email after you've carried out the step above – log into your DORS account, complete your registration, and begin registering your devices (see sub-section immediately above for Manufacturer/Device information required for registration);
- Finally, at the bottom of the MHRA – Register Medical Devices to Place on the Market page are links to MHRA's full instruction manuals on: creating & managing your DORS account (Account Management Reference Guide) and registering individual devices (Device Registration Reference Guide); as well, there is a list of video-tutorials that take you screen-by-screen through the DORS system.

MHRA Fees[9]

A statutory fee of £240 applies for each registration application.

Registrants can register up to 100 devices (GMDN) with a cumulative maximum of 20,000 products (UDI-DI, medical device name, model or version, catalogue/reference detail) within each application.

If registrants need to update any information within an existing registration, a £100 statutory fee is applicable.

Review Registration

MHRA encourages regular review of device registrations and sets out here their program of review notification within the DORS system.

[9] NB, MHRA is in the process of overhauling its fee structures/amounts following a Nov-22 public consultation; the consultation outcome – available at Consultation on Proposals for Changes to the Medicines and Healthcare products Regulatory Agency's Statutory Fees – sets out a fee regime set to come into force on 01 April 2023.

Making Changes to Your Registration

MHRA sets out here which changes to device registration – including address, company name, additional devices, change of UKRP – are chargeable.

Registration of Certain Medical Devices That Have Expired/Expiring CE Certificates

Please see Sections 3 & 4 above for details of EU revision of EU MDD-to-EU MDR transitional arrangements, steps required to rely on an expired CE certificate that has been deemed valid under EU MDR, and Transition Date Matrix.

See also specific MHRA guidance on:

- Registration of Medical Devices with an Expired/Expiring CE Certificate that is Valid under EU Medical Devices Regulations (EU MDR), which includes step-by-step date-based scenario examples
- MHRA-Authored EU MDR Article 120 Extension Confirmation Template

Registration of Certain Medical Devices which are EU MDD Class I Reusable Surgical Instruments or EU MDD Class I Medical Devices Up-Classified from Class I

Please see Sections 3 & 4 above for details of EU revision of EU MDD-to-EU MDR transitional arrangements, steps required to rely on an expired CE certificate that has been deemed valid under EU MDR, and Transition Date Matrix.

See also specific MHRA guidance on:

- Registration of Medical Devices with an Expired/Expiring CE Certificate that is Valid Under EU Medical Devices Regulations (EU MDR), which includes step-by-step date-based scenario examples
- MHRA-Authored EU MDR Article 120 Extension Confirmation Template

Public Register of Manufacturers

Once manufacturers and/or UKRPs have registered themselves and their devices with MHRA, registrants' name, address, and device information are added to the Public Access Database for Medical Device Registration. Basic search functionality allows searches by Medical Device Type or Manufacturer Name. Advanced Search functionality allows searches by:

- Manufacturer Name
- MHRA Reference Number
- GMDN Code (Global Medical Device Nomenclature™)
- Medical Device Type
- Medical Device Risk Classification

Reference Guides, Video Tutorials, and MHRA Contact Information

MHRA has published extensive reference guides on:

- DORS Account Management
- DORS Device Registration
- Certificates of Free Sale System (for exports of medical devices from the UK to other countries)

Likewise, MHRA has produced and makes available a collection of video tutorials on Account Management, Device Registration, and the Certificates of Free Sale System. Finally, MHRA is contactable for queries on device.registrations@mhra.gov.uk.

8. Guidance for Class I Medical Devices

MHRA – Guidance on Class I Medical Devices: Although derivative of the full guidance in Sections 7-8 above, this advice on Class I medical devices – eligible for self-certification in most cases because of their low risk profile – is a useful guide; e.g. MHRA lists areas that must be covered by a manufacturer's Technical File; in summary these are:

Product Description

Raw Material and Component Documentation

Intermediate Product and Sub-Assembly Documentation

Final Product Documentation

Packaging and Labelling Documentation

Packaging Specifications / Copies of All Labels / Any Instructions for Use

Design Verification

Risk Analysis

Compliance Requirements (per UK MDR 2002, Part II, Annex I (as modified by UK MDR 2002, Schedule 2A, Part II))

Clinical Evaluation (per UK MDR 2002, Part II, Annex X (as modified by UK MDR 2002, Schedule 2A, Part II))

Declaration of Conformity (per UK MDR 2002, Part II, Annex VII (as modified by UK MDR 2002, Schedule 2A, Part II))

9. Guidance for IVDs

MHRA – Guidance on Legislation for IVD Medical Devices: Thorough guidance on how the legislative requirements apply to IVDs, including explanation of classifications and conformity structure.

10. UK Responsible Persons (UKRPs) – Roles and Responsibilities

The Role of the UK Responsible Person (UKRP): See this guidance for the roles and responsibilities of a UKRP, which could form the basis of a contract between a manufacturer and a UKRP; in summary, a UKRP must:

- Ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer
- Keep available a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments/supplements for MHRA inspection
- In response to a request from the MHRA, provide conformity information and documentation
- Where they have samples of the devices or access to the device, comply with any request from the MHRA to provide such samples or access to the device
- Where they have neither samples of the device nor access to the device, communicate to the manufacturer any request from the MHRA to provide such samples or access
- Cooperate with the MHRA on any preventive or corrective action taken to mitigate/eliminate device risks

- Immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been appointed
- If the manufacturer acts contrary to its obligations under UK Regulations:
    - Terminate the legal relationship with the manufacturer; and
    - Inform the MHRA and, if applicable, the relevant Approved Body of that termination
    - Note: UKRP name and address must be included on the product labelling in the case where a UKCA mark is applied.

UK Responsible Person Association (UKRPA): The UKRPA is an alliance of providers of UKRP services. If you wish to find a professional UKRP, the email addresses of members can be found on the UKRP Members page.

European Association of Authorised Representatives (EAAR): The EAAR is an alliance of providers of EU Authorised Representative (EUAR) services. When placing devices on the EU or Northern Ireland markets, manufacturers from GB or other countries outside the EU must appoint either an EU-based or NI-based authorised representative[10]. If you wish to find a professional EUAR, the email addresses of members can be found on the EAAR Members page.

11. How the UKCA Mark Works

The UKCA mark has been/is the subject of much change. Until the planned inception of the new UK medical device regime on 01 July 2025, and the entry into force of the UKCA mark for UK market access, CE-marked medical devices with a valid declaration of conformity and/or CE certificate can continue to be placed on the UK market. As well, under the Transitional Arrangements outlined in MHRA's Apr-23 Statutory Instrument (including Explanatory Notes), under certain circumstances, the CE mark will continue to be accepted until between 2028 and 2030. Please see Sections 2-5 above for more detail, including Section 4 above for more specifics on Transitional Arrangements.

Transitional Arrangements notwithstanding, MHRA encourages all manufacturers to embark on the process of obtaining UKCA marking "as soon as possible." As outlined in Sections 2-5 above, obtaining a UKCA mark is materially similar to obtaining a CE mark – the main difference being that the Declaration of Conformity (for self-certified Class I devices or general IVDs) or Assessment Certificate (for 3rd-party assessed Class I Special Function, Class II-and-above device, self-test IVD, IVD included in Annex II list B, or IVD included in Annex II list A) issued by a UK Approved Body (UK AB) rather than an EU Notified Body (EU NB) against the UK MDR 2002 (as amended).

For more information on UKCA marking, please see:

- MHRA – Regulating Medical Devices in the UK – UKCA Mark and UK ABs: This section of MHRA's device regulation page provides an in-context summary of the UKCA Mark UK ABs
- MHRA – Approved Bodies for Medical Devices: Here MHRA outlines their definition of UK ABs, including their role and function within the UK medical device regulation process
- MHRA – Medical Devices – Conformity Assessment and the UKCA Mark: Detailed guidelines on conformity assessment and the UKCA mark for medical devices in particular (including Assessment Routes, International Standards Compliance, Clinical Investigations (if applicable), the UKCA Mark and NI considerations)
- BEIS – Using UKCA Marking: General guidance on using the UKCA Mark, including logo-type assets

[10] NB, there are some companies that provide both UKRP and EUAR services; in instances where these companies have a registered office in Northern Ireland, it is possible that a UKRP and EU authorised representative could be the same entity.

12. UK Approved Bodies (UK ABs) – Roles and Responsibilities

The UK Market Conformity Assessment Bodies (UKMCAB) database is the definitive source and a register of UK Government-appointed conformity assessment bodies who can certify goods for the Great Britain market. See here for UKMCAB entries for ***medical device UK ABs*** (currently numbering 6); see MHRA – Medical Device UK Approved Bodies for full information, including. The database also indicates the scope of AB designation per company, i.e. whether it covers medical devices and/or IVDs.

13. EU Notified Bodies (EU NBs) – Roles and Responsibilities

European Commission NANDO List of EU Notified Bodies – medical devices: This official EU list shows 37 entries for EU NBs designated under the EU MDR (including national offices of multinational NBs).

European Commission NANDO List of EU Notified Bodies – IVDs: This official EU list shows 10 entries for EU NBs designated under the EU IVDR (including national offices of multinational NBs).

European Association for Medical Devices of Notified Bodies: TeamNB is the trade association for EU NBs; contact details of their current members (32) and in-designation members (2) can be found on the Members page.

14. Non-Standard Routes to Placing Medical Devices on the UK Market

Exceptional Use of Non-UKCA-Marked Medical Devices: In this guidance MHRA outlines how manufacturers can apply for approval to supply non-compliant medical devices on humanitarian grounds. This usually applies to medical devices (including certain custom-made devices), that do not comply with the law, to protect a patient's health, but for which there are no legitimate alternatives available. It is a vanishingly rare exception, reflected in the application process, which requires input from both manufacturer and clinician on an individual patient-by-patient basis (please email dts@mhra.gov.uk for more information).

Exemptions From Devices Regulations During the Coronavirus (COVID-19) Outbreak: In this guidance MHRA outlines how manufacturers can apply for fast-track approval of medical devices during the COVID-19 pandemic which MHRA has indicated ***might*** be used, during a period of regulatory flux and/or UK AB/EU NB capacity shortfall.

15. BHTA / BIVDA / PAGB Updates on MHRA Policy and UK Medical Device Regulation

BHTA: See **UK Medical Device Registration and CE/UKCA/NI Marking** for an online version of this document and BHTA updates on the new UK regulatory regime as it unfolds; send regulatory queries to info@bhta.com.

BIVDA: BIVDA members can subscribe to the UKCA Sub-Group to receive email alerts relating to new information on the UK regulatory regime as it unfolds. Information is also communicated through the **BIVDA Regulatory Newsletter**. Regulatory queries can be sent to Regulatory@BIVDA.org.uk.

PAGB: PAGB members can access detailed regulatory intelligence on self-care medical devices from the **PAGB website** and subscribe to receive the regulatory intelligence newsletter. For more information on subscribing contact info@pab.co.uk. Regulatory queries can be sent to regulatory@pagb.co.uk. PAGB also offers a regulatory consultancy service to companies seeking early advice; for example, on the viability of bringing a product to market, understanding requirements for medical device regulation or exploring claims. Contact us about our regulatory and advertising consultancy services.

NB: This Guide has been produced by BHTA, BIVDA and PAGB ("the Associations") to provide our members with key points from MHRA guidance. This Guide does not constitute legal advice and members should not rely on it in lieu of reading MHRA guidance in full. This Guide is provided for information only; the Associations disclaim and exclude any liability in respect of the contents, or for action taken based on this information.