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Regulation of Medical Devices

August 26, 2021

There has been an update to GOV.UK guidance on "***Using the UKCA marking,***" which sets out the following:

Summary

- The UKCA (UK Conformity Assessed) marking is a new UK product marking that is used for some goods, including medical devices, being placed on the market in Great Britain (England, Wales, and Scotland).
- It came into effect on 1 January 2021; however, to allow businesses time to adjust to the new requirements, in most cases, the **CE marking can continue to be used until 1 January 2023**.
- It applies to most goods which previously required the CE marking, known as 'new approach' goods.
- The UKCA marking must be used **from 1 January 2023**.
- The UKCA marking **cannot be used** for goods placed on the Northern Ireland market. (Please refer to separate guidance on placing goods on the Northern Ireland market.)

Selling goods in Great Britain

- The **technical requirements** ('essential requirements'), as well as the **conformity assessment processes** and **standards** that can be used to demonstrate conformity, are largely **the same as they were for the CE marking**.
- The circumstances in which the self-declaration of conformity can be used for UKCA marking are the same as for CE marking, **for example, for some Class I devices**.
- If it was possible to self-declare conformity for the CE marking, it will be possible to do the same for the UKCA marking.
- **It is important to note that the CE marking is only valid in Great Britain for areas where GB and EU rules remain the same**. If the EU changes its rules and the product is CE-marked based on those new rules, it will not be possible to use the CE marking to sell in Great Britain, even before 31 December 2022.

Selling goods in the EU

- The **UKCA marking is not recognised on the EU market**. Products need a CE marking for sale in the EU.

When to use the UKCA marking

- The new UKCA marking is **only required before 1 January 2023** if all of the following apply:
  - the product is for the market in Great Britain
  - the product is covered by legislation which requires the UKCA marking
  - the product requires mandatory third-party conformity assessment
  - the conformity assessment has been carried out by a UK conformity assessment body
- This **does not apply to existing stock**, for example, if the goods were fully manufactured, CE-marked, and ready to be placed on the market before 1 January 2021.
- In these cases, the goods can still be sold in Great Britain with a CE marking even if covered by a certificate of conformity issued by a UK body before 1 January 2021.
- These goods will need to be placed on the market **before 31 December 2022**.

Placing the UKCA marking

- In most cases, the UKCA marking must be applied **to the product itself or to the packaging**.

- In some cases, it may be placed on the manuals or on other supporting literature.
- This will vary depending on the specific regulations that apply to the product.

General rules on using the UKCA marking

- The UKCA marking must be **clearly visible and legible** when it is affixed to the product.
- If it is not possible to affix the UKCA marking to the product, it must be attached to the packaging (if any) or accompanying documents.
- UKCA markings must only be placed on a product by the manufacturer or its authorised representative (where permitted in the relevant legislation).
- When affixing the UKCA marking, **full responsibility is taken by the manufacturer** for the product's conformity with the requirements of the relevant legislation.
- The UKCA marking must only be used to demonstrate conformity with the relevant UK legislation.
- No marking or sign may be placed that may misconstrue the meaning or form of the UKCA marking to third parties.
- No other markings may be attached on the product which affect the visibility, legibility, or meaning of the UKCA marking.
- The UKCA marking cannot be placed on products unless there is a specific requirement to do so in the legislation.
- A product may have additional markings and marks, as long as they:
  - fulfil a different function from that of the UKCA marking
  - are not likely to cause confusion with the UKCA marking
  - do not reduce the legibility and visibility of the UKCA marking

Rules for using the UKCA image

- There are specific rules on how to use the UKCA marking, including the **general rules** relating to the size, the letters, and the visibility of the UKCA marking.
- The UKCA marking can take different forms (for example, the colour does not have to be solid), as long as it remains visible, legible, and maintains the required proportions.

Recordkeeping

- The manufacturer or its authorised representative (where allowed for in the relevant legislation), must keep documentation to demonstrate that the product conforms with the regulatory requirements.
- This must be kept for up to **10 years** after the product is placed on the market.
- This information can be requested at any time by market surveillance or enforcement authorities to check that the product conforms with the statutory requirements.
- The information to keep will vary depending on the specific legislation relevant to the product.
- **General records** of the following must be kept:
  - how the product is designed and manufactured
  - how the product has been shown to conform to the relevant requirements
  - the addresses of the manufacturer and any storage facilities
- The information must be kept in the form of a **technical file** which can be supplied if requested by a market surveillance authority.

UK Declaration of Conformity

- The **UK Declaration of Conformity** is a document which must be drawn up for most products lawfully bearing a UKCA marking.

- The Medicines and Healthcare products Regulatory Agency (MHRA) recommends that manufacturers have a separate UK Declaration of Conformity from their EU Declaration of Conformity.
- In this UK Declaration of Conformity, the manufacturer, or its authorised representative (where allowed for in the relevant legislation), should:
  - declare that the product is in conformity with the relevant statutory requirements applicable to the specific product
  - make sure the document has the name and address of the manufacturer (or its authorised representative) together with information about the product and the conformity assessment body (where relevant)
- The UK Declaration of Conformity should be available to market surveillance authorities on request.
- The information required on the Declaration of Conformity is largely the same as what was required on an EU Declaration of Conformity.
- This can vary depending on the application legislation, but generally should include:
  - the manufacturer's name and full business address or that of its authorised representative
  - the product's serial number, model, or type identification
  - a statement, stating that the manufacturer takes full responsibility for the product's compliance
  - the details of the approved body which carried out the conformity assessment procedure (if applicable)
  - the relevant legislation with which the product complies
  - the manufacturer's name and signature
  - the date the declaration was issued
  - supplementary information (if applicable)
- The manufacturer will need to list:
  - the relevant UK legislation (rather than EU legislation)
  - the relevant UK designated standards rather than standards cited in the Official Journal of the European Union

Further information

- The guidance provides further information on product areas covered by the UKCA marking and on legislative areas where self-declaration of conformity for UKCA marking is permitted.

May 7, 2021

There has been guidance on "**Medical devices: EU regulations for MDR and IVDR (Northern Ireland)**" regarding the new EU regulations ("Regulations") for medical devices and in vitro diagnostic medical devices, and their implementation in Northern Ireland:

Overview

- The MHRA acts as the Competent Authority for medical devices in Northern Ireland
- Under the terms of the Northern Ireland Protocol, the rules for placing medical devices on the Northern Ireland market differ from those applicable to Great Britain
- Currently, devices are regulated under:
  - Directive 93/42/EEC on medical devices
  - Directive 90/385/EEC on active implantable medical devices

  - Directive 98/79/EC on in vitro diagnostic medical devices
- The above directives are given effect in UK law through the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) ("UK MDR 2002")
- Schedule 1 of the Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 sets out the specific requirements for Northern Ireland

New EU Regulations

- The EU Medical Device Regulations (2017/745) ("MDR") will apply in Northern Ireland from **26 May 2021**
- The EU in vitro Diagnostic Medical Device Regulations (2017/746) ("IVDR") will apply in Northern Ireland from **26 May 2022**

Compliance with the legal requirements

The new obligations set out in the Regulations for manufacturing or supplying a medical device ensure that:

- the device has been correctly classified against the *new risk classification criteria* (Annex VIII of the MDR and IVDR)
- general *safety and performance requirements* are met, including for *labelling*, and *technical documentation* and *quality management systems* (Annex I of the MDR and IVDR)
- increased requirements for *clinical evidence* are met (Annex XIV of the MDR and IVDR)
- manufacturers have a *person responsible for regulatory compliance* in place (Article 15 of the MDR and IVDR)
- the importer requirements set out in Article 13 of the MDR and IVDR are met
- the distributor requirements set out in Article 14 of the MDR and IVDR are met

Conformity Assessment marking

- For medical devices and IVDs, CE marking will continue to be used and recognised for the Northern Ireland market
- Manufacturers based in Northern Ireland will not require an authorised representative established in the EU
- For the purposes of the CE mark, an EU-recognised Notified Body, where required, must be used
- Where a UK Notified Body has been used for the conformity assessment, a CE UKNI mark must be placed on the device
- Goods bearing the CE UKNI marking will not be accepted on the EU market
- Class I manufacturers can continue to self-declare their conformity against the MDR from 26 May 2021

Importer requirements

- The MDR and IVDR define an 'importer' as "any natural or legal person established within the Union that places a device from a third country on the Union market"
- A company becomes an importer on bringing goods for the first time into Northern Ireland (or the EU) from either Great Britain or another non-EU country and placing them on the Northern Ireland (or the EU) market
- An importer can be an individual or a company, such as a retailer, retail outlet or wholesaler, who is placing the device on the market

- There may be cases where the end customer, such as a hospital or dentist, might be considered to be the importer
- The importer can be located in Northern Ireland, the Republic of Ireland or another EU Member State

Health Institutions in Northern Ireland

- The exemption for manufacturing or modifying and using medical devices or IVDs within the same health institution (also known as 'in house manufacture') continues to apply
- However, additional requirements for these devices must be met. The full requirements of implementing the healthcare institution exemption can be found in Article 5(5) of the MDR and IVDR
- Guidance sets out that Health institutions wishing to apply the exemption under the new Regulations need to ensure that:
  - products meet the relevant General Safety and Performance Requirements (Annex I of the MDR and IVDR)
  - there is an appropriate quality system in place
  - there is a justification for applying the exemption
  - technical documentation is in place

Legal obligations

An importer must ensure to meet the importer obligations, as set out in Article 13 of the MDR and IVDR, including that:

- the device has been CE marked or, for devices for the Northern Ireland market only, also has a UKNI indication
- the EU declaration of conformity of the device has been drawn up
- a manufacturer is identified and that, where relevant, an authorised representative has been designated by the manufacturer
- the device is labelled in accordance with MDR and accompanied by the required instructions for use
- where applicable, a UDI has been assigned by the manufacturer
- the device has been registered in Eudamed, once Eudamed is fully functional
- the manufacturer's transport and storage requirements are complied with
- a register of complaints, of non-conforming devices and of recalls and withdrawals, are kept and the manufacturer, authorised representative and distributors are provided with any information requested by them
- the manufacturer and their authorised representative is informed if there is any reason to believe a device does not conform to the requirements
- a copy of the EU declaration of conformity and relevant certificates is kept for 10 years (and 15 years for implantable devices)
- there is cooperation with the MHRA and samples are provided / access to the devices is granted

Labelling requirements

Importers need to provide the following details* along with the device:

- name, registered trade name or registered trademark
- the place of business
- the contact address

these details can appear on the packaging, instructions for use or in a document accompanying the device, such as an invoice

Registration requirements

- In cases where the Northern Ireland importer is not the Northern Ireland-based Authorised Representative or the UK Responsible Person, the importer is required to inform the relevant Northern Ireland-based Authorised Representative or UK Responsible Person of their intention to import a device, and they must then, in turn, provide the MHRA with a list of device importers
- This notification only needs to happen once, and not for every batch of device imported
- The requirements for this apply in line with the registration grace periods set out in further guidance (see bullet point below)
- If the device is already registered with the MHRA for the purposes of Great Britain, it will not need to undergo any further registration in Northern Ireland by the importer, so long as it has been indicated that the device is also for the Northern Ireland market

Summary of key requirements for placing a device on the Northern Ireland market

The following requirements apply to manufacturers wishing to place medical devices on the Northern Ireland market:

- The EU MDR and EU IVDR will apply in Northern Ireland from 26 May 2021 and 26 May 2022 respectively
  - Please see the interactive guide to the new EU Regulations for medical devices and in vitro diagnostic medical devices*

**since publication of the interactive guide the implementation timeline of the MDR has been delayed and will now fully apply from 26 May 2021 in Northern Ireland*

- CE marking is required
- In addition to the CE marking, the UKNI marking is required if a UK Notified Body undertakes mandatory third-party conformity assessment
- Certain medical devices, including in vitro diagnostic medical devices, placed on the Northern Ireland market need to be registered with the MHRA
- Class I devices and general IVDs placed on the market by Northern Ireland manufacturers and Authorised Representatives based in Northern Ireland must be registered as they were prior to 1 January 2021, as the registration timings will not apply to these devices
- For other device classes, devices must be registered by the dates below:
  - Class IIIs and Class IIb implantables, and all active implantable medical devices and IVD List A products must be registered from 1 May 2021
  - other Class IIb and all Class IIa devices and IVD List B products and Self-Test IVDs must be registered from 1 September 2021
- When placing devices on the Northern Ireland market, GB-based manufacturers must appoint an EU or NI-based Authorised Representative
- Most manufacturers based outside the UK must have a UK Responsible Person in place to act as a regulatory point of contact within the UK and comply with registration requirements

February 12, 2021

MHRA updates its guidance on using the UKCA marking

The MHRA has updated its guidance on using the UKCA marking to include additional instructions regarding the height of the UKCA marking. See the updated guidance here.

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February 12, 2021

MHRA updates its guidance on using the UKNI marking

The MHRA has updated its guidance on using the UKNI marking to include additional instructions regarding the height of the UKNI marking. See the updated guidance here.

February 12, 2021

MHRA updates its guidance on applying human factors to medical devices

The MHRA has updated its guidance on applying human factors to medical devices to reflect the end of the Brexit transition period. The updates are primarily around this guidance applying to Great Britain, changes in references to legislation and the introduction of the new UKCA mark. See the updated guidance here.

February 3, 2021

MHRA publishes guidance on virtual manufacturing of medical devices

The MHRA has published guidance on the virtual manufacturing of medical devices. See the guidance here.

January 29, 2021

MHRA updates its guidance on what a software application medical device is and how to comply with the legal requirements

The MHRA has updated its guidance that provides information on when software applications are considered to be a medical device and how they are regulated as a result of the end of the Brexit transition period. See the updated guidance here.

January 14, 2021

MHRA updates its guidance on notifying the MHRA about a clinical investigation for a medical device

The MHRA has updated its guidance on how to notify the MHRA about a clinical investigation for a medical device. The MHRA has added revised information about Health Research Authority (HRA) and Health and Care Research Wales (HCRW) Approval, as well as new information about the Coordinated assessment pathway pilot. See the updated guidance here.

January 6, 2021

MHRA publishes guidance on how to tell if your product is a medical device

The MHRA has published guidance on how it makes decisions on when a product is a medical device (borderline products). See the guidance here.

January 5, 2021

MHRA publishes guidance for retailers on supplying medical devices to Northern Ireland

The MHRA has published guidance explaining how the supply of medical devices into Northern Ireland works. See the guidance here.

January 1, 2021

MHRA publishes list of UK approved bodies for medical devices

The MHRA has published a list of UK approved bodies listed under Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002). This list includes 3 UK approved bodies for medical devices: (i) BSI Assurance UK Ltd; (ii) SGS United Kingdom Limited; and, (iii) UL International (UK) Ltd. See the list here.

January 1, 2021

MHRA publishes guidance on UK approved bodies for medical devices

The MHRA has published guidance on UK approved bodies listed under Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002). See the guidance here.

January 1, 2021

MHRA publishes guidance on the health institution exemption for in vitro medical devices and medical devices for health institutions in Northern Ireland

The MHRA has published guidance explaining that the Regulations for in vitro diagnostic medical devices (IVDs) and medical devices (MDs) will keep the exemption for manufacturing or modifying and using IVDs or MDs within the same health institution. The guidance is only relevant for healthcare institutions in Northern Ireland. See the guidance here.

December 31, 2020

MHRA publishes guidance on how to notify the MHRA about a clinical investigation for a medical device

The MHRA has published guidance on how to notify the MHRA of your intention to carry out a clinical investigation for medical devices. See the guidance here.

December 31, 2020

MHRA publishes guidance on the new EU Regulations for medical devices and in vitro diagnostic medical devices

The MHRA has published guidance on what you need to know about the new EU Regulations for medical devices (MDR) and in vitro diagnostic medical devices (IVDR), and their implementation in Northern Ireland. See the guidance here.

December 31, 2020

Department for Business, Energy & Industrial Strategy publishes guidance on using the UKCA marking

The Department for Business, Energy & Industrial Strategy has published guidance to explain when the UKCA marking needs to be used and how to use it. See the guidance here.

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December 31, 2020

MHRA publishes guidance on conformity assessment and the UKCA marking for medical devices

The MHRA has published guidance on to conform with the legal requirements for placing medical devices on the market. See the guidance here.

December 31, 2020

Department for Business, Energy & Industrial Strategy publishes guidance on using the UKNI marking

The Department for Business, Energy & Industrial Strategy has published guidance to explain when the UKNI marking needs to be used and how to use it. See the guidance here.

MHRA Issues Guidance on How to Register Medical Devices for the Markets in Great Britain and Northern Ireland from January 1, 2021

December 7, 2020

The MHRA has published **guidance** on the registration requirements and process for medical devices for the markets in Great Britain and Northern Ireland from 1 January 2021. From 1 January 2021, Class I medical devices, IVDs and custom-made devices will need to be registered with the MHRA under existing arrangements where the manufacturer is in the UK or the Authorised Representative is in Northern Ireland. All other classes of device placed on the Great Britain market will require registration with the MHRA subject to grace periods over the following 12 months, depending on the class of devices. The MHRA re-issued this guidance on December 31, 2020.

Guidance on What You Need To Do To Place a Medical Device on the Great Britain Market From January 1, 2021

November 12, 2020

Guidance on What You Need To Do To Place a Medical Device on the Great Britain Market From January 1, 2021

The MHRA has published new guidance titled "Regulating medical devices from January 1, 2021." This guidance was re-issued by the MHRA on December 31, 2020.

From January 1, 2021, the MHRA will take on the responsibilities for the UK medical devices market that are currently undertaken through the EU system.

In the guidance, 'medical device' includes in vitro diagnostic medical devices and active implantable medical devices. The guidance does not cover other CE-marked products. The proposals outlined in the guidance will take effect through legislative changes which are still subject to parliamentary approval and will be introduced later in 2020.

The guidance covers the following matters:

- **Summary of key requirements for placing a device on the Great Britain market:**
  - **CE marking:** Recognised in Great Britain until June 30, 2023

        - If you currently CE mark your medical device on the basis of self-certification, you will be able to continue to do so after January 1, 2021 and place your device on the Great Britain market until June 30, 2023
    - **Certificates issued by EU-recognised Notified Bodies:** Valid until June 30, 2023
        - From January 1, 2021, any mandatory third-party conformity assessment for the CE marking will need to be carried out by an EU-recognised Notified Body
            - This includes both EU-based Notified Bodies and Notified Bodies in countries which are listed on the EU's NANDO Information System
    - **UK Notified Bodies:** Will not be recognised by the EU after the transition period; will not be able to issue CE certificates (other than for the purposes of the "CE UKNI" marking, which will be valid in Northern Ireland); will become UK approved bodies from January 1, 2021
    - **Register with the MHRA:** Requirement for all medical devices placed on the UK market from January 1, 2021
    - **Manufacturers based outside the UK:** To place a medical device on the Great Britain market you will need to appoint a UK Responsible Person
    - **A new route to market and product marking** is available for manufacturers wishing to place a device on the Great Britain market
- **Legislation that will apply in Great Britain from January 1, 2021:** The Great Britain route to market and UK Conformity Assessed (UKCA) marking requirements will continue to be based on the requirements derived from current EU legislation
    - **The following directives are given effect in UK law through the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002):**
        - **Directive 90/385/EEC:** Active implantable medical devices
        - **Directive 93/42/EEC:** Medical devices
        - **Directive 98/79/EC:** In vitro diagnostic medical devices
            - The UK MDR 2002 will continue to have effect in Great Britain after the transition period has ended in the form in which they exist on January 1, 2021
- **EU legislation which will not be transposed into law in Great Britain and will not be implemented in Great Britain:**
    - **The EU Medical Devices Regulation (EU MDR):** Will fully apply in EU Member States from May 26, 2021
    - **EU in vitro Diagnostic Medical Devices Regulation (EU IVDR):** Will fully apply in EU Member States from May 26, 2022
- **The role of the MHRA:** Performs marketing surveillance of medical devices on the UK market and will be able to take decisions over the marketing and supply of medical devices in the UK; responsible for the designation and monitoring of UK Conformity Assessment Bodies
- **From January 1, 2021, any medical device, IVD, or custom-made device must be registered with the MHRA before being placed on the Great Britain market:**
    - To be registered with the MHRA, medical devices must conform to the UK MDR 2002, the EU MDR (until June 30, 2023), or the EU IVDR (until 30 June 2023)
    - The manufacturer or their UK Responsible Person must have a registered place of business in the UK
        - **Manufacturers based outside the UK:** Appoint a UK Responsible Person that has a registered place of business in the UK; this UK Responsible Person will then assume the responsibilities of the manufacturer in terms of registering the device with the MHRA

- **Grace periods for compliance with the new registration process:**
  - **Class IIIs and Class IIb implantables, and all active implantable medical devices and IVD List A products:** Must be registered from May 1, 2021
  - **Other Class IIb and all Class IIa devices and IVD List B products and self-test IVDs:** Must be registered from September 1, 2021
  - **Class I devices, custom-made devices, and general IVDs (that do not currently need to be registered):** Must be registered from January 1, 2022
    - It is possible to register devices ahead of the above dates
    - It will be possible for manufacturers to register devices of different classes, that are subject to different grace periods, at the same time
    - Registration for custom-made devices will be in line with the risk class of the device
    - Failure to register from these dates will mean that you will no longer be able to lawfully place your device on the Great Britain market
  - **Manufacturers of Class I devices, custom-made devices and general IVDs that, prior to January 1, 2021, were required to register their devices with the MHRA:** Must continue to register their devices from January 1, 2021 on the same basis as they do now until the new registration requirements start to apply to those devices
  - **Medical device already registered with the MHRA:** Does not need to be re-registered after January 1, 2021
    - Manufacturers (or their UK Responsible Person) will be required to review the information held by the MHRA to ensure it remains in line with the above grace periods
    - **Fee for changes to registrations:** £100 per application
  - **Northern Ireland-based manufacturers that have already registered their medical device with the MHRA for the purposes of Northern Ireland:** The medical device can be placed on the Great Britain market and will not need to undergo any further registration in Great Britain
- **UK Responsible Person:** Required for manufacturers based outside of Great Britain; importers and distributors will not be required to appoint a UK Responsible Person
  - Aim to appoint your UK Responsible Person ASAP
  - An importer or the distributor can act as a UK Responsible Person
  - **Responsibilities of the UK Responsible Person:** Will be set out in the UK MDR 2002
    - Register relevant devices with the MHRA in line with the above grace periods depending on the device class
    - Act on behalf of the outside-UK manufacturer to carry out specified tasks in relation to the manufacturer's obligations
    - 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 and supplements for inspection by the MHRA
    - In response to a request from the MHRA, provide the MHRA with all the information and documentation necessary to demonstrate the conformity of a device
    - Provide samples of a device to the MHRA or allow the MHRA access to the device where the UK Responsible Person has samples or access or, where they do not have access or samples, forward to the manufacturer any request from the MHRA for samples or access

        - 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.
        - 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 designated
        - Terminate the legal relationship with the manufacturer if the manufacturer acts contrary to its obligations under the applicable regulations and inform the MHRA and, if applicable, the relevant Notified Body of that termination
    - **Product labelling where the UKCA mark has been affixed:** From January 1, 2021, the name and address of the UK Responsible Person, where applicable, will need to be included
    - **Product labelling for CE-marked devices:** UK Responsible Person details will not need to be included
- **Importers and distributors:**
    - Where the Great Britain importer is not the UK Responsible Person, the importer will be required to inform the relevant UK Responsible Person of their intention to import a device; the UK Responsible Person will be required to provide the MHRA with a list of device importers
        - Other than this, there will be no additional obligations on distributors or suppliers of medical devices as of January 1, 2021
    - Existing obligations around storage, transportation, and checking device labels for the CE marking or the UKCA marking will continue to apply
    - The importer's name and address will not need to be present on the label unless the importer or the distributor are acting as the UK Responsible Person
- **The UKCA mark:** A new UK product marking that will be used for certain goods, including medical devices, being placed on the Great Britain market after the transition period
    - **Available to use:** From January 1, 2021 (on a voluntary basis)
    - **Mandatory:** From July 1, 2023
    - **Not recognised in the EU, EEA, or Northern Ireland markets; products currently requiring a CE marking will still need a CE marking for sale in these markets**
- **UK approved body:** Required where a third-party conformity assessment is required
    - From January 1, 2021, the MHRA will be able to designate UK approved bodies to conduct assessments against the relevant requirements for the purpose of the UKCA mark
    - Existing UK Notified Bodies with designations under the EU MDD, the EU IVDD, or the EU AIMDD will have their designations rolled over automatically, without having to undergo a new designation process
    - For the purposes of the Great Britain market, UK approved bodies will only be able to conduct conformity assessments in relation to the UKCA mark for medical devices; UK approved bodies will not be able to conduct conformity assessments in relation to the CE marking other than for the purposes of the "CE UKNI" marking, which will be valid in Northern Ireland
- **Manufacturers of Class I medical devices and general IVDs:** Able to self-declare their conformity against the EU MDD or the EU IVDD as transposed by the UK MDR 2002, before affixing a UKCA mark and placing the device on the Great Britain market
    - **Class I medical devices that are sterile or have a measuring function:** Still require approval from a UK approved body in order to be affixed with the UKCA mark and placed on the Great Britain market
- **Recognition of existing CE certificates for the Great Britain market:** From January 1, 2021 under the UK MDR 2002, CE-marked devices with a valid declaration of conformity or certificate will be viewed as meeting the UKCA mark requirements **until June 30, 2023**.

    - This will include devices placed on the market that are:
        - CE marked in conformance with the EU MDD, the EU IVDD, or the EU AIMDD
        - CE marked in conformance with the EU MDR or the EU IVDR
    - Any enforcement or market surveillance powers available in respect of the UKCA mark will apply to CE-marked devices placed on the Great Britain market
    - Where certificates have been issued by a UK Notified Body, the Notified Body will be re-designated as a UK approved body and will continue to oversee these devices and their manufacturers to ensure continued compliance with the applicable standards of safety and performance under the UKCA mark
- **Labelling requirements:** Depending on which legislation the medical device has been certified under, as of January 1, 2021, medical devices placed on the Great Britain market will need to have either a UKCA or a CE marking
    - Where relevant, the number of the Notified Body or the approved body will also need to appear on the label
    - **Valid CE marking on your device:** You will not be required to re-label the device with a UKCA mark until July 1, 2023
    - **Dual marking:** Both the CE mark and UKCA mark can be present on the labelling prior to July 1, 2023, and dual marking will continue to be accepted on the Great Britain market after July 1, 2023
    - **Where the UKCA mark has been affixed (including when devices have been dual marked):** From January 1, 2021, the name and address of the UK Responsible Person, where applicable, will need to be included on product labelling
- **Post-market surveillance and vigilance:**
    - Manufacturer is required to submit vigilance reports to the MHRA when certain incidents occur in the UK that involve their device
    - Manufacturer must take appropriate safety action when required
    - Manufacturer must ensure their device meets appropriate standards of safety and performance for as long as it is in use

Guidance on What You Need To Do To Place a Medical Device on the Northern Ireland Market from January 1, 2021

October 26, 2020

The Medicines & Healthcare products Regulatory Agency (MHRA) has published new **guidance** titled "Regulating medical devices from January 1, 2021." This guidance was re-issued by the MHRA on December 31, 2020.

Under the terms of the Northern Ireland Protocol, from January 1, 2021, the rules for placing medical devices on the Northern Ireland market will differ from those applicable to Great Britain.

In the guidance, "device" includes in vitro diagnostic medical devices and active implantable medical devices. The guidance does not cover other CE-marked products. The proposals outlined in the guidance will take effect through **legislative changes** which are still subject to parliamentary approval and will be introduced later in 2020.

The guidance covers the following matters:

- **Legislation:** The EU Medical Device Regulation (MDR) and EU In Vitro Diagnostic Regulation (IVDR) will apply in Northern Ireland from May 26, 2021 and May 26, 2022, respectively

- **Marking requirements:**

  - **CE marking required:**
    - If you currently CE mark your device on the basis of self-certification: you will be able to continue to do so from January 1, 2021 for the purposes of the Northern Ireland market
  - **UK Notified Body undertakes mandatory third-party conformity assessment:** UKNI marking required in addition to the CE marking
    - **To place a CE marking on your device for circulation in both Northern Ireland and the EU:** You must use an EU-recognised Notified Body to undertake any mandatory third-party conformity assessment; the results of conformity assessments carried out by UK Notified Bodies will not be recognised within the EU
  - **To place goods on the EU market:** Manufacturers must use the CE marking on its own, without the UKNI marking; goods bearing the CE and UKNI marking will not be accepted on the EU market

- **Registration requirements:** After January 1, 2021, certain medical devices (including in vitro diagnostics (IVDs)) placed on the Northern Ireland market must be registered with the MHRA
  - **Class I devices and general IVDs placed on the market by Northern Ireland manufacturers and Authorised Representatives:** must be registered from January 1, 2021
  - **Grace periods for registering other device classes:**
    - **Class IIIs and Class IIb implantables, and all active implantable medical devices and IVD List A products:** must be registered from May 1, 2021
    - **Other Class IIb and all Class IIa devices and IVD List B products and Self-Test IVDs:** must be registered from September 1, 2021
- **Great Britain-based manufacturers:** need to appoint an EU or Northern Ireland-based Authorised Representative to place medical devices on the Northern Ireland market
  - **Northern Ireland-based Authorised Representative appointed:** The Authorised Representative will need to register all device classes with the MHRA
  - **EU-based Authorised Representative appointed:** The manufacturer will need to register all device classes other than Class I devices, custom-made devices, and general IVDs with the MHRA
    - It will be possible for a single entity to act as both an Authorised Representative based in Northern Ireland and a UK Responsible Person
- **Manufacturers based in the EU or EEA, or a third country manufacturer that has an Authorised Representative based in the EU:** You will need to appoint a UK Responsible Person in place from January 1, 2021

  - The UK Responsible Person will act as a regulatory point of contact within the UK from this point and comply with the registration requirements when these begin to apply

- **The requirement to appoint a UK Responsible Person will not apply where:**
  - you are a manufacturer based in Great Britain;
  - you are a manufacturer based in Northern Ireland;
  - your Authorised Representative is based in Northern Ireland; or
  - you only intend to place a Class I medical device, custom-made medical device, or general IVD on the Northern Ireland market, which has been registered with an EU Competent Authority

- **Importer requirements:** Where the Northern Ireland importer is not the Northern Ireland-based Authorised Representative or the UK Responsible Person, the importer will be required to inform the relevant Northern Ireland-based Authorised Representative or UK Responsible Person of their intention to import a device
  - In such cases, the Northern Ireland-based Authorised Representative or UK Responsible Person will be required to provide the MHRA with a list of device importers

- **Unfettered access provisions:** The UK Government will guarantee unfettered access for Northern Ireland's businesses to the rest of the UK internal market from January 1, 2021
  - Northern Ireland business will be able to continue to place CE- and CE UKNI-marked devices on the Great Britain market after June 30, 2023
  - If you are Northern Ireland-based manufacturer and have already registered your device with the MHRA for the purposes of Northern Ireland, it can then be placed on the Great Britain market and will not need to undergo any further registration in Great Britain

- **Post-market surveillance and vigilance:** The MHRA will continue to be the Competent Authority for postmarket surveillance activity for devices placed on the Northern Ireland market
  - Incidents occurring in Northern Ireland will need to be reported to the MHRA