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Initial overview of requirements to import and sell Medical Devices

All devices need to be registered with the MHRA and have a single UK Responsible Person

Register your device to place on the Great Britain market

If the manufacturer is based outside of the UK, they must appoint a single UK Responsible Person to take responsibility for all of their medical devices.

Please note that the accounts of any former Great Britain-based Authorised Representatives that have not updated their role to UK Responsible Person on the MHRA registration system, as well as the accounts of any represented manufacturers, will be suspended from 1 January 2022 until the UK Responsible Person has updated their role.

The UK Responsible Person will then assume the responsibilities of the manufacturer in terms of registering the device with the MHRA.

See guidance for more information about the role of the UK Responsible Person.

Where any changes to registrations are made, a £100 statutory fee will apply per application.

Distributors and suppliers are not required to register with the MHRA.

In cases where the Great Britain importer is not the UK Responsible Person, the importer must inform the relevant manufacturer or UK Responsible Person of their intention to import a device.

In such cases, the UK Responsible Person or the manufacturer must provide the MHRA with the importer details, including their place of business in Great Britain.

The regulation is new and specific the UK to control products on the UK market.

It's based on the product being produce to current CE regulations.

The product file and product needs either self-certification or by a UK based accreditation body

The actions required to place a medical device on the Northern Ireland and Great Briton

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These are Class 1 items so it should be simpler

Class I medical device and general IVD manufacturers

Manufacturers of Class I medical devices and general IVDs can self-declare the conformity of their devices against the UK MDR 2002, before affixing a UKCA marking and placing the device on the Great Britain market.

Manufacturers of Class I medical devices that are sterile or have a measuring function must use a UK Approved Body to undertake third party conformity assessment in order to affix the UKCA marking and place their devices on the Great Britain market

This is my initial overview of the requirements and is based on the assumption you will be the only company importing these products

If they are already being imported then there should already be a responsible person in the UK

The system is controlled by the MHRA and is different for Northern Ireland and Scotland

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Below is the guidance for putting a new product into the UK Market

Guidance

Regulating medical devices in the UK

What you need to do to place a medical device on the Great Britain, Northern Ireland and European Union (EU) markets.

From:
Medicines and Healthcare products Regulatory Agency

Published
31 December 2020

Last updated
1 January 2022 — See all updates

Contents

Overview

The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating the UK medical devices market.

This guidance provides information on the UK system, including for:

- getting your device certified
- conformity marking your device
- registering your device with the MHRA

This guidance is divided into sections on the different rules that apply in Great Britain, Northern Ireland and the EU. Great Britain is England, Wales and Scotland.

Under the Northern Ireland Protocol, different rules apply in Northern Ireland to those in Great Britain. For more information on the regulatory system for medical devices in Northern Ireland, please see Regulation of medical devices in Northern Ireland below.

In this guidance, “medical device” includes in vitro diagnostic medical devices and active implantable medical devices.

This guidance only applies to medical devices and does not cover other CE or UKCA marked products, which are subject to separate guidance.

This information is meant for guidance only. You should consider whether you need separate professional advice before making specific preparations. Speak to your solicitor or trade association if you are unsure which regulatory framework applies to your goods.

Summary of key requirements for placing a device on the Great Britain market

Since 1 January 2021, there have been a number of changes, introduced through secondary legislation, to how medical devices are placed on the market in Great Britain (England, Wales and Scotland). These are:

- a new route to market and product marking (the UKCA marking) is available for manufacturers wishing to place medical devices on the Great Britain market

- all medical devices, including in vitro diagnostic medical devices (IVDs), custom-made devices and systems or procedure packs, need to be registered with the MHRA before they are placed on the Great Britain market
- if you are a medical device manufacturer based outside the UK and wish to place a device on the Great Britain market, you need to appoint a single UK Responsible Person for all of your devices, who will act on your behalf to carry out specified tasks, such as registration. Further detail on the UK Responsible Person is set out below
- CE marking will continue to be recognised in Great Britain until 30 June 2023
- certificates issued by EU-recognised Notified Bodies will continue to be valid for the Great Britain market until 30 June 2023
- the EU no longer recognises UK Notified Bodies
- UK Notified Bodies are not able to issue CE certificates - and have become UK Approved Bodies

Legislation that applies in Great Britain

Devices are regulated under the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) which, prior to the end of the transition period, gave effect in UK law to the directives listed below:

- 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)

This means that the Great Britain route to market and UKCA marking requirements are based on the requirements derived from the above EU legislation.

The EU Medical Devices Regulation and EU in vitro Diagnostic Medical Devices Regulation

Since 26 May 2021, the EU Medical Devices Regulation (Regulation 2017/745) (EU MDR) has applied in EU Member States and Northern Ireland. The in vitro Diagnostic Medical Devices Regulation (Regulation 2017/746) (EU IVDR) will apply in EU Member States and Northern Ireland from 26 May 2022. As these EU regulations did not take effect during the transition period, they were not EU law automatically retained by the EU (Withdrawal) Act 2018 and therefore do not and will not apply in Great Britain.

There is further information below on how devices that have already been registered with the MHRA under the EU MDR or the EU IVDR will be regulated.

The role of the MHRA

The MHRA performs market surveillance of medical devices on the UK market and is able to take decisions over the marketing and supply of devices in the UK.

The MHRA is responsible for the designation and monitoring of UK conformity assessment bodies.

Further guidance is available on how the MHRA enforces the legislation on medical devices.

Requirements for those manufacturing and supplying devices in Great Britain

Manufacturers wishing to place a device on the Great Britain market need to register with the MHRA. More information on registrations (including fees) can be found in the MHRA's registrations guidance.

Where a manufacturer is not established in the UK, they must appoint a UK Responsible Person to register and act on their behalf.
See guidance on UK Responsible Persons below for more information.

Manufacturers must comply with relevant product marking and conformity assessment requirements for medical devices. See below for guidance on the UKCA marking and UK Approved Bodies, and guidance on CE marking and Notified Bodies for more information.

Registrations in Great Britain

All medical devices, including IVDs, custom-made devices and systems or procedure packs must be registered with the MHRA before being placed on the Great Britain market. In Great Britain (England, Wales and Scotland), devices must conform to the UK MDR 2002, the EU MDR (until 30 June 2023), or the EU IVDR (until 30 June 2023) in order to be registered with the MHRA. In addition, devices that have been CE marked under the EU MDD, EU AIMDD or EU IVDD will continue to be accepted on the Great Britain market until 30 June 2023 if their certificates remain valid for the EU market under the transitional arrangements in the EU MDR and EU IVDR.

The MHRA will only accept registration of devices from manufacturers where the manufacturer is based in the UK. If the manufacturer is based outside the UK, they must appoint a UK Responsible Person. This UK Responsible Person will then assume certain responsibilities on behalf of the manufacturer as described below in the guidance for UK Responsible Persons, including registering the device with the MHRA.

Where any new registrations or changes to existing registrations are made, a £100 standard fee will apply per application.

Failure to register your devices will mean that you are unable to lawfully place your device on the Great Britain market.

If you are a Northern Ireland-based manufacturer and have already registered your device with the MHRA for the purposes of the Northern Ireland market, it can then be placed on the Great Britain market and will not need to undergo any further registration in Great Britain.

Further information on registration requirements for Northern Ireland is provided below.

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More information on registrations (including fees) can be found in the MHRA's registrations guidance.

UK Responsible Person

As noted above, to place a device on the Great Britain market (England, Wales and Scotland), manufacturers based outside the UK are required to appoint a UK Responsible Person.

The UK Responsible Person must provide written evidence that they have the manufacturer's authority to act as their UK Responsible Person. UK Responsible Person requirements for the Northern Ireland market are covered separately below. Importers and distributors are not required to appoint a UK Responsible Person.

Please note that the accounts of any former Great Britain-based Authorised Representatives that have not updated their role to UK Responsible Person on the MHRA registration system, as well as the accounts of any represented manufacturers, will be suspended from 1 January 2022 until the relevant UK Responsible Person has updated their role. For further information on registration requirements, please see guidance on registering medical devices.

The UK Responsible Person acts on behalf of the non-UK manufacturer to carry out specified tasks in relation to the manufacturer's obligations. As noted above, this includes registering the manufacturer's devices with the MHRA before the devices can be placed on the Great Britain market.

The responsibilities of the UK Responsible Person are set out in the UK MDR 2002. In summary, in addition to the above registration requirements, the UK Responsible Person 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 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
- 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, and communicate to the MHRA whether the manufacturer intends to comply with that request
- 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 appointed
- if the manufacturer acts contrary to its obligations under these Regulations:
  - terminate the legal relationship with the manufacturer; and
  - inform the MHRA and, if applicable, the relevant Approved Body of that termination.

There is nothing to prevent an importer or distributor from also acting as a UK Responsible Person.

The name and address of the UK Responsible Person, where applicable, must be included on the product labelling or the outer packaging, or the instructions for use in cases where the UKCA marking has been affixed. UK Responsible Person details do not need to be included on labelling for CE marked devices, unless the device bears both the CE and UKCA markings.

Importers and distributors

In cases where the Great Britain importer is not the UK Responsible Person, the importer is required to inform the relevant manufacturer or UK Responsible Person of their intention to import a device. In such cases, the manufacturer or the manufacturer's UK Responsible Person is required to provide the MHRA with details of device importers. Further guidance on device registrations.

Obligations around storage, transportation and checking device labels for the CE marking or UKCA marking also apply. The importer or distributor's name and address do not need to be present on the label unless the importer or distributor are acting as the UK Responsible Person for the purposes of the UKCA marking.

UKCA mark and Conformity Assessment Bodies

UKCA marking

The UKCA (UK Conformity Assessed) marking is a UK product marking used for certain goods, including medical devices, being placed on the Great Britain market (England, Wales and Scotland).
The UKCA marking is not recognised in the EU, EEA or Northern Ireland markets, so relevant products require a CE marking for sale in these markets.

Manufacturers of medical devices can use either the UKCA marking or the CE marking on devices they place on the GB market until 30 June 2023. From 1 July 2023, a UKCA marking will be required in order to place a device on the Great Britain market.

Where third party conformity assessment is required, a UK Approved Body is needed. However, manufacturers of non-sterile and non-measuring Class I devices and general IVDs can self-certify against the UKCA marking.

See the guidance Using the UKCA mark for further information.

UKCA marking requirements are based on the requirements of the relevant Annexes to the Directives listed below, which have been modified by Schedule 2A to the UK MDR 2002:

- 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)

UK Approved Bodies

The MHRA can designate UK Approved Bodies to conduct conformity assessments against the relevant requirements for the purpose of the UKCA marking.

UK Notified Bodies that previously had designations under the EU MDD, EU IVDD or EU AIMDD have had their designations rolled over automatically, without having to undergo a new designation process.

For the purposes of the Great Britain market, UK Approved Bodies can conduct conformity assessments in relation to the UKCA marking, for medical devices, active implantable medical devices and in vitro diagnostic medical devices under Parts II, III, and IV of the UK MDR 2002. UK Approved Bodies are not able to conduct conformity assessments in relation to the CE marking.

The UK Market Conformity Assessment Bodies (UKMCAB) database serves as the UK's database of conformity assessment bodies. It is the definitive source and a register of UK Government-appointed conformity assessment bodies who can certify goods for the Great Britain market.

See the guidance on conformity assessment bodies for further information.

The MHRA can designate UK Notified Bodies for the purposes of conducting conformity assessment for the combined CE and UKNI marking, which is valid on the Northern Ireland market. Please see the Northern Ireland guidance below for further information.

Class I medical device and general IVD manufacturers

Manufacturers of Class I medical devices and general IVDs can self-declare the conformity of their devices against the UK MDR 2002, before affixing a UKCA marking and placing the device on the Great Britain market.

Manufacturers of Class I medical devices that are sterile or have a measuring function must use a UK Approved Body to undertake third party conformity assessment in order to affix the UKCA marking and place their devices on the Great Britain market

CE marking and Notified Bodies

CE marking

We will continue to accept CE marked devices on the Great Britain market until 30 June 2023. This applies to devices that have been CE marked under and fully conform with the following applicable EU legislation:

- Directive 90/385/EEC on active implantable medical devices (EU AIMDD) (for devices that have been CE marked prior to 26 May 2021)
- Directive 93/42/EEC on medical devices (EU MDD) (for devices that have been CE marked prior to 26 May 2021)
- Directive 98/79/EC on in vitro diagnostic medical devices (EU IVDD) (for devices that have been CE marked prior to 26 May 2022)
- Regulation 2017/745 on medical devices (EU MDR)
- Regulation 2017/746 on in vitro diagnostic medical devices (EU IVDR)

From 1 July 2023, devices that are placed on the Great Britain market will need to conform with UKCA marking requirements.

In cases where you self-certify for the CE marking, you will be able to continue to do so and place your device on the Great Britain market until 30 June 2023. Please note that you will need to meet EU MDR requirements for CE marking Class I devices that you self-certify from 26 May 2021. Similarly, you will need to meet IVDR requirements for CE marking if you self-certify general IVDs from 26 May 2022.

Relevant devices that have been self-certified against the CE marking prior to these dates may continue to be placed on the Great Britain market providing their certificates remain valid for the EU market under the transitional arrangements in the EU MDR and EU IVDR.

For other product areas covered by the UKCA marking, a UKCA marking will be required earlier than 1 July 2023. For example, certain product areas listed here, will require a UKCA marking from 1 January 2023.

Where medical devices are subject to the requirements of any of the medical devices legislation cited above and, in order to be CE marked, must also meet the relevant requirements of another piece of EU legislation (such as the Directive restricting the use of certain hazardous substances), they can remain on the Great Britain market carrying a CE mark until 30 June 2023 - irrespective of whether the UK legislation governing the subject matter of that other piece of EU legislation would require a product to have a UKCA marking before 30 June 2023. In order to maintain the use of the CE marking for a medical device in Great Britain, the manufacturer will need to meet all relevant EU legislation that governs their device.

EU Notified Bodies

Any mandatory third-party conformity assessment for the CE marking must be carried out by an EU Notified Body. This includes both EU-based Notified Bodies and Notified Bodies in countries which are listed on the EU's NANDO Information System.

Certificates issued by EU-recognised Notified Bodies that are valid for the EU market, will continue to be valid for the Great Britain market until 30 June 2023.

Recognition of existing CE certificates for the Great Britain market

Under the UK MDR 2002, a CE marked device with a valid declaration of conformity or certificate is viewed as meeting the UKCA marking requirements whilst the CE marking continues to be recognised in Great Britain - until 30 June 2023. This includes devices placed on the market that are:

- CE marked in accordance with the EU MDD or EU AIMDD (prior to 26 May 2021), or EU IVDD (prior to 26 May 2022)
- CE marked in accordance with the EU MDR or EU IVDR

Therefore, any enforcement or market surveillance powers available in respect of the UKCA marking also apply to CE marked devices placed on the Great Britain market.

Where certificates have been issued by a UK Notified Body and those certificates have not been transferred to an EU Notified Body, the UK Notified Body has been 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 marking.

Labelling requirements

Medical devices placed on the Great Britain market must have a UKCA marking or a CE marking, depending on which legislation the device has been certified under.

Where relevant, the number of the Approved Body or Notified Body must also appear on the label.

If you already have a valid CE marking on your device, you are not required to re-label the device with a UKCA marking until 1 July 2023 for placement on the Great Britain market. Devices can have both the CE and UKCA markings present on the labelling prior to 1 July 2023, and dual marking will continue to be accepted on the Great Britain market after 1 July 2023. However, the name and address of the UK Responsible Person, where applicable, 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 have been dual marked).

Post-market surveillance and vigilance

Once a medical device has been placed on the UK market, the manufacturer is required to submit vigilance reports to the MHRA when certain incidents occur in the UK that involve their device. They must also take appropriate safety action when required. The manufacturer must ensure their device meets appropriate standards of safety and performance for as long as it is in use.

Further information about reporting adverse incidents and corrective actions to the MHRA is available for manufacturers of medical devices.

Regulation of medical devices in Northern Ireland

Overview

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 (England, Wales and Scotland).

The Government has introduced new legislation to make changes to how the Northern Ireland Protocol will apply. You should continue to

use the guidance below for now. It will be updated in due course, giving you time to prepare for any new requirements.

There is a requirement, in certain cases, to register devices with the MHRA and to have a UK Responsible Person if the manufacturer is based outside the UK, as set out below.

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:

- Since 26 May 2021, the EU MDR has applied in Northern Ireland. The EU IVDR will apply in Northern Ireland from 26 May 2022
- CE marking is required for the Northern Ireland market. In addition, the UKNI indication is required if a UK Notified Body undertakes mandatory third-party conformity assessment
- certain medical devices, including in vitro diagnostic medical devices (IVDs), placed on the Northern Ireland market need to be registered with the MHRA
- all custom-made devices must be registered with the MHRA within 28 days of being made available on the Northern Ireland market
- when placing devices on the Northern Ireland market, Great Britain-based manufacturers must appoint an EU or Northern Ireland-based Authorised Representative
- IVD manufacturers based outside the UK may be required to have a UK Responsible Person in place to act as a regulatory point of contact within the UK and comply with the registration requirements.

The EU MDR and EU IVDR in Northern Ireland

The EU Medical Devices Regulation (2017/745) has applied in Northern Ireland since 26 May 2021. The in vitro Diagnostic Medical Device Regulation (2017/746) will apply in Northern Ireland from 26 May 2022.

Please see guidance on the application of the MDR and IVDR in Northern Ireland.

CE marking for the Northern Ireland market and implications for UK Approved Bodies

Although the UKCA marking is available for use in Great Britain, a CE marking is needed for devices placed on the Northern Ireland market and EU rules need to be met.

Where allowed for in the relevant legislation, you can CE mark your device on the basis of self-certification for the purposes of the Northern Ireland market.

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 are not recognised within the EU.

UKNI indication

As noted above, for the purposes of the UKCA marking, a UK Approved Body must be used in cases where third party conformity assessment is required. However, for the purposes of the Northern Ireland market, UK-based conformity assessment bodies are referred to as ‘UK Notified Bodies’.

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.

To place goods on the EU market, manufacturers must use an EU-recognised Notified Body and then affix the CE marking on its own. Goods bearing the combined “CE & UKNI” marking will not be accepted on the EU market. If a device manufacturer uses an EU-recognised Notified Body for mandatory third-party conformity assessment, the CE marking on its own is sufficient to place a device on the Northern Ireland market.

In summary, you need to use the UKNI indication if:

- you are placing medical devices on the Northern Ireland market; and
- your medical devices require mandatory third-party conformity assessment; and
- you use a UK Notified Body to carry out those conformity assessments.

You do not need to use the UKNI indication if you have self-certified your medical device or have used an EU-recognised Notified Body for mandatory third-party conformity assessment.

The UKNI indication is sometimes referred to as the UK(NI) mark or the UK(NI) marking. These terms refer to the same marking.

Further guidance on applying the UKNI marking.

Registration and UK Responsible Person requirements for Northern Ireland

Certain medical devices, IVDs and custom-made devices that are placed on the Northern Ireland market need to be registered with the MHRA. The precise requirements depend on the location of the manufacturer, the location of the Authorised Representative and the

device class, as set out below. Please see the MHRA's guidance on registrations for more information.

If you are a non-UK manufacturer placing a IVD on the Northern Ireland market, you may be required to appoint a single UK Responsible Person within the UK. Non-UK manufacturers are not required to appoint a UK Responsible Person for the purpose of placing other devices on the Northern Ireland market.

The requirement to appoint a UK Responsible Person for the purposes of the Northern Ireland market applies in cases where:

- you are a manufacturer based in the EU or the EEA; and
- you place an Annex II device or a device for self-testing on the Northern Ireland market or make available such a device for performance evaluation; OR
- you are a manufacturer based outside the UK, the EU and the EEA; and
- you have an Authorised Representative based outside Northern Ireland; and
- you place an Annex II device or a device for self-testing on the Northern Ireland market or make available such a device for performance evaluation.

Great Britain manufacturers are required to appoint an Authorised Representative based in the EU or Northern Ireland in order to place a device on the Northern Ireland market. Where a Northern Ireland-based Authorised Representative is appointed, the Authorised Representative needs to register devices of all classes with the MHRA. Where an EU-based Authorised Representative is appointed, the Great Britain-based manufacturer needs to register all device classes other than Class I devices and general IVDs with the MHRA.

It is possible for a single entity to act as both an Authorised Representative based in Northern Ireland and a UK Responsible Person.

There is currently a requirement to register with the MHRA, certain medical devices (including IVDs, custom-made devices and systems or

procedure packs) that are placed on the Northern Ireland market. This requirement does not apply to manufacturers placing Class I medical devices or general IVDs on the Northern Ireland market in cases where:

- the manufacturer is based in the EU or EEA, OR
- the manufacturer is based outside Northern Ireland, the EU or EEA and has appointed an EU-based Authorised Representative.

Registration of custom-made devices in Northern Ireland

We have recently introduced legislation to supplement provisions that were introduced in Northern Ireland on 26 May 2021 when the EU Medical Devices Regulation (2017/745) (EU MDR) took effect. This legislation includes a requirement to register all custom-made devices with the MHRA within 28 days of being made available on the Northern Ireland market.

Unfettered access provisions

The UK Government has guaranteed unfettered access for Northern Ireland's businesses to the rest of the UK internal market.

For medical devices, this means that any CE marked device held by a Northern Ireland business is valid for the whole of the UK market provided it falls within the definition of a qualifying "Northern Ireland good". Therefore, Northern Ireland businesses can continue to place most CE and CE UKNI marked devices on the Great Britain market after 30 June 2023.

In addition, if you are a Northern Ireland-based manufacturer and have already registered your device with the MHRA for the purposes of Northern Ireland, it can 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 is the Competent Authority for post-market surveillance activity for devices placed on the Northern Ireland market. Where incidents occur in Northern Ireland, these need to be reported to the MHRA.

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Placing a medical device on the EU market

CE marking for the EU market

The UKCA marking is not recognised on the EU market. To place a device on the EU market you must adhere to the relevant EU legislation and affix a CE mark to demonstrate compliance.

If you use a UK-based Notified Body to conduct any mandatory third-party conformity assessment for your device, the following will apply:

- if your device was placed on the EU market before 1 January 2021, in accordance with the terms of the Withdrawal Agreement, it may remain on the EU market
- from 1 January 2021, you are not able to place a device on the EU market unless it has been assessed by an EU-recognised Notified Body

Conformity assessment

The results of mandatory conformity assessment carried out by UK based conformity assessment bodies are not recognised by the EU. This is the case even if the assessment was carried out before 1 January 2021, unless your product had already been placed on the EU market before 1 January 2021.

Where allowed for under the relevant legislation, you can CE mark your medical device on the basis of self-certification for the purposes of the EU market.

Authorised Representatives

Great Britain-based Authorised Representatives are no longer recognised in the EU. This means that they are not able to carry out tasks on the manufacturer’s behalf for the purposes of placing devices on the EU market.

If you are a manufacturer based in Great Britain or another country outside the EU, you must appoint an Authorised Representative based in the EU or Northern Ireland if you wish to supply devices to the EU market.

Labelling requirements

You must ensure that your device meets EU labelling requirements in order to place it on the EU market. Both the CE marking and UKCA marking can be placed on a product so long as neither impedes the visibility of the other and both marking requirements are met. Devices placed on the Northern Ireland market must meet EU labelling requirements.

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The Medical Device Regulations