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Guidance

Regulating medical devices from 1 January 2021

What you need to do to place a medical device on the Great Britain, Northern Ireland and European Union (EU) markets from 1 January 2021.

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From:
Medicines and Healthcare products Regulatory Agency
(https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency)

New rules for January 2021

The UK has left the EU, and the transition period after Brexit comes to an end this year.

This page tells you what you'll need to do from 1 January 2021. It will be updated if anything changes.

For current information, read: Medical devices regulation and safety (https://www.gov.uk/topic/medicines-medical-devices-blood/medical-devices-regulation-safety)

You can also read about the transition period (https://www.gov.uk/transition).

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Overview

From 1 January 2021 the Medicines and Healthcare products Regulatory Agency (MHRA) will take on the responsibilities for the UK medical devices market that are currently undertaken through the EU system.

This guidance provides information on how the UK system will operate, 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 will apply in Great Britain, Northern Ireland and the EU. Great Britain is England, Wales and Scotland.

For Northern Ireland, different rules will apply to those in Great Britain after the transition period. For more information on the regulatory system for medical devices in Northern Ireland, please see 'Regulation of medical devices in Northern Ireland'

This guidance does not cover other 'New Legislative Framework' products, which are subject to separate guidance.

The proposals outlined in this guidance notice will take effect through legislative changes that will be introduced later in 2020. They are still therefore subject to parliamentary approval.

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

From 1 January 2021, there will be a number of changes to how medical devices are placed on the market in Great Britain. These are:

- CE marking will continue to be used and recognised until 30 June 2023
- Certificates issued by European Economic Area (EEA)-based Notified Bodies will continue to be valid for the Great Britain market until 30 June 2023
- A new route to market and product marking will be available for manufacturers wishing to place a device on the Great Britain market from 1 January 2021
- From 1 January 2021, all medical devices and in vitro diagnostic medical devices (IVDs) placed on the UK market will need to be registered with the MHRA. There will be a grace period for registering:
    - 4 months for Class IIIs and Class IIb implantables, and all active implantable medical devices
    - 8 months for other Class IIb and all Class IIa devices
    - 12 months for Class I devices
- The above 12-month grace period will not apply to manufacturers of Class I devices and general IVDs that are currently required to register with the MHRA.

- If you are a manufacturer based outside the UK and wish to place a device on the UK market, you will need to establish a UK Responsible Person who will take responsibility for the product in the UK. Further detail on the UK Responsible Person is set out below.

The legislation

Legislation that will apply to Great Britain

Currently, devices are regulated under:

- Directive 90/385/EEC (https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:31990L0385&from=EN) on active implantable medical devices (EU AIMDD)
- Directive 93/42/EEC (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31993L0042) on medical devices (EU MDD)
- Directive 98/79/EC (https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:31998L0079&from=EN) on in vitro diagnostic medical devices (EU IVDD)

These directives are given effect in UK law through the Medical Devices Regulations 2002 (http://www.legislation.gov.uk/uksi/2002/618/contents/made) (SI 2002 No 618, as amended) (UK MDR 2002). These Regulations (in the form in which they exist on 1 January 2021) will continue to have effect in Great Britain after the transition period.

The EU Medical Devices Regulation (MDR) and EU in vitro Diagnostic Medical Devices Regulation (IVDR) from 1 January 2021

The MDR and IVDR will fully apply in EU Member States from 26 May 2021 and 26 May 2022 respectively. As these regulations will not take effect until after the transition period with the EU has ended, they will not be EU law automatically retained by the EU Withdrawal Agreement Act and will therefore not automatically apply in Great Britain.

The Independent Medicines and Medical Devices Safety Review, which delivered its report this July, has highlighted the importance of strengthened regulations that do more to protect patients. We are committed to improving the standards and scrutiny of medical devices that reach UK patients. This will be enabled through the powers currently being created through the Medicines and Medical Devices Bill (https://services.parliament.uk/bills/2019-21/medicinesandmedicaldevices.html).

We have the opportunity to develop a robust, world-leading regulatory regime for medical devices that prioritises patient safety. We will take into consideration international standards and global harmonisation in the development of our future system.

We will engage with stakeholders within the life sciences and healthcare sectors on this proposed regime this autumn. As part of these discussions, we will identify and prioritise elements of international practice that promote public health and patient safety. This will be followed by a formal public consultation with the aim of delivering an attractive world-class regulatory system.

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

The role of the MHRA

The MHRA will continue to perform market surveillance of medical devices on the UK market and will be able to take decisions over the marketing and supply of devices in the UK.

The MHRA will continue to be 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 (https://www.gov.uk/government/publications/report-a-non-compliant-medical-device-enforcement-process/how-mhra-ensures-the-safety-and-quality-of-medical-devices).

Requirements for those manufacturing and supplying devices in the UK

Overview

From 1 January 2021, the roles and responsibilities of those manufacturing and supplying medical devices and IVDs will change.

Manufacturers wishing to place a device on the UK market will first need to register with the MHRA. See guidance on registrations for more information (https://www.gov.uk/guidance/register-as-a-manufacturer-to-sell-medical-devices).

Where a manufacturer is not established in the UK, in most cases it will need to designate a UK Responsible Person to register and act on its behalf. See guidance on UK Responsible Persons below for more information.

Manufacturers will need to comply with relevant product marking and conformity assessment requirements for medical devices, including IVDs. See below for guidance on UKCA mark and Conformity Assessment Bodies and guidance on CE marking and Notified Bodies for more information.

Registrations in Great Britain

From 1 January 2021, any medical device, IVD or custom-made device will need to be registered with the MHRA before being placed on the Great Britain market.

The MHRA will only register devices where the manufacturer has a registered place of business in the UK. If the manufacturer is based outside the UK, they will need to designate 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.

These new registration requirements will not apply until 1 January 2021 and that there will be a grace period for registrations, as set out below.

The requirement for a manufacturer to have in place a UK Responsible Person is in line with the grace period for registering devices with the MHRA.

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

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

Registering your device from 1 January 2021

Given that this is an extension of existing registration requirements, there will be a grace period to allow time for compliance with the new registration process.

For the following devices, you will have 4 months to register with the MHRA (until 30 April 2021):

- Active implantable medical devices
- Class III medical devices
- Class IIb implantable medical devices
- IVD List A

For the following devices, you will have 8 months to register with the MHRA (until 31 August 2021):

- Class IIb non-implantable medical devices
- Class IIa medical devices
- IVD List B
- Self-test IVDs

For the following devices, you will have 12 months to register with the MHRA (until 31 December 2021):

- Class I medical devices
- General IVDs

Note that the above 12-month grace period will not apply to manufacturers of Class I devices and general IVDs that are currently required to register with the MHRA.

Registration for custom-made devices will be in line with the risk class of the device. Failure to register by these dates will mean that you will no longer be able to lawfully place your device on the UK market.

Class I devices, custom-made devices and general IVDs being placed on the Northern Ireland market must continue to register as normal as the 12-month grace period will not apply.

More information on registrations (including fees) can be found in the MHRA's registrations guidance (https://www.gov.uk/guidance/register-as-a-manufacturer-to-sell-medical-devices).

UK Responsible Person

As noted above, to place a device on the Great Britain market, manufacturers based outside the UK will need to designate a UK Responsible Person that is established in the UK.

Requirements for appointing a UK Responsible Person to place devices on the Northern Ireland market are covered separately below.

The UK Responsible Person will act on behalf of the outside-UK manufacturer to carry out specified tasks in relation to the manufacturer's obligations. This includes registering with the MHRA before the manufacturer's devices can be placed on the UK market.

The responsibilities of the UK Responsible Person will be set out in the UK MDR 2002 (in the form in which they exist on 1 January 2021). In summary, 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.
- Forward to the manufacturer any request by the MHRA for samples, or access to a device, and ensure that the MHRA receives the samples or has been given access to the device.
- 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 these Regulations and inform the MHRA and, if applicable, the relevant notified body of that termination.

UKCA mark and Conformity Assessment Bodies

UKCA mark

The UKCA (UK Conformity Assessed) mark is 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. The UKCA mark will not be recognised in the EU, EEA or Northern Ireland markets, and products currently requiring a CE marking will still need a CE mark for sale in these markets. Manufacturers will be able to use the UKCA mark from 1 January 2021.

See the guidance Using the UKCA mark from 1 January 2021 (https://www.gov.uk/guidance/using-the-ukca-mark-from-1-january-2021) for further information.

From 1 July 2023, to place a device on the Great Britain market, you will need to meet the requirements for placing a UKCA mark on your device. This requirement will not apply to Northern Ireland traders.

UK Conformity Assessment Bodies

From 1 January 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 MDD, IVDD or AIMDD will have their designations rolled over automatically, without having to undergo a new designation process.

UK Approved Bodies will only be able to conduct conformity assessments, in relation to the UKCA mark, for medical devices, active implantable medical devices and in vitro diagnostic medical devices under Parts II, III, and IV of the UK MDR 2002 (in the form in which they exist on 1 January 2021).

Class I device manufacturers

Manufacturers of Class I medical devices and general IVDs will be able to self-declare their conformity against Part II and Part IV of the UK MDR 2002 (in the form in which they exist on 1 January 2021), 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 will still require approval from an Approved Body in order to be affixed with the UKCA mark and placed on the Great Britain market.

CE marking and Notified Bodies

CE marking

The MHRA will continue to recognise the CE mark for devices until 30 June 2023. This will apply to devices placed on the Great Britain market that have been CE marked under and fully conform with the following applicable EU legislation:

- Directive 90/385/EEC (https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex:31990L0385) on active implantable medical devices (EU AIMDD)
- Directive 93/42/EEC (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31993L0042) on medical devices (EU MDD)
- Directive 98/79/EC (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31998L0079) on in vitro diagnostic medical devices (EU IVDD)
- Regulation 2017/745 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745) on medical devices (EU MDR)
- Regulation 2017/746 (https://eur-lex.europa.eu/eli/reg/2017/746/oj) on in vitro diagnostic medical devices (EU IVDR)

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

If you currently CE mark your medical device on the basis of self-certification, you will be able to continue to do so after 1 January 2021 and place your device on the Great Britain market until 30 June 2023.

Devices that have been CE marked by Northern Ireland traders will continue to be accepted on the Great Britain market beyond 30 June 2023. This will apply to devices that have been self-certified or have undergone mandatory third-party conformity assessment by an EEA-based Notified Body. Please see further guidance below on regulation of medical devices in Northern Ireland.

Notified Bodies

Certificates issued by EEA-based Notified Bodies will continue to be valid for the Great Britain market until 30 June 2023.

If you wish to place a CE marked device on the Great Britain market from 1 January 2021, any mandatory third-party conformity assessment and certification will need to have been conducted by an EEA-based Notified Body. This will allow you to place a CE mark on your device and place it on both the UK and EU markets. However, you will need to designate an EU, EEA or Northern Ireland based Authorised Representative if you wish to place your device on the Northern Ireland, EU or EEA markets.

Recognition of existing CE certificates for the Great Britain market

From 1 January 2021, under the UK MDR 2002 (in the form in which they exist on 1 January 2021), a CE marked device with a valid declaration of conformity or certificate will be viewed as meeting the UKCA mark requirements whilst the CE mark continues to be recognised in Great Britain. This will include devices placed on the market that conform with the EU MDR or EU IVDR.

Therefore, any enforcement or market surveillance powers available in respect of the UKCA mark will apply to CE marked devices. Where your certificate has been issued by a UK Notified Body, the 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

As of 1 January 2021, medical devices placed on the Great Britain market will need to have either a UKCA mark or a CE mark, depending on which legislation the device has been certified under.

Where relevant, the number of the Notified Body or Approved Body will also need to appear on the label.

If you already have a valid CE mark on your device, you will not be required to re-label the device with a UKCA mark until 1 July 2023 for placement on the Great Britain market. Devices that are dual labelled with both the CE and UKCA marks will continue to be accepted on the Great Britain market after 1 July 2023.

Post-market surveillance and vigilance

Once a medical device has been placed on the UK market, the manufacturer will continue to be required to submit vigilance reports to the MHRA when certain incidents occur in the UK that involve their device. They must also continue to take appropriate safety action when required. The manufacturer will need to 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 (https://www.gov.uk/government/collections/medical-devices-guidance-for-manufacturers-on-vigilance) is available for manufacturers of medical devices.

Regulation of medical devices in Northern Ireland

Overview

Under the terms of the Northern Ireland Protocol (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/840230/Revised_Protocol_to_the_Withdrawal_Agreement.pdf), from 1 January 2021, the rules for placing medical devices on the Northern Ireland market will differ from those applicable to Great Britain.

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

EU MDR and EU IVDR

The Medical Device Regulations (2017/745) and the in vitro Diagnostic Medical Device Regulations (2017/746) will apply in Northern Ireland from 26 May 2021, and 26 May 2022 respectively, in line with the EU's implementation timeline.

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

Although the UKCA mark will need to be used in Great Britain from 1 July 2023, a CE mark will continue to be needed for devices placed on the Northern Ireland market and EU rules will need to be met.

If you currently CE mark your device on the basis of self-certification, you will be able to continue to do so for the purposes of the Northern Ireland market. From 1 January 2021, the results of mandatory conformity assessment carried out by UK Notified Bodies (Approved Bodies) will not be recognised by the EU. You will need to use an EU-recognised Notified Body to undertake any mandatory third-party conformity assessment in order to CE mark your device. This will allow it to circulate in the EU.

UK Approved Bodies will be able to conduct conformity assessments for the purposes of the Northern Ireland market as follows: for medical devices, active implantable medical devices and in vitro diagnostic medical devices under Parts II, III, and IV of the UK MDR 2002 (in the form in which they exist in Northern Ireland).

Where a device has been assessed by a UK Approved Body, the UK(NI) mark will accompany, but not replace, the CE mark. Products carrying both the CE mark and UK(NI) mark cannot be placed on the EU market.

UKCA marked devices will not be accepted on the Northern Ireland market unless accompanied by the CE or CE UK(NI) mark.

Registration and UK Responsible Person requirements for Northern Ireland

From 1 January 2021, most medical devices, IVDs and custom-made devices will need to be registered with the MHRA before being placed on the Northern Ireland market. The precise requirements will 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 (https://www.gov.uk/guidance/register-as-a-manufacturer-to-sell-medical-devices) for more information.

Where the manufacturer is located in Northern Ireland

The obligation to register the device will be on the manufacturer. All device classes (including IVDs and custom-made devices) will need to be registered with the MHRA.

Where the manufacturer is located in Great Britain

The manufacturer will be required to designate an Authorised Representative before placing a device on the Northern Ireland market. If the Authorised Representative is based in Northern Ireland, they will be required to register all device classes (including IVDs and custom-made devices). If the Authorised Representative is based in the EU or the EEA, they will be required to register all devices except Class I devices, custom-made devices or general IVDs, which must instead be registered in the EU.

Where the manufacturer is located in the EU or the EEA

They will be required to designate a UK Responsible Person before placing a Class I device, Class IIa device, Class IIb device, Class III device, Annex II List A IVD, Annex II List B IVD or self-test IVD on the Northern Ireland market. The UK Responsible Person will be required to register the device.

Where the manufacturer is located in a third country (i.e. outside the UK, EU and EEA)

They will be required to designate a UK Responsible Person, who must register a Class I device, Class IIa device, Class IIb device, Class III device, Annex II List A IVD, Annex II List B IVD or self-test IVD before placing it on the Northern Ireland market. Where the manufacturer has an Authorised Representative established in Northern Ireland, they will not require a UK Responsible Person. In such cases, the Northern Ireland-based Authorised Representative must register all relevant devices and IVDs with MHRA.

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

These new registration requirements will not apply until 1 January 2021 and that there will be a grace period for registrations, as set out above.

Post-market surveillance and vigilance

The MHRA will continue to be the Competent Authority for post-market surveillance activity for devices placed on the Northern Ireland market. Where incidents occur in Northern Ireland, these will need to be reported to the MHRA.

Placing a medical device on the EU market

CE marking for the EU market after the transition period

From 1 January 2021, devices destined for the EU market will need to adhere to the relevant EU legislation and be affixed with the CE mark to demonstrate compliance.

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

- if your device is 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 will not be able to place a device on the EU market if your mandatory third-party conformity assessment has been conducted by a UK Notified Body.

Conformity assessment

The results of mandatory conformity assessment carried out by UK Notified Bodies (Approved Bodies) will not be recognised by the EU. This is the case even if the assessment is carried out before the end of the transition period, unless the product has already been placed on the EU market before 1 January 2021.

If you wish to place a medical device on the EU market after 31 December 2020 that must undergo mandatory third-party conformity assessment, you will need to use an EEA-based Notified Body.

If you currently CE mark your medical device on the basis of self-certification, you will be able to continue to do so after 1 January 2021 for the purposes of the EU market, but will need to appoint an EU or Northern Ireland-based Authorised Representative.

Your UK Notified Body may already be taking steps of its own, so that you can continue to export to the EU without needing to find a new EU Notified Body yourself.

If not, you will need to either:

- Get your devices reassessed by an EU-recognised Notified Body (http://ec.europa.eu/growth/tools-databases/nando/)
- Arrange for the files to be transferred to an EU-recognised Notified Body before 1 January 2021

Authorised Representatives

Great Britain-based Authorised Representatives will not be recognised in the EU from 1 January 2021, regardless of when products were placed on the market. This means that they will not be recognised as 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 outside the EU and you currently have a Great Britain-based Authorised Representative, you should make plans to engage an Authorised Representative based in the EU or Northern Ireland.

If you are a Great Britain-based manufacturer and wish to continue to supply CE marked devices to the EU market, you will need to establish an Authorised Representative based in the EU or Northern Ireland, to register and act on your behalf.

Labelling requirements

From 1 January 2021, you will need to ensure that your device meets EU labelling requirements in order to place it on the EU market. Devices placed on the Northern Ireland market from 1 January 2021 will also need to meet EU labelling requirements, but will need to be affixed with a CE (UK/NI) mark if any mandatory conformity assessment has been undertaken by a UK Approved Body.

Contact us

Please direct any queries to devices.regulatory@mhra.gov.uk.

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Transition period

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- Placing manufactured goods on the market in Great Britain from 1 January 2021 (https://www.gov.uk/guidance/placing-manufactured-goods-on-the-market-in-great-britain-from-1-january-2021)
- Using the UKCA mark from 1 January 2021 (https://www.gov.uk/guidance/using-the-ukca-mark-from-1-january-2021)
- Conformity assessment bodies: change of status from 1 January 2021 (https://www.gov.uk/guidance/conformity-assessment-bodies-change-of-status-from-1-january-2021)

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