Regulating medical devices in the event of a no-deal Brexit

What you need to know about the regulation of medical devices in the UK if we leave the EU with no deal.

Published 26 February 2019
Last updated 8 August 2019 — see all updates

From:

Medicines and Healthcare products Regulatory Agency

Contents

Details

This guidance will apply from exit day in line with the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 .

This guidance sets out how medical devices will be regulated in the UK in a no-deal Brexit scenario.

In a no deal scenario the UK's current participation in the European regulatory network for medical devices would end, and theMHRA would take on the responsibilities for the UK market currently undertaken through the EU system.

This guidance provides further detail on how the UK system would operate, including for:

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

These proposals are still subject to parliamentary approval of the changes to the relevant statutory instruments that are required to bring these proposals into law.

This guidance will apply from exit day in line with the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 .

This notice is meant for guidance only. You should consider whether you need separate professional advice before making specific preparations.

The legislation

How devices are regulated before the UK leaves the EU

In the UK, all devices placed on the UK market are subject to EU legislation, which requires a manufacturer to place a CE mark on their product to attest compliance to applicable European standards.

Devices are regulated under:

- 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)

These directives are transposed into UK law in the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002).

The MHRA's powers are found in various pieces of legislation: in the Consumer Rights Act 2015, the Consumer Protection Act 1987, and the General Product Safety Regulations 2005, with some powers contained in the UK MDR 2002.

There will also be certain pieces of EU tertiary legislation that has direct effect in UK law, namely:

- Regulation (EU) 722/2012
- Regulation 920/2013
- Directives 2003/12 and 2005/50
- Regulation 207/2012
- Regulation 2017/2185
- Commission Decisions 2002/364 and 2010/227

Furthermore, two new EU Regulations entered into force on 25 May 2017, namely:

- Regulation 2017/745 on medical devices (EU MDR)
- Regulation 2017/746 on in vitro diagnostic medical devices (EU IVDR)

The EU MDR and EU IVDR will fully apply in EU Member States from 26 May 2020 and 2022 respectively, but devices can already be placed on the market under these new Regulations (if they fully comply with the new Regulations).

How devices will be regulated from the day the UK leaves the EU

The EU AIMDD, EU MDD and EU IVDD will continue to apply to the UK through the UK MDR 2002.

The Medical Devices (Amendment etc.) (EU exit) Regulations 2019 (UK MDR 2019) will amend the UK MDR 2002 in part by fixing deficiencies in those Regulations to reflect the new regime for our departure from the EU.

The UK MDR 2019 will also transpose all the key elements contained in the EU MDR and EU IVDR, which will be brought into force in line with the transitional timetable being followed by the EU for the full application of those two Regulations.

These new requirements can be found in Part VIII of the UK MDR 2002 (for medical devices) and Part IX of the UK MDR 2002 (for IVDs).

The role of the MHRA

The MHRA will continue to perform market surveillance of medical devices on the UK market and be able to take a decision over the marketing and supplying of a device in the UK, regardless of the position of the European regulatory network, or any post-exit decision of the European Court of Justice.

There is a guidance page which contains information about how we enforce the legislation.

Role of those manufacturing and supplying devices

Overview

In the event of a no-deal Brexit, from the day the UK leaves the EU the roles and responsibilities of those manufacturing and supplying medical devices and IVDs will change.

Based on the European Commission's Notice to Stakeholders of 22 January 2018, we understand that UK-based Authorised Representatives will no longer be recognised in the EU. Under UK legislation a new role, known as a UK Responsible Person, will be created for manufacturers based outside of the UK.

Manufacturers

The UK MDR 2002 sets out requirements that a manufacturer must meet. Manufacturers seeking conformity with the EU Directives transposed by that statutory instrument should continue to follow these

criteria. A new Schedule (2A) has been inserted into the UK MDR 2002 which sets out how the Annexes to the Directives which are crossed referenced in Parts II, III and IV of the UK MDR 2002 should be read in a UK specific context after the UK has left the EU.

Action manufacturers must take

Manufacturers wishing to place a device on the UK market must first register with the MHRA (see the section titled 'Registrations' for more information on this).

Where a manufacturer is not established in the UK, it must designate a UK Responsible Person (see below) to register and act on its behalf.

These registration requirements are set out in regulation 7A (for medical devices), regulation 21A (for active implantable medical devices) and regulation 33A (for IVDs) in the UK MDR 2002 (as amended by the UK MDR 2019).

Additional responsibilities for manufacturers of medical devices

There are additional responsibilities for manufacturers wishing to comply with Part VIII or Part IX of the UK MDR 2002 (as amended by the UK MDR 2019), which transposes the relevant requirements from the EU MDR and the EU IVDR. These additional responsibilities include, but are not limited to:

- correctly classifying the device against the new risk classification criteria
- meeting general safety and performance requirements, including for labelling and technical documentation and quality management systems
- meeting increased requirements for clinical evidence
- having a person responsible for regulatory compliance in place
- meeting the new vigilance reporting timescales and creating an annual periodic safety update report

More information about these additional manufacturers' obligations can be found at regulation 76 (for medical devices) and regulation 145 (for IVDs) of the UK MDR 2002 (as amended by the UK MDR 2019).

Authorised Representatives

For medical devices and in vitro diagnostic medical devices (IVDs), after the UK leaves the EU, any UK-based Authorised Representative will no longer be recognised under EU law. This means they will not be recognised as able to carry out tasks on the manufacturer's behalf for the purposes of placing products on the EU market.

In order to place devices on the EU market, manufacturers with an Authorised Representative based in the UK will need to establish a new Authorised Representative in an EU country.

UK Responsible Person

A new role – the UK Responsible Person – has been created under the UK MDR 2002 (as amended by the UK MDR 2019), which applies from the day the UK leaves the EU. The UK Responsible Person, who must be established in the UK, acts on behalf of a manufacturer established outside the UK to carry out specified tasks in relation to the manufacturer's obligations. This includes registering with the MHRA before the device is placed on the UK market. If you are a designated UK Responsible Person of a non-UK manufacturer, we require documentary evidence supporting your position.

This evidence should be in the form of a headed letter (letter of designation) or signed contract, which states the company name and address for both the overseas manufacturer and the UK Responsible Person. This document must state that, you, as the UK Responsible Person, are acting with the consent of the overseas manufacturer and the legislation that applies for the devices being placed on the UK market.

Although you may make use of resources based outside of the UK, there must be someone physically located within the UK for the MHRA to communicate with.

You must provide an address which can be used for official communications, and you must be contactable at the address provided.

You are also obliged to keep certain information at the disposal of the MHRA, such as declarations of conformity and technical documentation.

You can read more about the UK Responsible Person's obligations in regulation 77 (for medical devices) and regulation 146 (for IVDs) of the UK MDR 2002 (as amended by the UK MDR 2019).

Importers

An importer is defined as "any person established within the United Kingdom that places a device from a country outside the United Kingdom on the market".

Currently, cross-sectorial legislation applies to importers, which means that you must ensure that your products are safe by:

- warning consumers about potential risks
- providing information to help consumers understand the risks
- monitoring the safety of products, including immediately forwarding any complaints or reports of suspected incidents concerning a medical device you have supplied to the manufacturer
- taking action if a safety problem is found, including co-operating with the manufacturer concerning any Field Safety Corrective Actions

In order to ensure that the device has been CE marked by the manufacturer, you should request the manufacturer's declaration of conformity.

There is a guidance document on our website which contains further advice and guidance for importers.
If a person places a product on the market under Part VIII or Part IX of the UK MDR 2002 (as amended by the UK MDR 2019), a number of additional obligations will apply to importers, which will include, but are not limited to, verifying that:

- the device has been CE marked

- the manufacturer is identified and has a UK Responsible Person, if required
- the device has been labelled correctly and a Unique Device Identifier (UDI) has been assigned to the device
- the device is registered with the MHRA

You can read more about the importer's obligations in regulation 78 (for medical devices) and regulation 147 (for IVDs) of the UK MDR 2002 (as amended by the UK MDR 2019).

Distributors

A distributor is defined as "any person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service."

Currently, cross sectorial legislation applies to distributors, which means that you must ensure that your products are safe by:

- warning consumers about potential risks
- providing information to help consumers understand the risks
- monitoring the safety of products, including immediately forwarding any complaints or reports of suspected incidents concerning a medical device you have supplied to the manufacturer
- taking action if a safety problem is found, including co-operating with the manufacturer concerning any Field Safety Corrective Actions

In order to ensure that the device has been CE marked by the manufacturer, you should request the manufacturer's declaration of conformity.

Distributors – for example shops and wholesalers – are not normally liable for harm to consumers or their property caused by an unsafe product, as long as they identify the producer. But distributors of devices do have some responsibility for safety and can face enforcement action.

There is additional advice and guidance for distributors, including product liability and safety law on our website.

If a person places a product on the market under Part VIII or Part IX of the UK MDR 2002 (as amended by the UK MDR 2019), a number of additional obligations will apply to distributors, which will include, but are not limited to, verifying that:

- the device has been CE marked
- the device is accompanied relevant information to be supplied by the manufacturer
- the importer has complied with their general obligations
- a UDI has been assigned to the device

You can read more about the distributor's obligations in regulation 79 (for medical devices) and regulation 148 (for IVDs) of the UK MDR 2002 (as amended by the UK MDR 2019).

Parallel importers

Before exit day, if you want to put a medical device which is already marketed in an EU country on the market in another EU country not intended by the manufacturer, this is known as a parallel import.

After the UK leaves the EU, parallel importing from the EU into the UK will not be possible. Any device that is imported from the EU and placed on the UK market will be treated as a new placing on the market, with all of the relevant manufacturer requirements applying to this importer, including the requirement to register the device with the MHRA. You will also need to ensure that there is a UK Responsible Person in place for this product.

Determining whether your product is a device

Overview

Before you place your product on the market, you will need to ensure it meets the relevant definition set out in the UK MDR 2002. There are three main types of devices: a medical device, an active implantable medical device, or an in vitro diagnostic medical device.

These definitions will change from 26 May 2020 (for medical devices) and 26 May 2022 (for IVDs). More information on these new definitions can be found below.

Definitions

General medical devices

According to the UK MDR 2002, a medical device is described as any instrument, apparatus, appliance, material or other article used whether used alone or combination, together with any software necessary for its proper application, in humans to:

- diagnose, prevent, monitor, treat or alleviate disease
- diagnose, monitor, treat, alleviate or compensate for an injury or handicap
- investigate, replace or modify the anatomy or a physiological process
- control conception

A medical device does not achieve its main intended action by pharmacological, immunological or metabolic means although it can be assisted by these

Examples of medical devices include bandages, hospital beds, surgical instruments and joint replacements.

See the guidance on borderline products if you are unsure whether your product is a medicine or a medical device.

Active implantable medical devices

The UK MDR 2002 describes an active implantable medical device as a medical device which:

- relies for its functioning on a source of electrical energy or a source of power other than that generated directly by the human body or by gravity
- is intended to be totally or partially introduced into the human body

- is intended to remain in the human body after completion of the surgical or medical procedure during which it is introduced.

Examples of active implantable medical devices include implantable hearing aids, cardiac pacemaker systems, and implantable infusion pumps.

In vitro diagnostic medical devices (IVDs)

According to the UK MDR 2002, these types of devices are reagents, calibrators, control materials, kits, instruments or apparatus that are intended to be used in vitro to examine specimens including blood and tissues donations from the human body.

Examples of IVDs include, but are not limited to:

- blood grouping reagents
- pregnancy test kits
- Hepatitis B test kits
- blood glucose self-test kits

We have issued further guidance on the legislation relating to in vitro diagnostic devices which covers the process of placing IVDs on the market in depth.
Some IVDs may be borderline products. The European Commission has published guidance on borderline IVD products.
The complete requirements for IVDs can be found in Part IV of the UK MDR 2002.

Future changes to definitions from May 2020

There have been some changes to the definition of medical device and IVDs, which will fully apply from 26 May 2020 and 26 May 2022 respectively. These definitions may apply to devices placed on the market before these dates if the device has followed a conformity assessment provided for in Parts VIII or IX of the UK MDR 2002 (as amended by the UK MDR 2019).

You can read more about the new definitions in regulation 69 (for medical devices) and regulation 137 (for IVDs) of the UK MDR 2002 (as amended by the UK MDR 2019).

Classification

Overview

Medical devices are given a classification depending on the level of risk associated with them. Risk classification rules set out in the legislation determine which risk class the device falls into.

These classification rules will change from 26 May 2020 (for medical devices) and 26 May 2022 (for IVDs). These classification rules may apply to devices placed on the market before these dates if the device has followed a conformity assessment provided for in Parts VIII or IX of the UK MDR 2002(as amended by the UK MDR 2019).

More information on these new classification rules can be in the section titled ‘Future changes to classification rules from May 2020’.

General medical devices

When you have established your product is a general medical device, you will need to decide which class your device falls under. The categories are:

- Class I – generally regarded as low risk
- Class IIa – generally regarded as medium risk
- Class IIb – generally regarded as medium risk
- Class III – generally regarded as high risk

How a medical device is classified will depend on factors including the intended purpose of the device, how long it’s intended to be in use for and if the device:

- is invasive/ surgically invasive
- is implantable or active
- contains a substance, which in its own right is considered to be a medicinal substance

Accessories to medical devices are classified separately to the device. Please refer to regulation 7 in the UK MDR 2002 for details on the classification of general medical devices.
Additionally, the European Commission has published a document that explains all classification rules in detail. This can be a helpful tool to establish which classification your product falls under.

Active implantable devices

Whilst active implantable medical devices and their accessories do not have a separate classification rule, due to the risk level associated with these devices and their accessories, they must follow the same conformity assessment route as for Class III medical devices.

In vitro diagnostic medical devices (IVDs)

IVDs are categorised differently.

IVDs can fall into four different groups. Each group will have a different conformity assessment procedure for placing devices on the market.

The four main groups are defined as devices that are:

- within list A – generally regarded as high risk
- within list B – generally regarded as medium risk
- to be used for 'self-testing' (which refers to IVDs that are intended for use by a lay-person) – generally regarded as medium risk
- general IVDs – generally regarded as low risk

Please refer to regulation 40 of the UK MDR 2002 for information about what list A and list B cover.

Future changes to classification rules from May 2020

The UK MDR 2019 introduces changes to classification rules for medical devices from 26 May 2020. This includes the addition of four new rules, as well as modifications to existing rules. The classification rules for medical devices can be found in Schedule 9 of the UK MDR 2002 (as amended by the UK MDR 2019).

In terms of IVDs, a brand new classification system will be introduced with the aim of classifying IVDs based on the risk they present. This is being achieved by introducing seven classification rules from 26 May 2022, with IVDs being classified into four risk classes. The classification rules for IVDscan be found in Schedule 23 of the UK MDR 2002 (as amended by the UK MDR 2019).

Additionally, devices without a medical purpose but with similar risk to medical devices, such as non-corrective contact lenses will be regulated as medical devices. Details on what groups will start to be considered can be found in Schedule 16 of the UK MDR 2002 (as amended by the UK MDR 2019).

Clinical investigations and performance evaluations

Overview

The UK will continue to recognise existing clinical investigation approvals – both for regulatory and ethics approvals – and there will be no need to re-apply. UK clinical investigation applications will continue to be authorised by MHRA and ethics committees as they are at present.

Manufacturers must hold clinical data to support claims made for all types of medical devices. This will be based on a robust evaluation of all clinical data pertaining to the device and may include evidence from clinical investigations. See more information on clinical evaluations by the European Commission.

Informing the MHRA about a clinical investigation

You must inform MHRA if you are planning to conduct a clinical investigation at least 60 days before starting your investigation. This does not currently apply to IVDs, although you must notify MHRA about IVDs for performance evaluations.

Future changes to clinical investigations and performance evaluations from May 2020

Under Part VIII of the UK MDR 2002 (as amended by the UK MDR 2019), for medical devices, from 26 May 2020 there will be increased requirements for clinical evidence, including an expectation for higher risk devices that clinical investigations specific to the device in question will be performed. Full requirements for clinical investigations of medical devices can be found in Schedule 15 of the UK MDR 2002 (as amended by the UK MDR 2019).

Under Part IX of the UK MDR 2002 (as amended by the UK MDR 2019), manufacturers of IVDs will need to conduct clinical investigations (known as performance studies) for virtually all IVDs.

This will include (but is not limited to) requirements for studies which obtaining specimens poses a particular risk for the subject, for reporting adverse events occurring in a performance study, for performance studies involving vulnerable subjects, and for submitting performance studies to the MHRA. Full requirements for performance studies of IVDs can be found in Schedule 28 of the UK MDR 2002 (as amended by the UK MDR 2019).

CE marking your devices and conformity assessment

Overview

This section addresses CE marking and conformity assessment for medical devices and IVDs and does not cover other ‘New Legislative Framework’ products. For further information on this process for other

products, please refer to guidance documents issued by the Department for Business, Energy and Industrial Strategy.

For medical devices and IVDs, you need to demonstrate that your device meets the requirements in the UK MDR 2002 (as amended by the UK MDR 2019).

Manufacturers of low risk devices can self-declare conformity to the legislation before affixing the CE mark. Higher-risk devices medical devices and IVDs must be certified by an independent Conformity Assessment Body, called a Notified Body, before the CE mark can be affixed.

CE marking

CE marking for a device is a claim of compliance with the relevant safety, quality and performance requirements of the relevant legislation made by the manufacturer and indicates that the device is safe and performs as intended. All devices, (except custom-made devices, those intended for clinical investigations, humanitarian use devices and IVD devices for performance evaluation) being placed on the EU market whether used in private or public hospitals and nursing homes or sold in retail outlets, must carry a CE mark.

After Brexit, the MHRA will continue to allow devices to be placed on the UK market 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)
- Directive 93/42/EEC on medical devices (EU MDD)
- Directive 98/79/EC on in vitro diagnostic medical devices (EU IVDD)
- Regulation 2017/745 on medical devices (EU MDR)
- Regulation 2017/746 on in vitro diagnostic medical devices (EU IVDR)

These EU Directives and Regulations have been incorporated into UK law under the provisions of the EU (Withdrawal) Act 2018 by the UK MDR 2002(as amended by the UK MDR 2019).

Definition of a Notified Body

For medical devices and IVDs, medium- and high-risk devices are assessed by independent Conformity Assessment Bodies called Notified Bodies, which have been designated to assess the device is in line with the applicable EUDirective. Certification is needed before the manufacturer can CE mark the device, for all but the lowest risk devices. For medium- and high-risk devices manufacturers must have their quality system and products' safety and performance assessed by a Notified Body, before any products can be placed on the market.

The assessment route depends on the classification of the device.

Once the conformity assessment has been successfully completed, you can place a CE mark on your device to show that the device has met the requirements.

Manufacturer requirements for low-risk medical devices and IVDs

For the lowest risk medical devices (Class I) and IVDs (general IVDs and Class A), once you are satisfied that your device complies with the requirements, you must write a statement (known as the Declaration of Conformity) to declare this. You can then place a CE mark on the product, which means that it can be placed on the EU market. The UK will also allow this product to be placed on its market.

See guidance on Class I medical devices for more information.

Manufacturer requirements for medium- and high-risk medical devices and IVDs

For all other medical devices (Class IIa, Class IIb, Class III and active implantable medical devices) and IVDs (Annex II List A and B, self-

test IVDs, Class B, Class C and Class D), you need to declare that your device meets the requirements of the UK MDR 2002 (as amended by the UK MDR 2019).

To do this, you will need to apply to a designated Notified Body to carry out a conformity assessment to confirm your declaration.

For certain Class I medical devices that include sterile products or a measuring function, you will also need to apply to a Notified Body to approve and certify the parts of your manufacturing process that relates to sterility or metrology.

You can then place a CE mark on your product and place it on the UK market when you have received a certificate from the Notified Body.

We have a flow chart which illustrates these conformity assessment routes.

Status of UK Notified Bodies and certificates issued by these Notified Bodies after the UK's left the EU

After Brexit we expect that UK-based Notified Bodies will no longer be recognised by the EU. This means that the devices they have certified will no longer be in conformity with the applicable EU Directive. The lack of CE certification means that these devices may not legally be able to be placed on the EU market.

To support the continuity of supply of devices to the UK market, we will give UK-based Notified Bodies an ongoing legal status and continue to recognise the validity of certificates that they issued prior to the UK's departure from the EU. This will allow devices covered by certificates issued by UK-based Notified Bodies to continue to be placed on the UK market after the UK leaves the EU.

These UK-based Notified Bodies will continue to oversee these devices and their manufacturers, to ensure continued compliance with the applicable standards of safety and performance.

Notified Bodies that can be used from after the UK leaves the EU

Certificates that have already been issued by UK-based Notified Bodies prior to the UK's departure from the EU will continue to be valid for the UK market. The MHRA will continue to oversee the activities of UK-based Notified Bodies.

From Exit Day, if you wish to place a new device, which requires a Notified Body to carry out a conformity assessment, on to the UK or EU market, you will need to use a Notified Body based in an EU Member State. Once the conformity assessment has been successfully completed, you can place a CE mark on your device and place the product on the UK or EU market.

Labelling requirements

Relevant labelling requirements will continue to apply from the day the UK leaves the EU, including the requirement for products to carry a CE mark and devices which require conformity assessment must also include the Notified Body number. This means that, should you change your Notified Body, you will be required to make the relevant changes to Notified Body numbers appearing on your device and packaging.

No labelling changes will be required to reflect the role of the 'UK Responsible Person'.

Future changes to labelling requirements from May 2020

Changes to labelling requirements will come in to force in May 2020 for medical devices and May 2022 for IVDs. The labelling requirements can be found in Schedule 3 (for medical devices) and Schedule 17 (for IVDs) of the UK MDR 2002 (as amended by the UK MDR 2019). This includes the UDIrequirements set out in Schedule 8 and Schedule 22.

Registrations

Overview

From the day the UK leaves the EU, any medical device or an IVD placed on the UK market must be registered with the MHRA.

The MHRA will only register manufacturers that have a registered place of business (see section on ‘Definition of ‘registered place of business’ for more information) in the UK. If the manufacturer is based outside the UK, the manufacturer must assign 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.

Before you register with MHRA, you must ensure that your device meets all relevant legal requirements set out above.

Once you are satisfied that your devices meet all the relevant requirements, you can register with MHRA. We will provide further guidance on how to register with us in due course.

Definition of ‘registered places of business’

If the manufacturer or its UK Responsible Person is a UK company then the “registered place of business” should be the same as its “registered office” under the Companies Act 2006. That would be the address held by the Registrar of Companies, which would have been included in the original application for company registration (and any change of address would have been notified to the Registrar).

In certain cases, the UK Responsible Person may not be a company. If this is the case, the person’s contact address, or any address where official documents can be sent, will need to be provided. Please note that this address will be made publicly available on the MHRA’s Public Access Registrations Database (PARD).

Registering your device after the UK leaves the EU

After exit day, all medical devices, active implantable medical devices, IVDsand custom-made devices will need to be registered with the MHRA prior to being placed on the UK market.

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 four months to register with the MHRA.

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

For the following devices, you will have eight months to register with the MHRA.

- 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.

- Class I medical devices
- General IVDs
- Class A IVDs (if complying with the EU IVDR 2017/746)

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.

Registration information to be provided to the MHRA

To register any class of device with MHRA, you will need to use Global Medical Devices Nomenclature (GMDN) to describe your device. You do not need to be a member of the GMDN Agency to find and select the appropriate GMDN terms within our online registration system.

Initially, the MHRA will require all devices to be registered at the level of GMDN code. If you do not know which GMDN code applies to your device, you will need to select the relevant description term from our system. However, for Class III devices, you must also provide the following product information:

- medical device name
- model
- catalogue or reference number

These are recognised common data elements in the IMDRF Primary Medical Device Identity information.
You can read more about the registration obligations in regulation 7A (for medical devices), regulation 21A (for active implantable medical devices) and regulation 33A (for IVDs) in the UK MDR 2002 (as amended by the UK MDR 2019).

If you're a manufacturer based outside of the UK

Registration of a device with the MHRA must be undertaken by a designated UK Responsible Person established in the UK and with a UK registered address who will take responsibility for the device in the UK.

You can read more about the UK Responsible Person above, in the section regarding 'Role of those manufacturing and supply devices'. You can also read about this Person's obligations in regulation 77 (for medical devices)and regulation 146 (for IVDs) of the UK MDR 2002 (as amended by the UK MDR 2019).

How to register your medical devices in a no deal Brexit

The Agency is making preparations to ensure that, in the event that the UK leaves the EU without a deal, we are able to process the anticipated volume of devices which will require registration with the MHRA.

For this reason, we intend to process registrations in phases in line with the regulatory deadlines set for each device class. We will take into account how many devices you intend to register.

In a no deal scenario, the deadline for all high-risk devices listed below to be registered with the MHRA is within 4 months of the UK's departure from the EU:

- Class IIb implantable devices
- Class III medical devices
- Active implantable medical devices
- Annex II List A IVDs
- Procedure packs that include any of the above devices

For all other medical devices and IVDs, we ask that you wait until we provide further updates on when to register with us.

Registration for custom-made devices will be in line with the risk class of the device.

If you intend to register high risk devices that fall within the above categories, please email device.registrations@mhra.gov.uk using the following subject line heading:

"[Your organisation name] - Intention to register high risk devices".

The body of the email should contain the following information:

1. Your contact details (including your organisation's legal address and an email address you can be contacted on)
2. Your organisation name

3. Whether you are a UK Responsible Person acting on behalf of a manufacturer based outside of the UK (further information on the role of a UK Responsible Person can be found in our guidance published on 26 February 2019)
4. An indication of how many devices and products you intend to register with us (for each organisation if you are the authorised representative)

If you are currently a UK based authorised representative, please provide details of all organisations that you represent.

You will receive an auto-response confirming receipt of your email, and we will then contact you in due course with further instructions on the registration process.

To prepare for registering your devices with us, we advise that you compile lists of the devices you intend to register, along with the GMDN code/term. We will also require copies of the associated CE certificates.

For Class III devices you will also need to compile the corresponding product information (device name, model, catalogue number, UDI (if applicable).

Fees

You will be charged a statutory fee of £100 per registration application. Depending on the number of devices you have, you may be able to register all of these in one application.

A fee of £100 also applies for adding new and/or subsequent changes to medical device(s) and/or in vitro diagnostic device(s) registrations.

Manufacturers who are already registered with the MHRA

If you are already registered with the MHRA, you will need to confirm the accuracy of the information registered with the MHRA by the relevant dates set out above. There will be no charge for this, unless you need to make any changes.

You must notify us of changes to your registration details and a statutory fee of £100 is chargeable for a change of:

- your registered place of business
- company name
- company type e.g. if you become a limited company
- adding device(s) to your registration record
- status of an IVD, for example a change from ‘performance evaluation’ to ‘new’

Where the manufacturer is currently registered on our systems through an EU Authorised Representative, you must update the information to include a UK Responsible Person. The fee of £100 will apply if you need to update information to include the details of a UK Responsible Person.

The fee is not chargeable for:

- change of email address or telephone numbers
- adding or removing product information for your registered devices
- removing devices from your registration record

Requirement to regularly update the information

You must renew your registration one year after your registration application or confirmation was made and every two years after this date. For each renewal, you will be charged the £100 statutory fee (see below for further information).

Failure to renew your registration will result in the removal of your records from our database, after which you will need to complete a new registration application or you will no longer be able to place your device on the UK market.

Register of manufacturers

Once registered, your company name and address are added to the Public Access Database for Medical Device Registration. Records

are listed by manufacturer name, address, MHRA reference number and list the device types registered with us.

Registering your devices with MHRA does not mean that we give you any form of accreditation, certification or approval for the device and you should not claim this in any marketing materials, on the packaging or in the instructions for use.

Future changes to registering your device from May 2020

Changes to registration requirements will come into force on 26 May 2020 for medical devices and on 26 May 2022 for IVDs. The additional registration requirements can be found in regulations 91 to 95 (for medical devices) and regulations 157 to 160 (for IVDs) of the UK MDR 2002 (as amended by the UK MDR 2019).

Post-market surveillance and vigilance

Overview

MHRA operates the system for reporting and recording details of suspected adverse incidents relating to a medical device or IVD which occur in the UK. A key responsibility of the MHRA is to investigate device-related adverse incidents or monitor investigations carried out by the manufacturer and take appropriate action to prevent or reduce the likelihood of recurrence as part of its market surveillance role. If a non-compliances are found during an investigation of a manufacturer, the manufacturer has a statutory obligation to resolve these non-compliances.

Once a medical device has been placed on the UK market in compliance with the applicable legislation, the manufacturer must continually monitor the safety and performance of their device. The manufacturer must submit vigilance reports to the MHRA when certain incidents occur in the UK involving their device and take appropriate safety action when

required. The manufacturer must ensure the device meets appropriate standards of safety and performance for as long as it is in use.

From the day the UK leaves the EU, where a manufacturer is based outside of the UK, it must have in place a UK Responsible Person. This UK Responsible Person will be required to meet certain reporting requirements, as set out in regulation 7A (for medical devices), regulation 21A (for active implantable medical devices) and regulation 33A (for IVDs) in the UK MDR 2002 (as amended by the UK MDR 2019).
Please see our guidance page for further information on manufacturer reporting requirements.

Future changes to post-market surveillance requirements from May 2020

From 26 May 2020 (for medical devices) and May 2022 (for IVDs) new requirements relating to a manufacturer's post market surveillance system will be in place that will require manufacturers to adhere to increased requirements around post-market surveillance and vigilance. This will include maintaining a post-market surveillance plan and issuing periodic safety update reports (PSURs). Further information for post-market surveillance requirements can be found under regulations 121 to 124 (for medical devices)and regulations 186 to 189 (for IVDs) of the UK MDR 2002 (as amended by the UK MDR 2019).
Additionally, the new vigilance requirements define specific reporting requirements which include but are not limited to defined time frames for notifying the MHRA of incidents and the preparation of manufacturer reports after the occurrence of incidents. Full information on vigilance can be found under regulations 125 to 129 (for medical devices) and regulations 190 to 194 (for IVDs) of the UK MDR 2002 (as amended by the UK MDR 2019).

Contact us

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

Stay up to date

This page tells you what to do if you the UK leaves the EU without a deal. It will be updated if anything changes, including if a deal is agreed.

Sign up to email alerts to get the latest information.

This guidance will apply from exit day in line with the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 .