

Requirements for the Medical Devices Regulation Directive and Related Legislation

EU requirements: If you are selling items in the EU that are or might be medical devices (including accessories of medical devices), you should consult Directive 93/42/EEC on medical devices (the “MDD”). The MDD contains the EU requirements for selling medical devices, including device classification, compliance requirements, and registration obligations. Please note that in vitro diagnostic medical devices and implantable devices are not covered by the MDD, but ~~they do~~ fall within the scope of two other Directives: (Directive 98/79 and Directive 90/385).

The MDD, Directive 98/79 and Directive 90/385 will be replaced by two new Regulations. The new Regulation on medical devices will enter into force, following a transition period, on 26 May 26, 20202021. The new Regulation on in vitro diagnostic medical devices will enter into force, following a transition period, on 26 May 26, 2022.

It is your responsibility to comply with the ~~rules and regulations~~ MDD for medical devices ~~– sold in the EU. You must also comply with laws and regulations in EU Member States.~~

Please see below for further information about EU requirements

UK requirements: If you are selling items in the UK that are or might be medical devices (including accessories of medical devices), you should consult the Medical Devices Regulations 2002 SI 2002/618 (the “UK MDR”). The UK MDR contains the UK requirements for selling medical devices, including device classification, compliance requirements, and registration obligations. Please note that in vitro diagnostic medical devices and implantable devices are also covered by the UK MDR, but the provisions regulating these sectors are not discussed in this material.

The UK MDR implemented three EU Directives (Directive 90/385, Directive 93/42/EEC and Directive 98/79) whilst the UK was still a member of the EU. These EU directives have been replaced at an EU-level by two new EU Regulations. The new EU Regulation on medical devices will apply in all EU Member States, following a transition period, on 26 May 2021. The new EU Regulation on in vitro diagnostic medical devices will apply in all EU Member States, following a transition period, on 26 May 2022.

From 1 January 2021, an amended version of the UK MDR applies to medical devices and in vitro diagnostic medical devices as a result of the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019/791. Further, at the time of writing, a draft of the Medicines and Medical Devices is currently being considered by Parliament which may further adapt the UK’s regulatory regime. Different rules apply to goods you sell in: (1) Great Britain (England, Scotland and Wales); and (2) Northern Ireland.

It is your responsibility to comply with the UK requirements for medical devices sold in

[the UK. If you also sell medical devices on Amazon EU website\(s\), then you must also comply with laws and regulations in EU Member States.](#)

[Please see below for further information about UK Requirements.](#)

This material is for informational purposes only. It is not intended as legal advice. We encourage you to consult your legal counsel if you have questions about the laws and regulations concerning your product, ~~as well as any national laws and regulations and how you will be affected by the upcoming changes.~~ [This material only reflects the position at the date of writing and requirements in the EU and the UK may change. You should refer to current UK Brexit guidance about your products \(see below\) to learn more about changes that may affect you from 1 January 2021.](#)

I. EU Requirements

What is a "Medical Device"?

Medical devices range from plasters to stethoscopes, ~~from~~ [to](#) thermometers to ventilators, to pacemakers and more. The MDD defines a medical device is any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and ~~that~~[which](#) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

The MDD also applies to “accessories,” which ~~are~~[is](#) defined as ~~any~~[an](#) article ~~that,~~[which](#) whilst not being a device, is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device.

What are the Essential Safety Requirements for Medical Devices?

All medical devices [\(and accessories\)](#) must meet the “essential requirements” set out in Annex I of the MDD.

In general terms, these requirements specify that:

- (1) devices must be designed and manufactured in a way, ~~that,~~ when used under the conditions and for the purposes intended, they will not ~~comprise~~[compromise](#) the clinical condition or the safety of patients, or the safety and health of users or other persons;

- (2) the manufacturer of the medical devices ~~has taken~~**must take** adequate measures in relation to the risks that cannot be eliminated, including informing users of the residual risks due to any shortcomings of the protection measures adopted; and
- (3) the devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage.

Additionally

In addition, each medical device must be accompanied by sufficient information to use the device safely.

What are the Compliance and Registration Requirements?

Each medical device must undergo **at the appropriate** conformity assessment to ensure ~~that~~ it complies with implementing legislation of the MDD. In addition, each medical device must bear a CE mark confirming that the device has undergone and passed the conformity assessment ~~and the relevant Notified Body's identification number.~~ The CE mark must appear in a visible, legible and indelible form on the device or its sterile pack, and on the instructions for use. ~~Labelling must be in the language(s) of the Member State(s) in which the product is available for sale or supply.~~

Furthermore, any ~~manufacturers~~**manufacturer** who ~~sells~~**sells** a device in accordance with the conformity assessment procedures ~~are~~**is** required to inform the competent authorities of the Member State in which ~~they have their~~**he has his** registered place of business of:

- (1) the address of the registered place of business; and
- (2) the description of the devices concerned.

~~If the manufacturer is established in the EU, they must label the product with their name and address.~~ If a manufacturer does not have a registered place of business in Member State, the manufacturer is required to designate a single authorised representative in the European Union. ~~This authorised representative must be mentioned on the product including the respective symbol.~~

~~Amazon does not sell professional use only Medical Devices. Check with the manufacturer/instructions for use before listing such products for sale on Amazon.~~

Up until 31 December 2020, if a manufacturer does not have a registered place of business in the EU the manufacturer is required to designate a person established in the UK as the UK Responsible Person, to act on their behalf in relation to manufacturer obligations under the UK MDR.

The New Regulations

The new medical devices Regulations (Regulation 2017/745 and Regulation 2017/746) supplement the current regulation with several new rules. These include:

- the inclusion of certain aesthetic devices which present the same characteristics and risk profile as analogous medical devices under the scope of these Regulations;

- improved transparency through the establishment of a comprehensive EU database on medical devices and of a device traceability system based on Unique Device Identification;
- the strengthening of ~~post-market~~ surveillance requirements for manufacturers ~~and~~;
- improved coordination mechanisms between EU countries in the fields of vigilance and ~~market~~ surveillance.

Additional Information

We strongly encourage you to visit the following sites for more information on rules and regulations that apply to medical devices:

- European Commission Medical Devices Homepage:
https://ec.europa.eu/growth/sectors/medical-devices_en
- Legally non-binding guidance documents, adopted by the Medical Device Coordination Group (MDCG): https://ec.europa.eu/growth/sectors/medical-devices/guidance_en

II. UK Requirements

Where does the UK MDR apply?

The UK MDR applies to all products sold in the UK, but the provisions apply differently to Great Britain (England, Scotland and Wales, “GB”) and Northern Ireland. You can read more about the position in Northern Ireland (“NI”) below.

What is a “Medical Device” under the UK MDR?

Medical devices range from plasters to stethoscopes to thermometers to ventilators to pacemakers and more. The UK MDR defines a “medical device” as an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which is:

- a) intended by the manufacturer to be used for human beings for the purpose of:
 - diagnosis, prevention, monitoring, treatment or alleviation of disease,
 - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
 - investigation, replacement or modification of the anatomy or of a physiological process, or
 - control of conception; and
- b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means.

It includes devices intended to administer a medicinal product or which incorporate a substance (that forms an integral part of that device), which would be a medicinal product if used separately and have a similar impact on the body.

The UK MDR also applies to “accessories”. An accessory is defined as an article which, whilst not being a medical device, is intended specifically by its manufacturer to be used together with a medical device to enable it to be used in accordance with the use of the medical device intended by its manufacturer.

What are the Essential Safety Requirements for Medical Devices?

All medical devices (and accessories) must meet the “essential requirements” set out in Annex I of EU Directive 93/42/EEC (as immediately before 31 January 2020).

In general terms, these requirements specify that:

- (1) devices must be designed and manufactured in a way, that, when used under the conditions and for the purposes intended, they will not comprise the clinical condition or the safety of patients, or the safety and health of users or other persons;
- (2) the manufacturer of the medical devices must take adequate measures in relation to any risks that cannot be eliminated, including informing users of the residual risks due to any shortcomings of the protection measures adopted; and
- (3) the devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage.

In addition, each medical device must be accompanied by sufficient information to use the device safely.

What are the Compliance and Registration Requirements?

Each medical device must undergo the appropriate conformity assessment to ensure it complies with implementing legislation of the UK MDR, where applicable. In addition, each medical device must bear a CE mark confirming that the device has undergone and passed the conformity assessment. The CE mark must appear in a visible, legible and indelible form on the device or its sterile pack, and on the instructions for use. In the future, a UK-specific compliance mark may be required.

Furthermore, any manufacturer who sells certain medical devices in the UK, under his own name and with a registered place of business in the UK, is required to register with the UK Medicines and Healthcare products Regulatory Agency (“MHRA”) and provide details of:

- (1) the address of their registered place of business in the UK; and
- (2) the description of the devices concerned.

Northern Ireland

Please note that different rules apply in NI from 1 January 2021 as a result of the Northern Ireland Protocol. In particular:

- You should ensure that products meet EU requirements and that you use the CE mark.

- You are an importer if you are established in the EU or NI and you sell products from a country outside of the EU and Northern Ireland (including from GB) into NI. Products sold in NI should be marked with details of any EU / NI based importer.
- Authorised representatives can be based in NI or the EU. From 16 July 2021, new rules come into force under EU Regulation 2019/1020 and some businesses may need to appoint a responsible person in the EU or NI to carry out compliance functions (if there is no other entity in the supply chain who is able to carry out the functions). Further guidance on the new rules will be made available by the UK Government.
- If you are using a UK body to carry out mandatory third-party conformity assessment, you will need to apply a UKNI marking as well as a CE mark to products placed in NI from 1 January 2021. Goods with the CE and UKNI marking can't be sold in the EU. You do not need to use the UKNI marking if you self-certify compliance or use an EU body to carry out a mandatory third-party assessment.
- "Qualifying Northern Ireland goods" will be able to be sold in GB with the CE mark. The UK Government is issuing guidance on how this will work.

BREXIT: UK Government Guidance

The UK Government has released guidance outlining changes that apply from 1 January 2021 in respect of the sale of medical devices in Great Britain, meaning England, Scotland and Wales, ("GB"). Key changes include:

- All medical devices and in vitro diagnostic medical devices sold in GB will need to be registered with the MHRA. Grace periods will apply for certain categories of devices:
 - 4 months: Class IIIs and Class IIb implantable medical devices and all active implantable medical devices;
 - 8 months: other Class IIb and all Class IIa medical devices; and
 - 12 months: Class I medical devices.
- Manufacturers based outside the UK who want to sell a medical device in GB will need to establish a UK Responsible Person to take responsibility for the product in the UK.
- Between 1 January 2021 and 30 June 2023, either the CE or the UKCA mark can be used. Only the UKCA mark will be recognised for all medical devices after 30 June 2023.
- Certificates issued by European Economic Area based Notified Bodies will continue to be valid for GB sales until 30 June 2023.
- There are special status rules for NI.

We encourage you to review this guidance (linked below), alongside any other specific UK Government Guidance that applies to your product. You should consult your legal counsel if you have questions about how the laws and regulations apply to your products from 1 January 2021.

The Brexit guidance can be found here:

- Regulating medical devices in GB and NI from 1 January 2021

Additional Information

We strongly encourage you to visit the following UK Government websites for more information on rules and regulations that apply to medical devices.

- UK General information: <https://www.gov.uk/topic/medicines-medical-devices-blood/medical-devices-regulation-safety>
- UK helpdesks: <https://www.gov.uk/guidance/contact-mhra>~~UK help desks:~~

We also encourage you to visit the Business Companion website, which contains guidance on UK product compliance rules:

- <https://www.businesscompanion.info/en/get-started>