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EUROPEAN COMMISSION PUBLISHES FACTSHEET FOR AUTHORIZED REPRESENTATIVES, IMPORTERS AND DISTRIBUTORS OF MEDICAL DEVICES AND *IN VITRO* DIAGNOSTIC MEDICAL DEVICES

On 5 April 2017, two new Regulations on medical devices and *in vitro* diagnostic medical devices were adopted, both establishing a modernized and more robust EU legislative framework to ensure better protection of public health and patient safety. The Regulations entered into force on 25 May 2017 and will progressively replace the existing Directives (Directive 90/385/EEC on Active Implantable Medical Devices, Directive 93/42/EEC on Medical Devices and Directive 98/79/EC on *in vitro* Diagnostic Medical Devices). They will be fully applicable in May 2020 (for medical devices) and May 2022 (for *in vitro* diagnostic medical devices).

We would like to draw your attention to a factsheet that was recently published by the European Commission in this regard. The factsheet aims to inform authorized representatives, importers and distributors of medical devices and *in vitro* diagnostic medical devices about the timeline and the most important changes of the new Regulations. Furthermore, the factsheet contains a selection of the most frequently asked questions on this topic. We attached the relevant factsheet to this email for your convenience.


The European Commission published similar factsheets intended for authorities in non-EU/EEA States, procurers, and (*in vitro* diagnostic) medical devices manufacturers.

For a general overview of the impact of the Regulations, please refer to the Medical Devices section on the [DG GROW website](#).

We hope this information is useful. You should not hesitate to contact us should you have any questions or require further information.

Kind regards,

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European Commission



Factsheet for Authorised Representatives, Importers and Distributors of Medical Devices and *in vitro* Diagnostic Medical Devices¹

This Factsheet is aimed at authorised representatives, importers and distributors of medical devices and In vitro diagnostic medical devices. For a general overview of the impact of the Regulations please refer to the Medical Devices section on the DG GROW website.

The new Medical Devices Regulation (EU) 2017/745 (MDR) and the *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR) bring EU legislation into line with technical advances, changes in medical science, and progress in law making.

The new Regulations create a robust, transparent, and sustainable regulatory framework, recognised internationally, that improves clinical safety and creates fair market access for manufacturers.

In contrast to Directives, Regulations are directly applicable and do not need to be transposed into national law. The MDR and the IVDR will therefore reduce the risks of discrepancies in interpretation across the EU market.

MEDICAL DEVICES CHANGE OF LEGISLATION

What you need to know!



Introduction to the Medical Devices Regulation (MDR) and the *In Vitro* Diagnostic Medical Devices Regulation (IVDR)

The MDR will replace the existing Medical Devices Directive 93/42/EEC (MDD) and the Active Implantable Medical Devices Directive 90/385/EEC (AIMDD). The MDR was published in May 2017, marking the start of a three-year period of transition from the MDD and the AIMDD.

The IVDR will replace the existing *In Vitro* Diagnostic Medical Devices Directive (98/79/EC) (IVDD). The IVDR was published in May 2017, marking the start of a five-year period of transition from the IVDD.

¹ The term 'devices' in this document refers to medical devices and *In vitro* diagnostic medical devices. For definitions of what is understood to be a device, see Article 2 of the MDR and the IVDR.

For medical devices (MDs) the transition period will end on **26 May 2020**, the “Date of Application” (DoA) of the MDR.

For *in vitro* diagnostic devices (IVDs) the transition period will end on **26 May 2022**, the DoA of the IVDR.

During these two periods of transition, both Regulations will come into application gradually, starting with the provisions related to the designation of Notified Bodies and the ability of manufacturers to apply for new certificates under the Regulations.

To avoid market disruption and allow a smooth transition from the Directives to the Regulations, several transitional provisions are in place. Some devices with certificates issued under the Directives may continue to be placed on the market² until 27 May 2024, and made available³ until 27 May 2025.



Timeline

Until May 2025, products certified under the Directives and products certified under the Regulations will coexist on the market. Both will have equal status under the legislation, and no discrimination in public tenders may take place.

A transition period is needed as the new Regulations require the designation of Notified Bodies. In addition, manufacturers need to meet more stringent criteria, particularly in terms of clinical and performance evaluation requirements.

The designation process for Notified Bodies, which may take 18 months or more, involves assessors from both national and European authorities. This means that the first Notified Bodies designated under the new Regulations might be available by the beginning of 2019. You can find the Notified Bodies designated under the MDR and IVDR, as well as the scope of devices for which they are designated, on [NANDO](#)⁴. For more information refer to the contact points of the [competent authorities](#)⁵.

The rules for designating Notified Bodies are also more rigorous and add new requirements and responsibilities. The process of designating Notified Bodies will take up a significant part of the transition period, meaning that there will be limited time for manufacturers to get all their products certified before the respective DoAs.

This makes it unlikely that all devices available on the market will be certified under the new Regulations by the DoAs, especially if the designation of Notified Bodies takes longer than foreseen. To avoid market disruption and the unavailability of medical devices, manufacturers may under certain conditions continue to produce MDD/IVDD-compliant devices and place them on the market after the respective DoAs. These will be available for sale to end customers until 27 May 2025.



What has changed?

In general, the MDR and the IVDR retain all the requirements of the Directives, while adding some new requirements of their own. Compared to the current Directives, the new Regulations emphasise a life-cycle approach to safety, backed up by clinical data.

The Regulations add more stringent rules for the designation of Notified Bodies. For national competent authorities and the Commission, they add more control and monitoring requirements. The Regulations clarify the obligations of manufacturers, authorised representatives, importers and distributors.

The MDR reclassifies certain devices and has a wider scope than the Directives. It introduces an additional pre-market consultation procedure for certain high-risk medical devices. For IVDs, the biggest change concerns the risk classification of *in vitro* diagnostic devices and the role of Notified Bodies. As a result, around 85% of all IVDs will need oversight from Notified Bodies, compared to 20% under the Directive. The IVDR also tightens the requirements for clinical evidence and conformity assessment.

The Regulations increase transparency, requiring the publication of information on devices and on clinical and performance studies related to their conformity. The new European Database for Medical Devices and *In Vitro* Diagnostic Medical Devices – EUDAMED – will play a central role in making data available and increasing both the quantity and quality of data (MDR Article 33 and IVDR Article 30).

² ‘Placing on the market’ means the first making available of a device, other than an investigational device, on the EU market (Article 2 Section 28 of the MDR).

³ ‘Making available on the market’ means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge (Article 2 Section 27 of the MDR).

⁴ <http://ec.europa.eu/growth/tools-databases/nando/>, NANDO (New Approach Notified and Designated Organisations)

⁵ http://ec.europa.eu/growth/sectors/medical-devices/contacts_en

 **CE marking**

The assessment of the conformity of a device for CE marking (Conformité Européenne, or European Conformity) varies according to the risk class for both MDs and IVDs. Apart from the risk classification, certain features may influence the conformity assessment procedure, for example when an MD is required to be sterile or an IVD is designed for use by patients.

For MDs, all Class IIa, IIb and III devices as well as some specific Class I devices require the intervention of a Notified Body (MDR Article 52(7)(a⁶, b⁷, c⁸). MDR Article 52 and MDR Annexes IX, X and XI describe the different assessment routes according to the class of the device. In some cases manufacturers can choose their conformity assessment route from several options described in the Regulation.

There is a new clinical evaluation consultation procedure for Class III implantable devices and certain Class IIb devices, to be carried out by an independent expert panel. The Notified Body will have to take into consideration the scientific opinion expressed by the expert panel (MDR Article 54).

For IVDs, most Class A devices can be self-certified by their manufacturers unless they are sold sterile. Devices in Classes B, C and D will require conformity assessment by a Notified Body.

The conformity assessment of Class D devices will require the involvement of an EU Reference Laboratory designated for that type of device to verify the performance claimed by the manufacturer and compliance with the applicable Common Specifications (IVDR Article 48(5)). For innovative Class D devices where no Common Specifications exist, an independent expert panel must provide its views on the performance evaluation report of the manufacturer (IVDR Article 48(6)).

You can find the Notified Bodies designated under the MDR and IVDR, as well as the scope of devices for which they are designated, in NANDO. For more information refer to the contact points of the competent authorities of your country.

**Supply chain traceability and Unique Device Identifiers (UDIs)**

A completely new feature of the Regulations is the system of Unique Device Identifiers (UDIs) (MDR Article 27 and IVDR Article 24). This will enhance the identification and traceability of devices.

The UDI will allow all stakeholders to access basic information on devices through the European Database on Medical Devices (EUDAMED).

Each MD or IVD and, as applicable, each package will have a UDI composed of two parts. The first part is a device identifier (UDI-DI) specific to a manufacturer and a device. The second part is a production identifier (UDI-PI) – such as a lot number or a serial number – to identify the unit of device production and, if applicable, the package. Every level of packaging will be uniquely identified.

For both Regulations, the deadline for assigning UDIs is the respective DoA. However, the obligation to affix the UDI on the labelling will be implemented in three stages. This means that, depending on risk class, some devices may not yet bear a UDI at the DoA (MDR Article 123(3)(f) and (3)(g); IVDR Article 113(3)(e)).

**Traceability**

Distributors and importers shall co-operate with manufacturers or authorised representatives to achieve an appropriate level of traceability of devices. They must keep the UDIs for Class III implantable devices, preferably by electronic means. The obligation to keep UDIs for these devices also applies to health institutions, and Member States may extend this obligation on health institutions to other devices also (MDR Article 27(9) and IVDR Article 24(9)).

**Transparency**

The new EUDAMED database will include information on UDIs, registration of economic operators (except for distributors) and devices, certificates, clinical and performance investigations, post-market surveillance, vigilance and market surveillance (MDR Article 33 and IVDR Article 30).

The information in EUDAMED will be uploaded by, and accessible to, all (including the general public) at levels depending on their access rights and the information they are responsible for uploading. The database will facilitate access to the regulatory documentation through the UDI, providing access to the certificates covering the devices.

EUDAMED will also be used by manufacturers to report incidents and as a platform for EU/EEA authorities to cooperate and exchange information.

6 "Devices placed on the market in sterile condition, to the aspects relating to establishing, securing and maintaining sterile conditions".

7 "Devices with a measuring function, to the aspects relating to the conformity of the devices with the metrological requirements".

8 "Reusable surgical instruments, to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use".



Roles and responsibilities

Roles and responsibilities of authorised representatives

The Regulations describe the responsibilities of authorised representatives. Many of the general obligations of authorised representatives are described in MDR/IVDR Article 11.

An authorised representative means any natural or legal person established within the European Union who has received and accepted a written mandate from a manufacturer, located outside the EU, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under the Regulations.

The Regulations also describe the tasks that can be delegated by the manufacturer to the authorised representative and the conditions under which this can take place. This relationship should be covered by a precise mandate.

At a minimum, authorised representatives' obligations include verifying that the EU 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 (MDR/IVDR Article 11(3)(a)). An authorised representative must also keep copies available of all documents and make them accessible to authorities on request. This includes technical documentation, declarations of conformity, and certificates, including their amendments and supplements (MDR/IVDR Article 11(3)(b)).

In addition, authorised representatives will have to verify that the manufacturer has registered the requested information in EUDAMED (MDR/IVDR Article 11(3)(c)).

An authorised representative will have to cooperate with authorities on preventive and corrective actions, and inform the legal manufacturer immediately about complaints and authorities' requests for samples of devices.

The authorised representative will be liable for defective devices together with the manufacturer, if the manufacturer has not complied with its obligations under the Regulations and is not located in the EU (MDR/IVDR Article 11(5)).

The authorised representative should terminate the mandate if the manufacturer acts contrary to its obligations (MDR/IVDR Article 11(3)(h)). In such situations, the authorised representative shall immediately inform the Member State in which it is established and, where applicable, the Notified Body involved in conformity assessment of the device, of the termination and the reasons behind it.

The Regulations also describe activities that cannot be delegated to an authorised representative and that may not be part of the mandate between a manufacturer and an authorised representative (MDR/IVDR Article 11(4)). Examples include requirements related to the design of a device, the quality management system, or the drafting of technical documentation; these are the exclusive responsibilities of the manufacturer.

The authorised representative should have permanent and continuous access to a person responsible for regulatory compliance (MDR/IVDR Article 15(6)).

A change of authorised representative requires a proper agreement that defines the arrangements between the manufacturer and both the outgoing and the new authorised representatives (MDR/IVDR Article 12).

Roles and responsibilities of importers

The Regulations also describe the roles and responsibilities of importers.

An importer is defined as any natural or legal person established in the EU that places a device from a third country on the EU market⁹.

MDR/IVDR Article 13 describes many of the general obligations of importers.

The importer is responsible for making sure that the devices they place on the market bear the CE marking, are accompanied by the required information and labelled in accordance with the Regulation, and have been assigned a UDI where applicable.

In addition, the importer should verify that devices are registered in EUDAMED.

If an importer considers that a device is not compliant with the Regulations, the device shall not be placed on the market and the importer shall inform the manufacturer and the authorised representative. The importer should also inform the authorities if they suspect that a device has been falsified or that there is a serious risk to health.

Importers should make sure that storage and transport conditions when under their responsibility do not jeopardise compliance. Importers shall indicate on the device or its packaging, or in a document accompanying the device, their name, registered trade name or registered trade mark, their registered place of business and the address at which they can be contacted.

Importers also have the responsibility to inform manufacturers and their authorised representatives in the event of complaints. They should also keep a register of complaints, non-conforming devices, recalls and withdrawals, and escalate non-compliance to authorities if they suspect that a device has been falsified or that there is a serious risk to health.

Importers are also required to cooperate with authorities and provide samples or grant access to the devices.

Roles and responsibilities of distributors

A distributor is defined as any natural or legal 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.

The Regulations describe the roles and responsibilities of distributors, who should make sure, by representative sampling, that the devices they distribute are compliant with the obligations described in MDR/IVDR Article 14.

Distributors should verify that the devices have been CE marked, that an EU Declaration of Conformity has been drawn up, and that labels and instructions for use (MDR/IVDR Annex 1 section 23) are provided in the official languages of the Member States in which the device is made available (or in languages accepted by those Member States). Distributors should also verify that the importer's name is indicated on each device or in the accompanying documentation, and that the device bears a UDI.

Distributors shall ensure that storage and transport conditions when under their responsibility are appropriate and in line with the recommendations of the manufacturer.

If a distributor considers a device to be non-compliant with the Regulations, the device shall not be made available on the market. In this case, the distributor should inform the other economic operators. Distributors should inform the authorities if they suspect that a device has been falsified or that there is a serious risk to health.

They should also keep a register of complaints, non-conforming devices, recalls and withdrawals.

Distributors shall cooperate with authorities and make available all the documentation and information they have at their disposal.



Frequently asked questions

For a complete list, see the list of FAQs from the Competent Authorities for Medical Devices at:

<https://www.camd-europe.eu/regulatory/available-now-mdr-ivdr-transitional-faqs/>

When do the Regulations apply?

The Medical Devices Regulation (MDR) (2017/745/EU) will apply from 26 May 2020 and the *In Vitro* Medical Device Regulation (IVDR) (2017/746/EU) will apply from 26 May 2022 – the respective Dates of Application (DoAs).

Some provisions of these Regulations will apply earlier (e.g. regarding Notified Bodies and the Medical Device Coordination Group). Some will apply later (e.g. Unique Device Identification and labelling).

When do the existing Directives cease to apply?

In general, Directives 90/385/EEC and 93/42/EEC will be repealed with effect from 26 May 2020 and Directive 98/79/EEC will be repealed with effect from 26 May 2022. However, there are some exceptions, such as:

- for the continued marketing of devices that comply with the Directives (see below); and
- to serve as a backup in case EUDAMED is not fully functional by the DoA.

What is the applicable legislation up to the respective DoA?

Until the DoA, the laws and regulations adopted by Member States in accordance with the Directives will continue to apply. However, there are some exceptions.

Is it possible to place devices on the market that are compliant with the Regulations prior to the DoA?

Yes, manufacturers may place compliant devices on the market before the end of the transitional period. This applies to devices in all risk classes, and includes for example custom-made devices, systems and procedure packs.

Medical devices that are subject to the clinical evaluation consultation procedure according to MDR Article 54, and IVD Class D devices according to IVDR Article 48(6), may not be placed on the market before the expert panels have been established.

Depending on the risk class of the device, conformity assessment may involve an appropriate Notified Body. This requirement may create further delays before such devices can be placed on the market.

Which obligations of the Regulations do manufacturers need to fulfil in order to place compliant devices on the market before the DoA?

Manufacturers should meet as many obligations as possible, bearing in mind that the complete MDR/IVDR infrastructure, including EUDAMED, may not be fully functional before the respective DoA.

Both the device and the manufacturer must comply with the Regulations. Manufacturers should undertake an assessment of the conformity of their device.

Do certificates issued by Notified Bodies under the existing Directives remain valid after the DoA?

Yes, certificates will generally remain valid until the end of the period indicated on the certificate, or until 27 May 2024, whichever is the earlier. After 27 May 2024 certificates issued under the Directives will become void.

Can manufacturers still place on the market/put into service Directive-compliant devices after the end of the transition period?

Yes, under certain conditions there will be an option to continue placing on the market/putting into service devices that comply with the Directives until their existing certificates expire. This may avoid the immediate need for a new certificate under the Regulations.

To use this option, all the existing certificates will have to be valid (including, for example, the QMS), the purpose and nature of the device must not change, and manufacturers must apply the new requirements with regard to registration, surveillance and vigilance.

What is the “sell-off” provision about?

The “sell-off” provision is intended to limit the time during which devices that are compliant with the Directives and have already been placed on the market may be made available.

Any devices that are still within the supply chain and that have not reached their final user as being ready for use, for example a hospital, on 27 May 2025 are no longer marketable and must be withdrawn.

Once a Directive-compliant device has been made available to the final user by the deadline, the further making available of this device is not subject to the Regulations.

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