European Commission

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

This Factsheet is aimed at authorised representatives, importers, and distributors of medical devices and in vitro diagnostic medical devices[1]. 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 (2017/745/EU) (MDR) and the In-Vitro Diagnostic Medical Devices Regulation (2017/746/EU) (IVDR) bring EU legislation into line with technical advances, changes in medical science, and progress in law making.

The new Regulations will 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 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 IVDR.

During the transitional period both Regulations will come into force 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.

The transitional period for the MDR will end on 26 May 2020 and, for the IVDR, on 26 May 2022 - the respective "Dates of Application" (DoA) of the Regulations. From these dates the Regulations will apply in full.

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 market[2] until 27 May 2024, and made available[3] until 27 May 2025.

Timeline

This means that during the transition phase, products certified under the Directives and products certified under the Regulations will coexist on the market. Both will have equal status under the law, and no discrimination in public tenders may take place.

A long 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 evaluation requirements.

The designation process for Notified Bodies, which might take 12 months or more, involves auditors from both national and European authorities. This means that the first Notified Bodies designated under the new Regulations might be available by the end of 2018 at the earliest.

The rules for the designation of Notified Bodies are more rigorous and add new requirements and responsibilities. The process of designating Notified Bodies is expected to take a significant part of the transition period, meaning that there will be limited time for manufacturers to get all their products certified under the Regulations before the Date of Application.

To avoid disruption on the market and the unavailability of medical technologies, manufacturers may continue to produce and place on the market most devices that are compliant with the Directives after the Date of Application. These will be available for sale to end customers for a limited period of time.

What has changed?

No requirements from the Directives (MDD and IVDD) have been removed; the Regulations (MDR and IVDR) add new ones. Compared to the current Directives, the new Regulations emphasise a life-cycle approach to safety, backed up by clinical data.

The Regulations add rules for the designation of Notified Bodies. For national competent authorities and the Commission, they add 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 and, for some devices, it introduces an evaluation procedure. For IVDs, the biggest change concerns the risk classification of in-vitro diagnostic devices and the role of Notified Bodies. The IVDR also tightens the requirements for clinical evidence and conformity assessment. As a result, around 85% of all IVDs will need oversight from Notified Bodies compared to 20% under the Directive.

The Regulations will also increase transparency using a unique device identification system to enhance traceability, with information on devices and studies made publicly available. The new European Database for Medical Devices – Eudamed – will play a central role in making data available and increasing both the quantity and quality of data.

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 the requirement that the device be sterile for MDs, or self-tests for IVDs.

For MDs all Class IIa, IIb and III devices as well as some specific Class I devices need the intervention of a Notified Body (see MDR Article 52, paragraphs 7a[4], b[5], and c[6]). Article 52 and Annexes IX, X and XI describe the different assessment routes applicable based on the class of the device. In some cases manufacturers can choose the conformity assessment route from several options described in the Regulation.

For IVDs, 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.

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

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

6 "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".

The conformity assessment of Class D devices will require the involvement of an EU Reference Laboratory, if designated for that type of device, to verify the performance claimed by the manufacturer and compliance with the applicable Common Specifications (Article 48.5 IVDR). 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 (Article 48.6 IVDR).

You can find the Notified Bodies designated under MDR and IVDR, as well as the scope of devices for which they are designated, on *NANDO*[7]. For more information, refer to the *contact points*[8] of the competent authorities.

Supply chain traceability and unique device identifiers (UDI)

A completely new feature of the Regulations is the system of unique device identifiers (UDIs) (see Article 27 of the MDR and Article 24 of the IVDR). This will enhance the identification and traceability of devices.

The UDI number will allow all stakeholders to access basic information on devices through the European Database.

Each MD or IVD and, as applicable, each package will have a UDI composed of two parts: a device identifier (UDI-DI) specific to a device, and a production identifier (UDI-PI) to identify the production of the device (such as a lot number or a serial number).

The timeline for implementing UDIs is the Date of Application for both Regulations. However, the obligation to affix the UDI on the labelling is implemented in three stages. This means that, depending on risk class, some medical devices and IVDs may not bear a UDI at the Date of Application (MDR: Article 123 paragraph 3 (f) and (g); IVDR: Article 113 paragraph 3 (e)).

Transparency

The Eudamed database is designed to include information on UDI, registration of economic operators and devices, certificates, clinical/performance investigations, post-market surveillance, vigilance and market surveillance.

The database also provides access to basic information on devices, and can be used to verify that the devices are covered by an appropriate certificate.

The Eudamed database will also be used to report incidents and as a platform for authorities to cooperate and exchange information.

Traceability

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

Roles and responsibilities

The Regulations set out some cases where other economic operators, such as importers, distributors and others, have to assume the obligations of a manufacturer, for example when a person or economic operator makes the device available on the market under its name or trade name. Another example would be when the intended purpose is changed or when the device is modified in such a way that it affects its compliance with the Regulations.

Article 16 paragraph 2 MDR describes device modifications that are considered as not affecting compliance. In this case, economic operators shall indicate their name on the packaging or, if impracticable, on a document accompanying the device. They must also have a quality management system in place, and have the obligation to inform the original manufacturer and the competent authority of the Member States in which they intend to make the relabelled or re-packaged device available.

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 Article 11 MDR (and IVDR).

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 will have to verify that all the regulatory documentation and the information to demonstrate the compliance of the device has been drafted and is accessible to authorities on request. This includes technical documentation, declaration of conformity and certificates.

In addition, authorised representatives will have to verify that the manufacturer has registered the requested information in the European database (Articles 11 §3.c MDR).

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

The authorised representative may terminate a mandate should the legal manufacturer act contrary to the requirements of the Regulations. In this case they should inform the national competent authority.

7 http://ec.europa.eu/growth/tools-databases/nando/

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

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 European Union, (Article 11 paragraph 5 MDR and IVDR).

The Regulations 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 (Article 11 paragraph 4 MDR and IVDR). 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 dedicated to regulatory compliance (Article 15§6 MDR and IVDR).

A change of authorised representative can be made only under certain conditions (Article 12 MDR and IVDR).

Roles and responsibilities of an importer

The Regulations also describe the roles and responsibilities of importers.

An importer is defined as any natural or legal person established in the European Union that is placing a device from a third country on the European Union market. Situations may arise where there are no importers. For example, there is no importer when the legal manufacturer is based in the European Union.[9]

Article 13 (MDR and IVDR) describes many of the general obligations of importers.

The importer is responsible for making sure that the devices they place on the market are compliant with the MDR. This includes ensuring that devices bear the CE marking, that devices are accompanied by the required information, that the labelling is compliant and that a UDI has been assigned.

In addition, the importer should make sure that devices are registered in Eudamed along with their details, and that the manufacturer has met all its obligations in full.

If an importer finds out that a device is not compliant with the Regulations, the device shall not be placed it on the European market. The importer should 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 do not jeopardise compliance.

Importers also have the responsibility to inform manufacturers or authorised representatives in the event of complaints. They should keep registers of complaints and non-conformity and escalate non-compliance to authorities.

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

Roles and responsibilities of a distributor

The Regulations describe the roles and responsibilities of distributors, who should make sure that the devices they distribute are compliant. Article 14 (MDR and IVDR) describes many of the general obligations of distributors.

Distributors should verify that the devices have been CE marked and that they are accompanied by the required regulatory information and documentation. Distributors should also verify that the importer has complied with all obligations and that the devices bear a UDI.

Distributors shall ensure that storage and transport conditions are appropriate and are 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. The distributor should inform the authorities if they suspect that a device has been falsified or that there is a serious risk to health.

Distributors shall inform manufacturers and other economic operators immediately about complaints and incidents. They should also keep a register of complaints and non-conformities.

Distributors should cooperate with authorities and other economic operators on corrective actions. They should make available all the documentation and information that they have at their disposal.

Under the Regulations every economic operator has the responsibility to check whether the previous operator has fulfilled its obligations.

9 For further information related to imports into the EU, refer to the European Commission's Blue Guide: *http://ec.europa.eu/DocsRoom/documents/18027/.*

Frequently asked questions

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

MDR *https://www.camd-europe.eu/wp-content/uploads/2018/05/FAQ_MDR_180117_V1.0-1.pdf*

IVDR *https://www.camd-europe.eu/wp-content/uploads/2018/05/FAQ_IVDR_180117_V1.0-1.pdf*

When do the Regulations apply?

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

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. regarding UDI 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.

However, some in-vitro devices (Class D) may not be marketed before the Medical Device Coordination Group (MDCG) and 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, is unlikely to be complete before the 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 there will be no more valid certificates.

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/covered by the Regulations.

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