European Commission

Factsheet for healthcare professionals and health institutions

This factsheet is aimed at healthcare professionals and health institutions. For a general overview of the Regulations please refer to the Medical Devices[1] section on the on the ***European Commission website***[2].

The new medical devices Regulation (2017/745/EU) (MDR) and the new *in vitro* diagnostic medical devices Regulation (2017/746/EU) (IVDR), entered into force in May 2017, will replace the existing medical devices Directive (93/42/EEC) (MDD), the active implantable medical devices Directive (90/385/EEC) (AIMDD) and the *in vitro* diagnostic medical devices Directive (98/79/EC) (IVDD).

The publication of the MDR in May 2017 marked the start of a 4 year period of transition from the MDD and the AIMDD.

The publication of the IVDR in May 2017 marked the start of a 5 year period of transition from the IVDD.

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 new Regulations will create a robust, transparent and sustainable regulatory framework, recognised internationally, that improves clinical safety and creates fair market access conditions 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 risk of discrepancies in interpretation across the EU.

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

2 *https://ec.europa.eu/health/md_newregulations/overview_en*

Both Regulations will come into force gradually over a transition period of 4 years (up to May 2021) for the MDR and 5 years (up to May 2022) for the IVDR. From these dates the Regulations will apply in full. This transition will allow manufacturers and other economic operators to prepare for the implementation of the Regulations, while healthcare professionals and health institutions will have time to learn what will be required from them, notably in terms of the traceability of devices.

During the transition period both Regulations will come into force gradually, starting with 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 also in place. Some devices with certificates issued under the Directives may continue to be placed on the market[3] until 26 May 2024, and made available[4] or put into service[5] until 26 May 2025.

What does this mean in practice?

Certificates delivered by Notified Bodies under the MDD will remain valid until their date of validity or for a maximum of 4 years (and until 26 May 2024 at the latest, except for some exceptions described in MDR Article 120(2)).

Certificates delivered by Notified Bodies under the IVDD will remain valid until their expiry dates or until 26 May 2024 at the latest.

Until May 2025, certain devices placed on the market under the Directives and certain devices placed on the market under the new Regulations will coexist on the market. Both will have equal status under the law, and no discrimination in public tenders may take place.

Devices that are in stock in health institutions can still be used after 2025 until they reach their expiration dates. Furthermore, the Regulations do not regulate the further making available of devices, including after 25 May 2025, after they have already been made available or put into service, for example in the case of second-hand sales (MDR and IVDR recital 3).

What has changed?

In general, no requirements from the Directives (MDD, AIMDD 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.

Risk classification of devices and scope of the Regulations

The classification of MDs into four classes (Class I, IIa, IIb, III) remains, but the MDR reclassifies certain devices and has a wider scope. For example, the Regulation explicitly covers devices for cleaning, sterilising or disinfecting other medical devices. The Regulation also covers reprocessed single-use medical devices, and certain devices with no intended medical purpose (MDR Chapter I and Annex XVI).

For IVDs, the biggest change concerns the new risk-based classification of *in vitro* diagnostic devices and the role of Notified Bodies. Each IVD will now be assigned to one of four risk classes (Classes A, B, C or D, the level of risk increasing from A to D) using internationally recognised rules (IVDR Article 47 and Annex VIII).

As a result, around 85 % of all IVDs will need Notified Body oversight under the IVDR, compared to 20 % previously under the IVDD (IVDR Article 48).

Devices or services sold via the internet are now explicitly covered by the Regulations (MDR and IVDR Article 6).

These changes could have consequences for the availability of medical devices for health institutions. For instance, manufacturers may choose to stop the production of certain medical devices. Furthermore, if certain medical devices do not get their certificates on time these products may become temporarily unavailable. Ask your suppliers to inform you in good time about the availability of the devices you need.

3 'Placing on the market' means the first time the device is made available, other than an investigational device (or 'other than a device for performance study' according to the IVDR), on the Union market (MDR Article 2(28) and IVDR Article 2(21)).

4 'Making available on the market' means any supply of a device, other than an investigational device (or 'other than a device for performance study' according to the IVDR), 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 (MDR Article 2(27) and IVDR Article 2(20)).

5 'Putting into service' means the stage at which a device, other than an investigational device (or 'other than a device for performance study' according to the IVDR), has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose (MDR Article 2(29)and (IVDR Article 2(22)).

Clinical investigations (MDR Articles 62 to 82) and performance studies (IVDR Articles 57 to 77)

The rules on clinical investigations for medical devices and performance studies for *in vitro* medical devices have been reinforced. The new rules describe clearly how these investigations shall be designed, notified and/or authorised, conducted, recorded and reported. If you are a sponsor or take part in clinical investigations or performance studies, please read the relevant articles carefully so that you are informed of all the new obligations.

Obligations and regulatory requirements of economic operators[6]

The Regulations clarify the respective obligations of manufacturers, authorised representatives, importers and distributors (MDR and IVDR Articles 10 to 16).

For manufacturers, the Regulations add new requirements and reinforce existing requirements. Manufacturers have to put systems in place for risk and quality management, conduct clinical or performance evaluations, draw up technical documentation and keep all of this up to date. Manufacturers are also required to apply conformity assessment procedures in order to place their devices on the market. The level of clinical evidence needed to demonstrate the conformity of a device depends on its risk class.

Once they have completed their obligations, manufacturers should draw up a declaration of conformity and apply the CE mark to their devices:

CE

The Regulations also clarify the distinction between vigilance and post-market surveillance. The former includes identifying and reporting serious incidents and conducting safety-related corrective actions. It requires direct and efficient cooperation between healthcare professionals, health institutions, manufacturers and national competent authorities for medical devices. Post-market surveillance involves monitoring the available information to periodically reconfirm that the benefits of the device continue to outweigh its risks.

The Regulations require manufacturers to implement post-market surveillance follow-up plans. This includes compiling safety reports and updating the performance and clinical evaluation throughout the life cycle of a device. This could lead to manufacturers calling on health institutions to provide more information about their experience with their medical devices. Health institutions could prepare for this by thinking about convenient ways to gather information about their experience with medical devices.

Manufacturers outside the EU market should have a contract with an authorised representative inside the EU.

CE marking of conformity (MDR Article 20 and IVDR Article 18)

Devices, other than custom-made[7] or investigational devices[8], that are considered to be in conformity with the requirements of the Regulations shall bear the CE mark.

MDs in Class I and IVDs in Class A, which are the less risky devices, generally do not require the involvement of a Notified Body (NB) for their placement on the market. All other devices need a certificate issued by a Notified Body. In these cases the CE mark is followed by the number of the NB.

The Regulations add stricter rules for the designation of Notified Bodies with evaluators who are independent from manufacturers and their devices (MDR/IVDR Chapter IV). All Notified Bodies will have to be designated under the Regulations.

Notified Bodies' tasks include:

- assessing the manufacturer's quality management system;
- evaluating the technical documentation – sometimes together with product sample verification;
- issuing CE marking certificates;
- announced annual surveillance audits;
- unannounced audits at least every 5 years, with sample testing;
- post-market surveillance review.

The list of designated Notified Bodies can be found on the NANDO database.[9]

6 'Economic operator' means a manufacturer, an authorised representative, an importer or a distributor (MDR Article 2(35) and IVDR Article 2(28)).
7 'Custom-made device' means any device specifically made in accordance with a written prescription by any person authorised by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs (MDR Article 2(3)).
8 'Investigational device' means a device that is assessed in a clinical investigation (MDR Article 2(46)).
9 *http://ec.europa.eu/growth/tools-databases/nando/*, NANDO (New Approach Notified and Designated Organisations).

In addition to the evaluation made by the Notified Bodies, certain high-risk devices are subject to additional scrutiny of their clinical files by an independent expert panel with clinical, scientific and technical expertise (MDR Article 54 and IVDR Article 50).

The new Regulations reinforce the responsibilities of national competent authorities and the Commission in terms of controlling and monitoring devices on the market.

Traceability

A completely new feature of the Regulations is the unique device identification (UDI) system (MDR Article 27 and IVDR Article 24), which will apply to all devices placed on the EU market. The UDI will be a barcode, a QR code or any other machine-readable code. This will enhance the identification and traceability of devices and the effectiveness of post-market safety-related activities through targeted field safety corrective actions and better monitoring by competent authorities. Economic operators shall be able to identify any health institution or healthcare professional to which they have directly supplied a device (MDR Article 25 and IVDR Article 22).

UDI should also help to reduce medical errors and fight against falsified devices. Use of the UDI system should also improve purchasing, waste disposal and stock management by health institutions and other economic operators; where possible, UDI should be compatible with other authentication systems already in place in those settings (MDR recital 41 and IVDR recital 38).

Identification

Unique device identifiers (UDIs) will be used to uniquely and unambiguously identify devices, both individually and when packaged, or in the case of reusable devices by direct marking of the device itself.

Each MD or IVD and, when applicable, each level of their packaging will have a UDI that will be indicated on the labels. UDIs will be added to labels in stages but will be completed by 2027, depending on the risk class of the device.

For Class III implantable devices, health institutions shall store and keep – preferably by electronic means – the UDIs of the devices they have supplied, or with which they have been supplied (MDR Article 27(9)). The MDR and IVDR invite Member States to encourage and to require health institutions to store and keep the UDIs of the devices with which they have been supplied. Also, Member States shall encourage, and may require, healthcare professionals to store and keep the UDIs of the devices with which they have been supplied.

With each implantable device the manufacturer will have to deliver implant card-carrying-appropriate information. This card, including the patient's identity, shall be supplied to each patient fitted with an implant. Health institutions shall allow rapid access to the information contained on the implant card to any patient fitted with a device, unless the type of implant is exempt from this obligation MDR Article 18.

EUDAMED database

The Regulations will increase transparency by making the UDI the key to publicly available information on devices and in studies. EUDAMED, the new European database for medical devices and *in vitro* diagnostic medical devices, 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).

The central European database will allow all stakeholders to access basic information on MDs and IVDs, such as the identity of the device, its certificate, the manufacturer, the authorised representative and the importer.

The EUDAMED database (MDR Article 92 and IVDR Article 87) will adequately inform the public, including healthcare professionals, about:

- clinical investigation reports on medical devices and performance study reports on *in vitro* medical devices, the summaries of the main safety and performance aspects of the device, and the outcome of the clinical/performance evaluation;
- field safety notices by manufacturers and certain aspects of serious incident reports.

Healthcare professionals can use this information and may expect questions from patients about what they have read in EUDAMED.

In addition, Member States shall take appropriate measures, such as organising targeted information campaigns, to encourage and enable healthcare professionals, users and patients to report to the competent authorities on suspected serious incidents occurring with devices (MDR Article 87(10) and IVDR Article 82(10)).

Labelling and instructions for use

In addition, the Regulations improve labelling. New requirements aim to make it easier to identify products, find instructions for use, and get information about the safety and performance of devices. For example, labels will contain new information, along with symbols showing the presence of hazardous or medicinal substances (MDR Annex I Chapter III(23) and IVDR Annex I Chapter III(20)).

In general, each device shall be accompanied by the information needed to identify it and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website.

Carcinogenic, mutagenic or reprotoxic (CMR) substances and endocrine disruptors

The MDR foresees that device labels will have to indicate the presence of CMR substances or endocrine-disrupting substances in medical devices above certain concentrations. This labelling requirement does not mean a device is unsafe. The fact that it has been CE marked means that both the manufacturer and the Notified Body have established a positive benefit-risk ratio (MDR Annex I, Chapter II, section 10.4.1)

In-house devices

The Regulations allow health institutions under certain conditions to manufacture, modify and use devices 'on a non-industrial scale' when equivalent ones are not available commercially (MDR and IVDR Article 5). With the exception of the general safety and performance requirements set out in MDR/IVDR Annex I, in-house devices are exempt from the requirements of the Regulations as long as they are not transferred to another legal entity. Nevertheless, health institutions should have appropriate quality management systems in place; compile documentation on the manufacturing process, the design and performance data of the devices, including their intended purpose; and review the experience gained from the clinical use of the devices and take all necessary corrective actions.

This information shall be made available to competent authorities on request, and a declaration with certain details should be made publicly available.

If healthcare professionals manufacture and use devices that do not comply with Article 5 they must follow the same rules as manufacturers.

Member States may require that such health institutions submit to the competent authority any further relevant information about such devices that have been manufactured and used on their territory. Member States shall retain the right to restrict the manufacture and use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions.

Custom-made devices

A 'custom-made device' means any device specifically made in accordance with a written prescription by any person authorised by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.

The procedure for custom-made devices is described in MDR Article 52(8) and Annex XIII. As long as a device is shown to be for the exclusive use of a particular patient, in accordance with a written prescription, to have been manufactured and used according to the safety provisions of MDR Annex I, and properly documented, it is exempt from other specific requirements of the MDR.

Nanomaterials

The MDR notes scientific uncertainty about the risks and benefits of nanomaterials used in MDs (MDR recital 15), and requires manufacturers to take special care when there is 'high or medium' potential for internal exposure to nanoparticles. Such devices should be subject to the most stringent conformity assessment procedures, and take into account the opinions of the relevant scientific committees. MDR Article 2 (definitions 18 to 21) defines nanoparticles, while MDR Article 3 allows the definition to be changed in the light of future research.

Reprocessing of single-use medical devices

The MDR allows reprocessing of single-use MDs to enable their safe re-use, as long as this is also permitted by national law and only in accordance with MDR Article 17. A reprocessor would assume all the responsibilities of the original manufacturer of this device (MDR Article 17(2)), but Member States may decide to relax this rule somewhat for devices that are reprocessed and used within a health institution (MDR Article 17(3)) or reprocessed by a third party at the request of a health institution (MDR Article 17(4)). In these cases the safety and performance of the reprocessed device must be equivalent to that of the original, and systems must be in place for risk management, process validation, performance testing, quality management, incident reporting and traceability. Member States may require health institutions to inform patients that they are using reprocessed devices. The European Commission will publish common specifications to harmonise the practice in those Member States where it is allowed.

Checklist for preparedness of healthcare institutions

Traceability	For Class III implantable devices, health institutions shall store – preferably by electronic means – the UDIs of the devices they have supplied, or with which they have been supplied. An implant card and information related to the device shall be supplied to each patient with an implanted device (MDR Article 18).
In-house devices / health institution exemption	Check with your competent authority to ensure you are prepared to apply the healthcare institution exemption if you manufacture, modify or use medical devices or IVDs in-house.
Reprocessing of single-use devices	Check with your national competent authority on national rules and prepare for the application of the Common Specifications to be published by the European Commission by 2020.
Clinical investigations / performance studies	If the health institution itself is sponsoring or the healthcare professional is taking part in a clinical investigation or a performance study, it needs to be aware of enhanced obligations.

Frequently asked questions

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

FAQs – MDR Transitional provisions

FAQs - IVDR Transitional provisions

When do the Regulations apply?

The medical devices Regulation (EU) 2017/745 (MDR) will apply from 26 May 2021 and the *in vitro* medical device Regulation (EU) 2017/746 (IVDR) will apply from 26 May 2022 – the respective Dates of Application.

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 UDIs and labelling).

What is the applicable legislation up to the respective dates of application?

Until the dates of application (DoA), the national rules adopted by Member States in accordance with the Directives will continue to apply. To allow a smooth transition from the Directives to the Regulations, several transitional provisions are in place. Some devices with certificates issued under the Directives (AIMDD/MDD/IVDD) may continue to be placed on the market until 26 May 2024 and made available until 26 May 2025. During the transition phase, products certified under the Directives and products certified under the Regulations will coexist on the market.

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

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[10] and procedure packs[11].

10 'System' means a combination of products, either packaged together or not, which are intended to be interconnected or combined to achieve a specific medical purpose (MDR Article 2(11)).

11 'Procedure pack' means a combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose (MDR Article 2(10)).

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, as well as the European Union reference laboratories for Class D devices.

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.

Do certificates issued by Notified Bodies under the existing Directives remain valid after the dates of application of the Regulations?

Yes, certificates will generally remain valid until the end of the period indicated on the certificate, or until 26 May 2024, whichever is the earlier. After this date there will be no more valid certificates.

01/08/2020

https://ec.europa.eu/health/md_newregulations/overview_en

Funded under the Third EU Health Programme

ISBN: 978-92-76-03182-6 DOI: 10.2873/761339