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 impact of the regulations please refer to the Medical Devices section on the European Commission website.

In April 2017, the European Parliament and the Council adopted the Medical Devices Regulation (EU) 2017/745 (MDR) and the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR).

These two Regulations aim to create a robust, transparent, and sustainable regulatory framework that is recognised internationally, improves clinical safety and creates fair market access for manufacturers.

The MDR replaced the Medical Devices Directive 93/42/EEC (MDD) and the Active Implantable Medical Devices Directive 90/385/EEC (AIMDD). The MDR became applicable on 26 May 2021.

The IVDR replaced the In Vitro Diagnostic Medical Devices Directive (98/79/EC) (IVDD). The IVDR became applicable on 26 May 2022.

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

Several provisions are in place to support the transition from the Directives (MDD, AIMDD, IVDD) to the Regulations (MDR, IVDR). During these transition periods, most devices with certificates or declarations of conformity issued under the Directives may continue to be placed on the market after the respective dates of application of the two Regulations. Therefore, devices that are compliant with the previously applicable Directives and devices that are compliant with the current Regulations co-exist and may simultaneously be placed or made available on the EU market during the transition period. The Regulations (MDR, IVDR) set rules concerning the placing on the market, making available on the market or putting into service of medical devices and in vitro diagnostic medical devices (IVDs). Once devices have been placed on the market or put into service in accordance with the MDD, AIMDD, IVDD or the MDR, IVDR, they can continue to be used by the user.

Risk classification of devices and scope of the Regulations

Medical devices are classified into four classes (I, IIa, IIb, III). In comparison with the Directives, 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).

Under the Regulations, IVDs are now also categorised into four classes (A, B, C or D, with the level of risk increasing from A to D) and are assessed on a risk-based approach. As a result, around 80 % of all IVDs now need notified body oversight under the IVDR (Article 48), compared to 8 % previously under the IVDD.

Devices sold via the internet, including devices used for therapeutic or diagnostic services offered via the internet to users in the EU, are now explicitly covered by the Regulations (MDR and IVDR Article 6).

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

Devices, other than custom-made[1], in-house[2], investigational devices[3] or devices for performance studies[4], that are considered to be in conformity with the requirements of the Regulations must bear the CE mark:

CE

Medical devices in Class I and IVDs in Class A, which are the devices with lower risk, generally do not require the involvement of a notified body for their placement on the market. All other devices need a certificate issued by a notified body; in that case the CE mark is followed by the number of the notified body.

Notified bodies are organisations designated by EU Member States to assess a device's compliance with the applicable provisions in MDR/IVDR before it is placed on the market and can be procured and used by healthcare professionals and patients. 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[5].

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). For certain high risk IVDs, European reference laboratories are involved in conformity checks (IVDR Article 100)[6].

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

Reinforced rules on clinical investigations for medical devices and performance studies for IVDs are included in the Regulations. They describe how these investigations must 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 relevant obligations.

Sponsors must summarise the results of clinical investigations and performance studies in a report. The report begins with an executive summary intended to give healthcare professionals a quick understanding of the content and significance. The summaries of the clinical investigation and performance study reports will be made available in the European Database on Medical Devices (EUDAMED) – see section below for more information.

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 experience gained from clinical use of the devices and take all necessary corrective actions.

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

If health institutions 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 which have been manufactured and used on their territory. Member States have the right to restrict the manufacture and use of any specific type of such devices and are permitted access to inspect the activities of the health institutions.

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[1] 'Custom-made device' means any device specifically made in accordance with a written prescription of 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)).

[2] 'In-house device' means a device that is manufactured and used within EU health institutions, on a non-industrial scale, to address the specific needs of target patient groups which cannot be met, or cannot be met at the appropriate level of performance, by an equivalent CE-marked device available on the market (MDR/IVDR Article 5(5)).

[3] 'Investigational device' means a device that is assessed in a clinical investigation (MDR Article 2(46)).

[4] 'Device for performance study' means a device intended by the manufacturer to be used in a performance study (IVDR Article 2(45)).

[5] https://webgate.ec.europa.eu/single-market-compliance-space/notified-bodies

[6] For more information, consult: https://health.ec.europa.eu/medical-devices-vitro-diagnostics/eu-reference-laboratories-eurls_en

Custom-made devices

A 'custom-made device' means any device specifically made in accordance with a written prescription of 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. Custom-made devices are exempt from several specific requirements of the MDR, such as CE marking, unique device identifiers (UDIs), summary of safety and clinical performance.

Obligations and regulatory requirements of economic operators[7]

The Regulations clearly define the obligations of the various actors and their relations.

Manufacturers have to put in place systems 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 marking to their devices.

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

As of 10 January 2025, manufacturers must provide information to Member States, as well as distributors and healthcare professionals, in case of disruption of supply of certain medical devices and IVDs where this discontinuation or disruption of supply may pose a risk to patients or public health. Manufacturers must provide this information at least 6 months before the anticipated interruption or discontinuation, except for in exceptional circumstances (MDR/IVDR Article 10a).

Reporting of incidents

The Regulations distinguish 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 can lead to manufacturers calling on health institutions to provide more information about their experience with their medical devices. To ensure adequate reporting of safety issues, Member States must take appropriate measures, such as organising targeted information campaigns, to encourage and enable healthcare professionals, users and patients to report to the competent authorities suspected serious incidents occurring with devices (MDR Article 87(10) and IVDR Article 82(10)).

Traceability

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. All economic operators will have to store and keep the UDIs for Class III implantable devices they have sold or received, as required by MDR Article 27(8). This same obligation applies to health institutions (MDR Article 27(9)). The obligation on health institutions can be extended to other categories of devices by Member States on a national basis (MDR Article 27(9) and IVDR Article 24(9)). Member States may also have requirements for healthcare professionals to store UDIs (MDR Article 27(9) and IVDR Article 24(9)).

UDI carriers must be affixed to each device and all higher levels of device packaging (except for devices for clinical investigations and performance studies as well as custom-made devices and in-house devices). It should appear in both plain text with human readable interpretation format and in a machine-readable information format (e.g. barcode). However, some exceptions exist, allowing either format to be used. Manufacturers are also responsible for assigning the UDI (and Basic UDI-DI), and entering the required information into the UDI database, which is part of EUDAMED (see next section for more information on EUDAMED).

Each device (except custom-made medical devices, investigational devices and devices for performance study), and, as applicable, each higher level of device packaging, will have a UDI assigned according to the rules of the EU issuing entities. The UDI is composed of a device identifier (UDI-DI) specific to a manufacturer and a device and 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.

In addition, all medical devices and IVDs need to be assigned a Basic UDI-DI. It is the main access key for device-related information in the UDI database and is to be referenced in relevant documentation (e.g. certificates (including certificates of free sale), EU declaration of conformity, technical documentation, and summary of safety and (clinical) performance). However, the Basic UDI-DI does not appear on any label or device and is never presented as machine-readable information.

[7] 'Economic operator' means a manufacturer, an authorised representative, an importer, or a distributor (MDR Article 2(35) and IVDR Article 2(28)).

For both Regulations, the deadline for assigning UDIs is the respective date of application. However, the obligation to affix the UDI carrier to the label is being implemented in three stages (see dates below).

Before the dates outlined below, manufacturers are not legally required to label their devices with UDI carriers, although some may choose to do so. During the transition periods, devices which are CE marked under the MDD/AIMDD/IVDD are not subject to MDR/IVDR UDI requirements.

For medical devices, the UDI should be affixed at the latest by:

1. Class III devices and implantable devices: **26 May 2021**
2. Class IIa and class IIb devices: **26 May 2023**
3. Class I devices: **26 May 2025**

For IVDs, the UDI should be affixed at the latest by:

1. Class D devices: **26 May 2023**
2. Class B and class C devices: **26 May 2025**
3. Class A devices: **26 May 2027**

For reusable devices, there will be a requirement to affix the UDI carrier to the device itself. The timeline for affixing the UDI carrier to the device itself is also staggered and comes into effect 2 years after the date applicable to the corresponding risk class shown in the lists above.

European Database on Medical Devices (EUDAMED)

EUDAMED includes UDI related information (Basic UDI-DIs and UDI-DIs) together with their related device or system/procedure pack information, as well as information on economic operators (except for distributors), sponsors, notified bodies, certificates, clinical investigations and performance studies, vigilance, post-market surveillance and market surveillance (MDR Article 33 and IVDR Article 30).

EUDAMED allows all stakeholders to access basic information on medical devices and IVDs, such as the identity of the device, its certificate, the manufacturer, the authorised representative and the importer. The information in EUDAMED is in large part accessible to the public. Different modules of the database become mandatory to use gradually, in accordance with the indicative timeline published on the Commission website[8].

Labelling and instructions for use

The Regulations 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 medicinal or certain hazardous substances (MDR Annex I Chapter III and IVDR Annex I Chapter III).

In general, each device must 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 must, if the manufacturer has a website, be made available and kept up to date on the website.

Summary of (clinical) safety and performance

The Regulations require manufacturers to draw up a summary of (clinical) safety and performance for implantable and class III medical devices, and class C and class D IVDs (MDR Article 32 and IVDR Article 29). The summaries intend to provide healthcare professionals and, where relevant, patients certain key information regarding the device. The summaries must be validated by a notified body and made available to the public via EUDAMED.

Implant cards

The MDR obliges manufacturers of implantable medical devices to make available, together with the device, information allowing the identification of the device (MDR Article 18). This includes the device name, serial number, lot number, the UDI, the device model, as well as the name, address and the website of the manufacturer. Devices listed in MDR Article 18(3) are exempt from this requirement.

This information can be made available either directly as a card or as stickers that are to be placed on a card by the healthcare professionals.

Healthcare institutions and healthcare professionals are required to provide the implant card to the concerned patient (MDR Article 18(2)). Their identity must be visible on the implant card. For this purpose, the implant card provided together with the device by the manufacturer should contain blank spaces with the following information which must be filled out by the health institution or healthcare professional: name of the patient or patient ID, name and address of the health institution or healthcare professional who performed the implantation, date of implantation.

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

The MDR requires that device labels 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)

[8] Available at: https://health.ec.europa.eu/document/download/04ce2012-97df-4dd0-8a39-d4f6993b9e16_en?filename=md_eudamed_roadmap_en.pdf

Reprocessing of single-use medical devices

The MDR allows reprocessing of single-use medical devices 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 assumes the responsibilities of the original manufacturer of this device (MDR Article 17(2)), but Member States may decide not to apply the rules relating to manufacturers' obligations 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 has published common specifications to harmonise the practice in those Member States where it is allowed[9].

[9] Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R1207

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