European Commission

Factsheet for Procurement Ecosystem of medical devices and *in vitro* diagnostic medical devices

This factsheet is aimed at people within hospitals, clinics (or associations of clinics), ministries and competent bodies responsible for the procurement 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 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 risks 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 (DoAs) of the two Regulations. Therefore, **devices that are compliant with the previously applicable Directives and devices that are compliant with the current Regulations coexist and may be placed or made available simultaneously on the EU market.**

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. Devices that have been placed on the market and put into service and have reached the end user can continue to be used by the user.

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 medical devices and IVDs. Apart from the risk classification, certain features may influence the conformity assessment procedure, for example when a medical device is required to be sterile, or an IVD is designed for use by lay persons ('self-testing').

For medical devices, all class IIa, IIb and III as well as some specific class I require the intervention of a notified body (MDR Article 52(7) (a[1] , b[2] , c[3]). 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-declared by their manufacturers as being in conformity with the IVDR, unless they are sold in sterile condition. Devices in classes B, C and D will require a conformity assessment with the involvement of a 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[4].

Timelines

During the transition period, manufacturers may, under certain conditions, continue to produce devices which are CE marked under the MDD/AIMDD/IVDD (also referred to as 'legacy devices') and place them on the EU market after the respective DoAs of the Regulations. During the transition period, devices covered by a certificate issued by a notified body under the MDD/AIMDD/IVDD remain subject to notified body surveillance.

Timelines under the MDR:

No extended transition period applies to medical devices that do not require the involvement of a notified body under the MDR. These are 'simple' class I medical devices (i.e. non-sterile, no measuring function, not reusable surgical instruments) and all custom-made devices, except for class III custom-made implantable devices. All these devices have had to comply with the MDR since 26 May 2021. Also, all 'new' devices, i.e. devices not previously covered by a certificate or declaration of conformity issued under the MDD/AIMDD, must comply with the MDR.

Medical devices that did not require the involvement of a notified body under the MDD/AIMDD, but do so under the MDR (e.g. class I reusable surgical instruments and certain medical device software), may continue to be placed on the market or put into service until 31 December 2028 at the latest. This only applies to devices whose declaration of conformity was drawn up before the DoA: 26 May 2021.

Medical devices that are covered by a certificate issued by a notified body under the MDD/AIMDD between 25 May 2017 and 26 May 2021, and which was valid on 26 May 2021, may continue to be placed on the market or put into service at the latest until 31 December 2027 or 31 December 2028, depending on the risk class of the device. This is subject to certain conditions (see below). The corresponding notified body certificate remains valid until the end of the applicable transition period (i.e. until 31 December 2027 or 31 December 2028), unless the certificate has been withdrawn by the notified body.

As the validity of the certificates has been extended by law (Regulation (EU) 2023/607), they remain valid beyond the end of the period indicated on the certificate, until the end of the applicable transition periods set out in the amended MDR. Under certain conditions, this also applies to certificates that have expired before 20 March 2023 (MDR Article 120(2), second subparagraph).

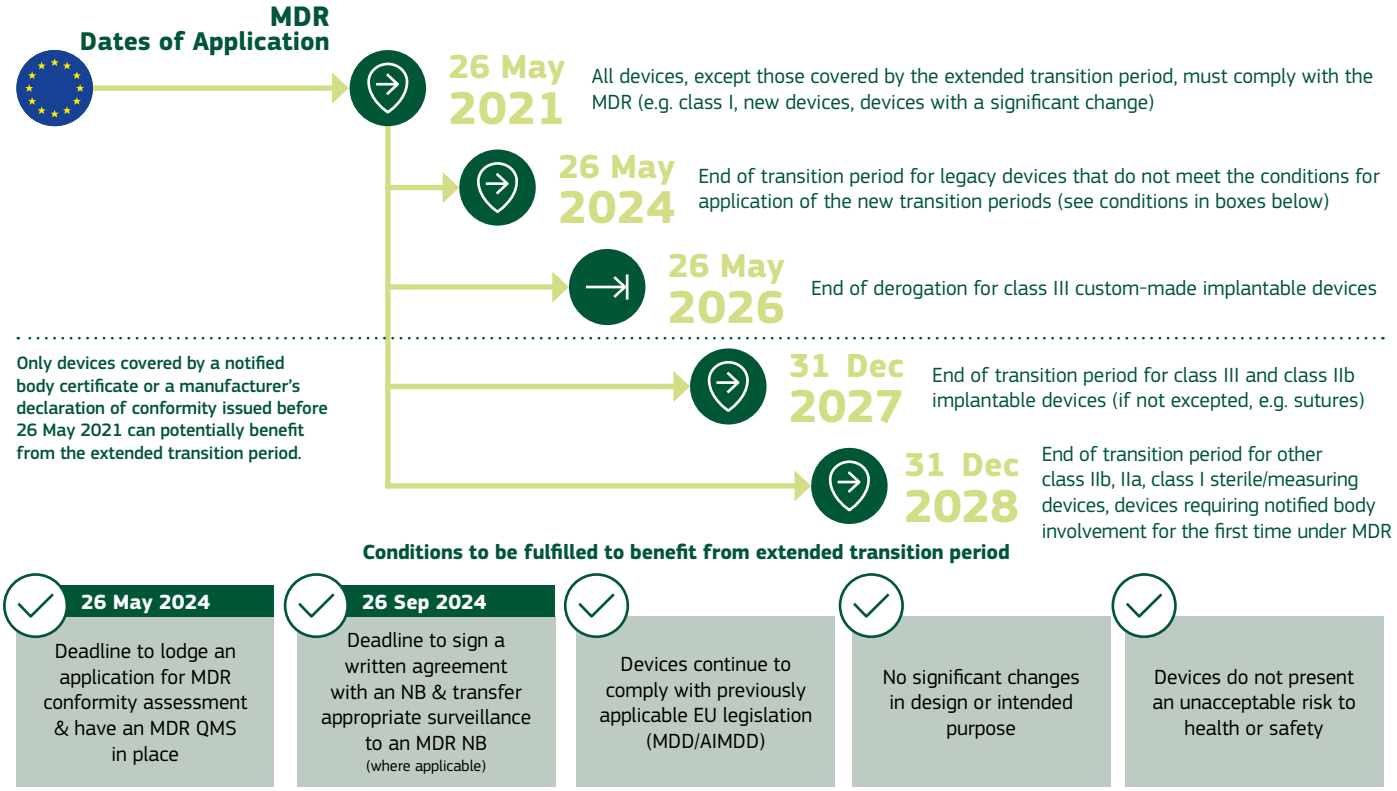
The length of the transition period depends on the risk class of the device, which is to be determined in accordance with the MDR classification rules:

- 31 December 2027: class III devices and class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors;
- 31 December 2028: class IIb implantable devices that are sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors, class IIb non-implantable devices, class IIa devices, class I sterile/measuring devices, and devices that did not require notified body involvement under MDD but do so under MDR (e.g. class I reusable surgical instruments).

Class III custom-made implantable devices need to be covered by a Quality Management System (QMS) certificate issued by a notified body at the latest by 26 May 2026.

There are conditions to be fulfilled to make use of the transition periods. For the MDR, these include that manufacturers must apply to a notified body before 26 May 2024 and have signed an agreement with a notified body by 26 September 2024. For more information on the extended transition periods of the MDR and its conditions, see the Commission's Q&A[5].

[1] Devices placed on the market in sterile condition.
[2] Devices with a measuring function.
[3] Reusable surgical instruments.
[4] http://ec.europa.eu/growth/tools-databases/nando/NANDO (New Approach Notified and Designated Organisations).
[5] European Commission (2023). Q&A on extension of the MDR transition period and removal of the 'sell-off' period. Available at: https://health.ec.europa.eu/document/download/592008f6-3456-4afb-a13a-733a87da1b00_en?filename=mdr_proposal_extension-q-n-a.pdf



Timelines under the IVDR:

No transition period applies to IVDs that do not require the involvement of a notified body under the IVDR (i.e. class A non-sterile IVDs). These have had to comply with the IVDR since 26 May 2022. Also, all 'new' IVDs, i.e. devices not previously covered by a certificate or declaration of conformity issued under the IVDD, must comply with the IVDR. IVDs that did not require the involvement of a notified body under the IVDD, but do so under the IVDR, may continue to be placed on the market or put into service by 31 December 2029 at the latest, depending on the risk class of the device. This only applies to devices whose declaration of conformity was drawn up before the DoA: 26 May 2022.

IVDs that are covered by a certificate issued by a notified body under the IVDD between 25 May 2017 and 26 May 2022, and which was valid on 26 May 2022, may continue to be placed on the market or put into service until 31 December 2027 at the latest. This is subject to certain conditions (see below). The corresponding notified body certificate remains valid until the end of the transition period, unless the certificate has been withdrawn by the notified body.

As the validity of the certificates has been extended by law (Regulation (EU) 2024/1860), they remain valid beyond the end of the period indicated on the certificate, until the end of the applicable transition periods set out in the amended IVDR. Under certain conditions, this also applies to certificates that have expired before 9 July 2024 (IVDR Article 110(2) points (a) or (b)).

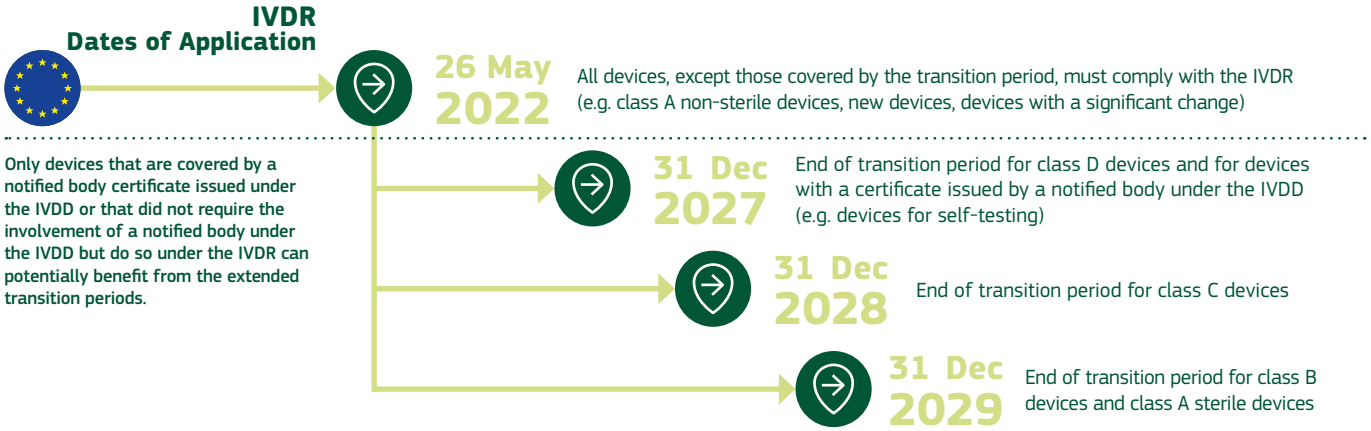
The lengths of the transition periods are:

- **31 December 2027:** class D devices and devices with a certificate issued by a notified body under the IVDD;
- **31 December 2028:** class C devices;
- **31 December 2029:** class B devices and class A sterile devices.

There are conditions to be fulfilled to make use of the transition periods. For the IVDR, these include that manufacturers must put in place an IVDR QMS by 26 May 2025. Manufacturers must also apply to a notified body before 26 May 2025 (for class D devices and for devices with a certificate issued by a notified body under the IVDD), 26 May 2026 (for class C devices) or 26 May 2027 (for class B and class A sterile) and have signed a written agreement with a notified body by 26 September 2025 (for class D and for devices with a certificate issued by a notified body under the IVDD), 26 September 2026 (for class C) or 26 September 2027 (for class B and class A sterile).

For more information on the extended transition periods of the IVDR and its conditions, see the Commission's Q&A[6].

[6] European Commission (2024). Q&A on extension of the IVDR transition period. Available at: https://health.ec.europa.eu/document/download/dfd7a1c6-f319-4682-9bac-77bef1165818_en?filename=mdr_qna-ext-ivdr.pdf



Conditions to be fulfilled to benefit from extended transition period

26 May 2025	**26 May 2025 | 26 May 2026 | 26 May 2027**	**26 Sep 2025 | 26 Sep 2026 | 26 Sep 2027**
Deadline to have an IVDR QMS in place	Deadline to lodge an application for IVDR conformity assessment	Deadline to sign a written agreement with an NB & transfer appropriate surveillance to an IVDR NB (where applicable)
Devices continue to comply with previously applicable EU legislation (IVDD)	No significant changes in design or intended purpose	Notified body certificate or declaration of conformity drawn up before 26 May 2022

Validity of medical device certificates

In principle, MDD/AIMDD/IVDD/MDR/IVDR certificates for medical devices and IVDs are valid until the period indicated on the certificate.

For MDD/AIMDD devices that benefit from the transition period, certificates remain valid beyond the end of the period indicated on the certificate, until the end of the applicable transition periods set out in the amended MDR (until 31 December 2027 or 31 December 2028, as explained above).

For IVDD devices that benefit from the transition period, certificates remain valid beyond the end of the period indicated on the certificate, until the end of the applicable transition periods set out in the amended IVDR (until 31 December 2027, 31 December 2028 or 31 December 2029, as explained above).

To show that the conditions for the application of the extended transition period are met for a given device, device group or category, manufacturers can use a 'self-declaration'. This self-declaration may be supported by a 'confirmation letter' issued by a notified body. Manufacturers could also provide evidence of having lodged an application and concluded a written agreement by other means (e.g. copy of relevant documents).

Please find the templates of the 'self-declaration' and 'confirmation letter' on the website of the European Commission[7].

Medical devices and IVDs with valid MDD/AIMDD/IVDD certificates (as described above) and medical devices/ IVDs with valid MDR/IVDR certificates may both be placed or made available on the EU market.

MDD/AIMDD/IVDD products in the supply chain

Medical devices that were placed on the market prior to 26 May 2021 in accordance with the MDD/AIMDD, or after 26 May 2021 during the applicable transition period, may continue to be made available on the market or put into service without any limitations in time, other than the devices' shelf-life or expiry date.

IVDs that were placed on the market prior to 26 May 2022 in accordance with the IVDD, or after 26 May 2022 during the applicable transition period, may continue to be made available on the market or put into service without any limitations in time, other than the device's shelf life or expiry date.

Responsibilities of economic operators

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

[7] European Commission. Medical Devices sector – New Regulations: https://health.ec.europa.eu/medical-devices-sector/new-regulations_en

MDR/IVDR Article 10 describes the responsibilities of manufacturers, for example regarding risk management systems (paragraph 2), the unique device identifier (UDI) system (paragraph 7) (see next section for more information on UDI), and quality management systems (paragraph 9). The article also specifies the need to conduct clinical evaluations or performance studies (paragraph 3), draw up technical documentation (paragraph 4) and put in place conformity assessment procedures (paragraph 6). The Regulations make manufacturers responsible for their devices once they are on the market (paragraphs 12, 13 and 14). Manufacturers must have systems in place to cover their financial responsibility for harm caused by defective devices (paragraph 16).

Manufacturers must have a named person responsible for regulatory compliance (Article 15).

The Regulations set out the conditions under which manufacturers can delegate tasks to **authorised representatives**. An authorised representative can only be changed under certain conditions (MDR/IVDR Article 12). The Regulations describe the roles and responsibilities of **importers** (MDR/IVDR Article 13) and **distributors** (MDR/IVDR Article 14):

1. **Importers** are responsible for ensuring that the devices they place on the market comply with the Regulations and are registered in EUDAMED, and that the manufacturer has fulfilled its obligations. They also have the responsibility to inform manufacturers and authorised representatives in the event of complaints or reports of suspected incidents from healthcare professionals, patients or users.

2. **Distributors** should ensure by representative sampling, that the devices they distribute comply with the Regulations (MDR/IVDR Article 14(2)). They also have the responsibility to inform manufacturers or authorised representatives and importers of complaints and incidents.

All economic operators must be able to identify the economic operator who has supplied them with a device and the economic operator or the healthcare institution / healthcare professional to whom they have supplied a device. In addition, economic operators are responsible for verifying that some basic requirements are met, such as availability of CE marking, declaration of conformity and the information to be supplied by the manufacturer.

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.

All economic operators will have to store and keep the UDIs for class III implantable devices that they have sold or received, as required by MDR Article 27(8) and IVDR Article 24(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)). Manufacturers must affix a UDI carrier to each device or the device label, 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 one or the other 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 of a production identifier (UDI-PI) – such as a lot number, serial number, software identification, manufacturing or expiry date – to identify the unit of device production and, if applicable, the packaged device. 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. For both Regulations, the deadline for assigning UDIs is the respective DoA. 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, there is no legal requirement for manufacturers to label their devices with UDI carriers, although some manufacturers 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).
The information in EUDAMED is in large parts accessible to the public. For economic operators, sponsors and notified bodies, the information is accessible at varying levels depending on their access rights and the information they are responsible for entering into the system.

EUDAMED is structured around 6 interconnected modules:

- Actor registration
- UDI/device registration
- Notified bodies and certificates
- Vigilance and post-market surveillance
- Market surveillance
- Clinical investigations and performance studies

EUDAMED will be rolled out gradually, according to the planning published on the Commission website[8]. Once each individual module is audited, the Commission will confirm the functionality of the module by a notice published in the Official Journal of the EU. The use of the module will become mandatory, 6 months after the publication of the notice. It is expected that the use of some modules will become mandatory in 2026.

Glossary

'Making available on the market' means any supply of a device, other than an investigational device, for distribution, consumption or use on the EU market, whether in return for payment or free of charge (MDR Article 2 definition 27, IVDR Article 2 definition 20).

'Placing on the market' means the first making available of a device, other than an investigational device, on the EU market (MDR Article 2 definition 28, IVDR Article 2 definition 21).

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

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

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