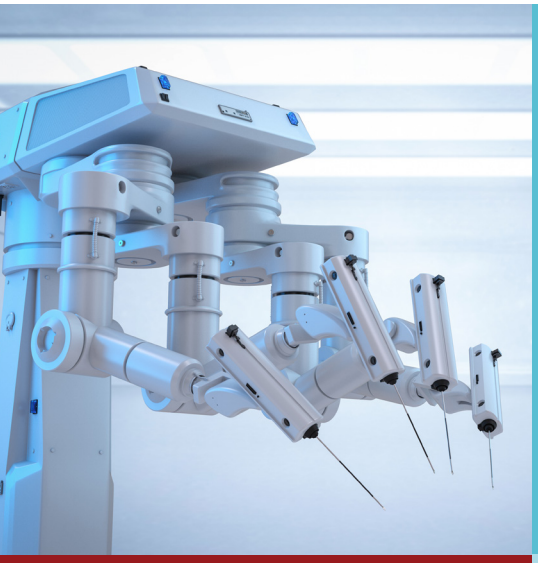


European Commission

Factsheet for authorities in non-EU/EEA states on medical devices and *in vitro* diagnostic medical devices[1]

This factsheet is for regulatory/competent authorities in countries that are not part of the EU/EEA. For a general overview of the regulations please refer to the Medical Devices section on the European Commision 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 create a robust, transparent, and sustainable regulatory framework, recognised internationally, which 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**.

Both Regulations provide for additional transition periods. The requirements enter 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.

The MDR and the IVDR are directly applicable to all EU countries and therefore create a level playing field across the EU market.

Manufacturers in third countries wishing to place devices on the EU market should familiarise themselves with the rules, timelines, and obligations applicable under the Regulations. General information is available on the website of the European Commission, where there are also contact points for the national authorities for further enquiry into the application of the Regulations or for guidance. The European Commission also provides information on access to the EU market on its Access2Markets webpage.

As an authority in a third country that imports devices from the EU, you need to know about the timelines for implementing the Regulations. Please also bear in mind that during the transition periods, devices that are compliant with the previously applicable rules and devices that are compliant with the current Regulations co-exist and may be placed on the EU market. This is of particular importance for those third countries that rely on the CE marking of devices to grant access to their markets.

To avoid disruptions in your market, health institutions, procurement bodies, customs officers and importers should be informed about the requirements and applicable timelines.

To avoid market disruption and allow a smooth transition from the Directives (AIMDD, MDD and IVDD) to the Regulations (MDR and IVDR), several transitional provisions are in place. 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 until the end of the relevant transition period.

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.

Timelines

During the transition period, manufacturers may, under certain conditions, continue to produce MDD/AIMDD/IVDD-compliant devices and place them on the EU market after the respective dates of application of the Regulations. You may, therefore, still receive MDD/AIMDD/IVDD-compliant products in your territory and be provided with certificates or declarations of conformity issued under the Directives. During the transition period, they have the same status as devices which are CE marked under the MDR/IVDR.

Timelines under the MDR:

No 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 validity indicated on the certificate until the applicable transition period ends.

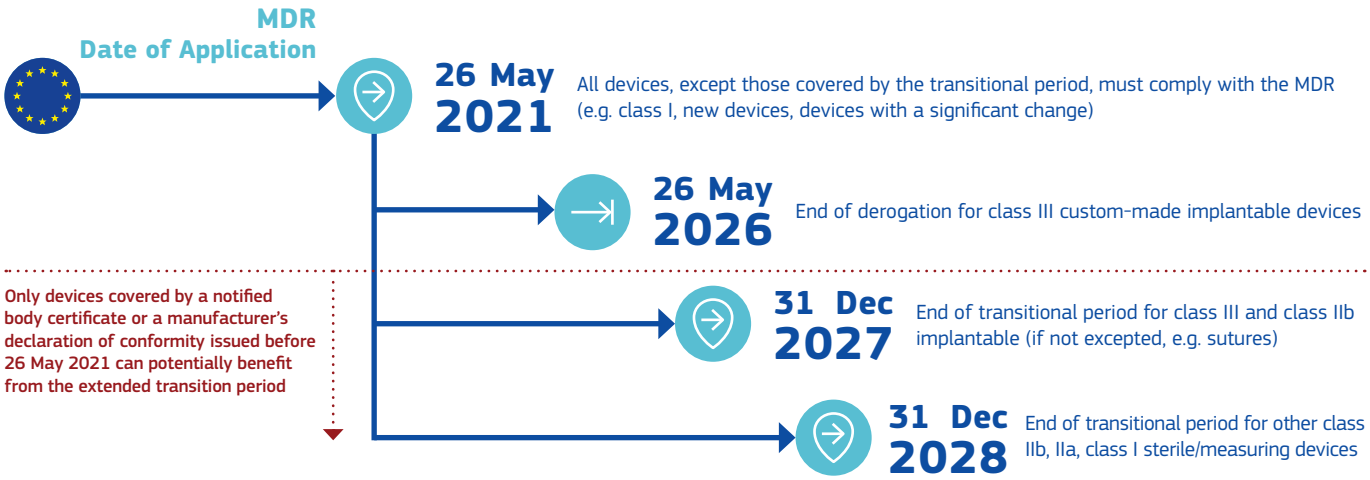
The length of the transition period depends on the risk class of the device, which is to be determined in accordance with the MDR classification rules:

- 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.

Class III custom-made implantable devices that are not covered by a certificate or declaration of conformity need to transition by 26 May 2026.

There are conditions to be fulfilled to make use of the transitional 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. Manufacturers can use a 'self-declaration' to demonstrate by themselves that the conditions for the application of the extended transition period are met for a given device, device group, or category. This self-declaration may be supported by a 'confirmation letter' issued by a notified body. For more information on the extended transition periods of the MDR and its conditions, see the Commission's Q&A[2].

2. European Commission (2023). Q&A on extension of the MDR transition period and removal of the 'sell off' period. Available at: health.ec.europa.eu/system/files/2023-03/mdr_proposal_extension-q-n-a.pdf



Conditions to be fulfilled to benefit from extended transition period

26 May 2024	26 Sep 2024			
Deadline to lodge an application for MDR conformity assessment & have an MDR QMS in place	Deadline to sign a written agreement with a NB & transfer appropriate surveillance to an MDR NB (where applicable)	Devices continue to comply with previously applicable EU legislation (MDD/ AIMDD)	No significant changes in design or intended purpose	Devices do not present an unacceptable risk to health or safety

Timelines under the IVDR:

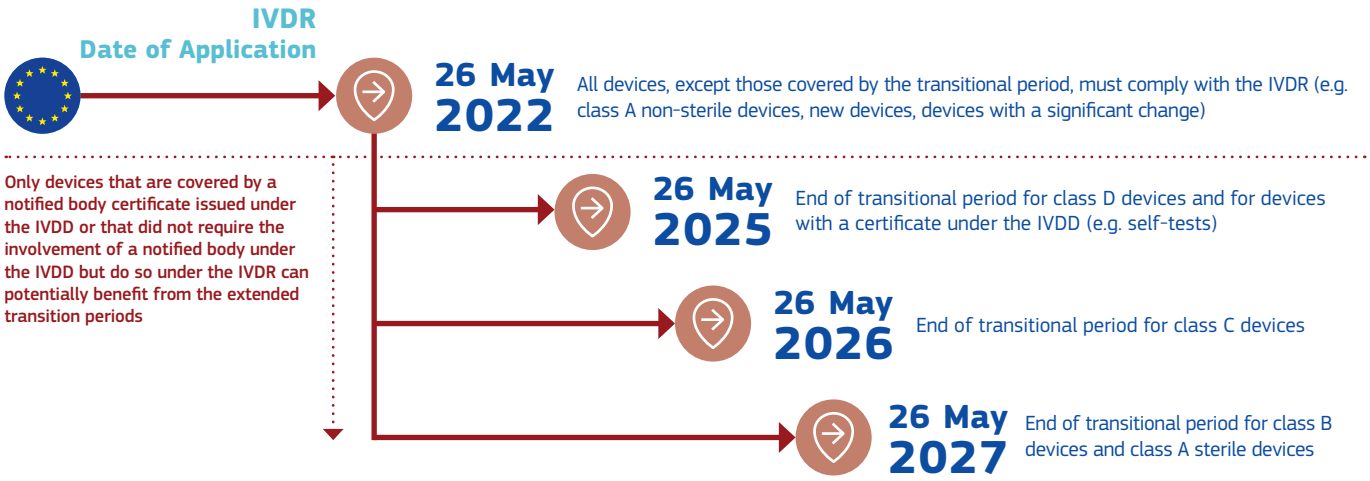
No transition period applies to IVDs that do not require the involvement of a notified body under the IVDR (i.e., class A non-sterile IVDs). These have had to comply with the IVDR since 26 May 2022. Also, all 'new' IVDs, i.e., devices not previously covered by a certificate or declaration of conformity issued under the IVDD must comply with the IVDR.

IVDs that are covered by a certificate issued by a notified body under the IVDD may continue to be placed on the market or put into service as long as the certificate is valid.

Certificates issued under the IVDD after 25 May 2017, as well as those issued in accordance with Annex VI of the IVDD before 25 May 2017, remain valid until the end of the period indicated on the certificate and at the latest until 27 May 2025.

IVDs that did not require the involvement of a notified body under the IVDD but do so under the IVDR, and for which the manufacturer has drawn up a declaration of conformity before the DoA (26 May 2022) may continue to be placed on the market or put into service until the end of the applicable transition period. The length of the transition periods vary according to the risk class of the IVD:

- **26 May 2025:** class D devices
- **26 May 2026:** class C devices
- **26 May 2027:** class B devices and class A sterile devices



Conditions to be fulfilled to benefit from extended transition period

- 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

Certificates of free sale

For the purpose of export, the competent authority of the EU Member State in which the manufacturer or the authorised representative has its registered place of business, may issue a certificate of free sale declaring that the device in question bearing the CE marking may be marketed in the Union.

Certificates of free sale may be issued on the basis of the corresponding notified body's certificates or manufacturer's declarations of conformity under both the MDD/AIMDD and the MDR (for MDs), or both the IVDD and the IVDR (for IVDs). The issuance of the MDR or IVDR certificate does not automatically lead to the invalidation of the MDD/AIMDD or IVDD certificate that had already been issued. Certificates of free sale that are based on valid certificates issued by notified bodies under the Directives remain valid after 26 May 2021 (MDD/AIMDD) or 26 May 2022 (IVDD), until the corresponding certificates expire.

MDD/IVDD products in the supply chain

MDs 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 on time, other than the device's 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 on time, other than the device's shelf-life or expiry date.

Conformity assessment and CE marking

The assessment of the conformity of a device for CE marking (Conformité Européenne, or European Conformity) varies according to 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 lay persons ('self-testing').

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)(a[3], b[4], c[5])). 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 that will 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 by a notified body.

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 (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)).

Notified bodies are organisations designated by EU Member States to assess a device's compliance with EU legislation before it is placed on the market to be used by doctors 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[6].

More stringent clinical evaluation requirements

The new Regulations reinforce the requirements for clinical and performance evaluations (MDR/IVDR Chapter VI). These introduce some of the biggest changes compared to the previous regime.

Clinical and performance evaluations involve collecting clinical data already available in the literature, as well as setting up any necessary clinical investigations (MDs) or performance studies (IVDs).

For medical devices, the concept of equivalence with other devices for which clinical data already exists can still be used, but the new rules are tighter (MDR Article 61(4, 5, 6), section 3 Annex XIV).

Safety and clinical performance

Clear summaries of safety and clinical performance will be made publicly available for implantable and class III MDs (MDR Article 32) and for IVDs in classes C and D (IVDR Article 29). These summaries will form part of the manufacturer's technical documentation and will be available via EUDAMED.

Reinforced post-market surveillance

The new Regulations strengthen the post-market surveillance requirements for manufacturers. They also reinforce cooperation between EU Member States in market surveillance.

1. **Periodic safety update reports**
   Periodic safety update reports have to be prepared for all MDs (MDR Article 86) and IVDs (IVDR Article 81), except MDs in class I and IVDs in classes A and B. These reports summarise the analysis of post-market surveillance data. The frequency of the updates depends on the classification of the device. The updates must be submitted to the notified bodies and competent authorities.
2. **Trend reporting**
   The Regulations also require trend reporting for all devices. Trend reports record any increase in the frequency or severity of non-serious incidents or expected undesirable effects, particularly when they may affect the risk assessment of the device (MDR Article 88 and IVDR Article 83).

3. Devices placed on the market in sterile condition, to the aspects relating to establishing, securing and maintaining sterile conditions
4. Devices with a measuring function, to the aspects relating to the conformity of the devices with the metrological requirements
5. Reusable surgical instruments, to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilisation, maintenance and functional testing and the related instructions for use
6. http://ec.europa.eu/growth/tools-databases/nando/, NANDO (New Approach Notified and Designated Organisations)

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 manufacturer is responsible for affixing the UDIs and entering the required information into the UDI database, which is part of EUDAMED. In most cases, the UDI will be available in human-read able form and also, for example, as a barcode.

Each medical device 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 carrier to the label is being implemented in three stages. 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**

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

Before these dates, there is no legal requirement for manufacturers to label their devices with UDIs, although some manufacturers may choose to do so.

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 two years after the date applicable to the corresponding risk class shown in the two lists above.

European Database on Medical Devices (EUDAMED)

EUDAMED includes information on UDIs, economic operators (except for distributors), sponsors, notified bodies, devices, 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 partially accessible to the general 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:
- Actors registration
- UDI/devices registration
- Notified bodies and certificates
- Clinical investigations and performance studies
- Vigilance and post-market surveillance
- Market surveillance
- EUDAMED public website

EUDAMED will become fully functional and mandatory to use six months after the publication of a Commission notice in the Official Journal of the EU. Until then, the use of the available modules of EUDAMED is voluntary.

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).

ET-02-18-961-EN-N

XX/XX/2023

ISBN: 978-92-79-90405-9 DOI: 10.2873/850249

ec.europa.eu/health/md_newregulations/overview_en