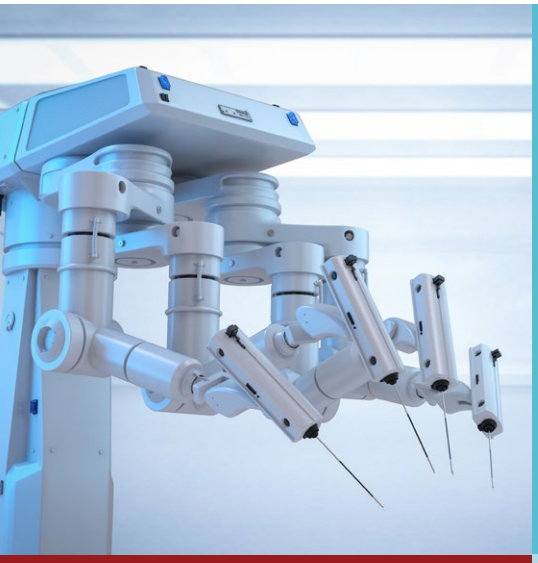


European Commission

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

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 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 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, under certain conditions. 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 certificates under the Regulations.

The MDR and the IVDR are directly applicable to all EU Member States 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 Directives and devices that are compliant with the current Regulations co-exist and may simultaneously be placed or made available 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. The exact timelines are further explained in this factsheet.

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 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 devices, as well as some specific class I devices, require the intervention of a notified body (MDR Article 52(7)(a[2], b[3], c[4])). 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 with the involvement of 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 from the manufacturer (IVDR Article 48(6)).

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 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[5]. Where a notified body is involved in the conformity assessment procedure, the CE marking must be followed by the identification number of that notified body.

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. You may, therefore, still receive devices which are CE marked under the MDD/AIMDD/IVDD 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. 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)

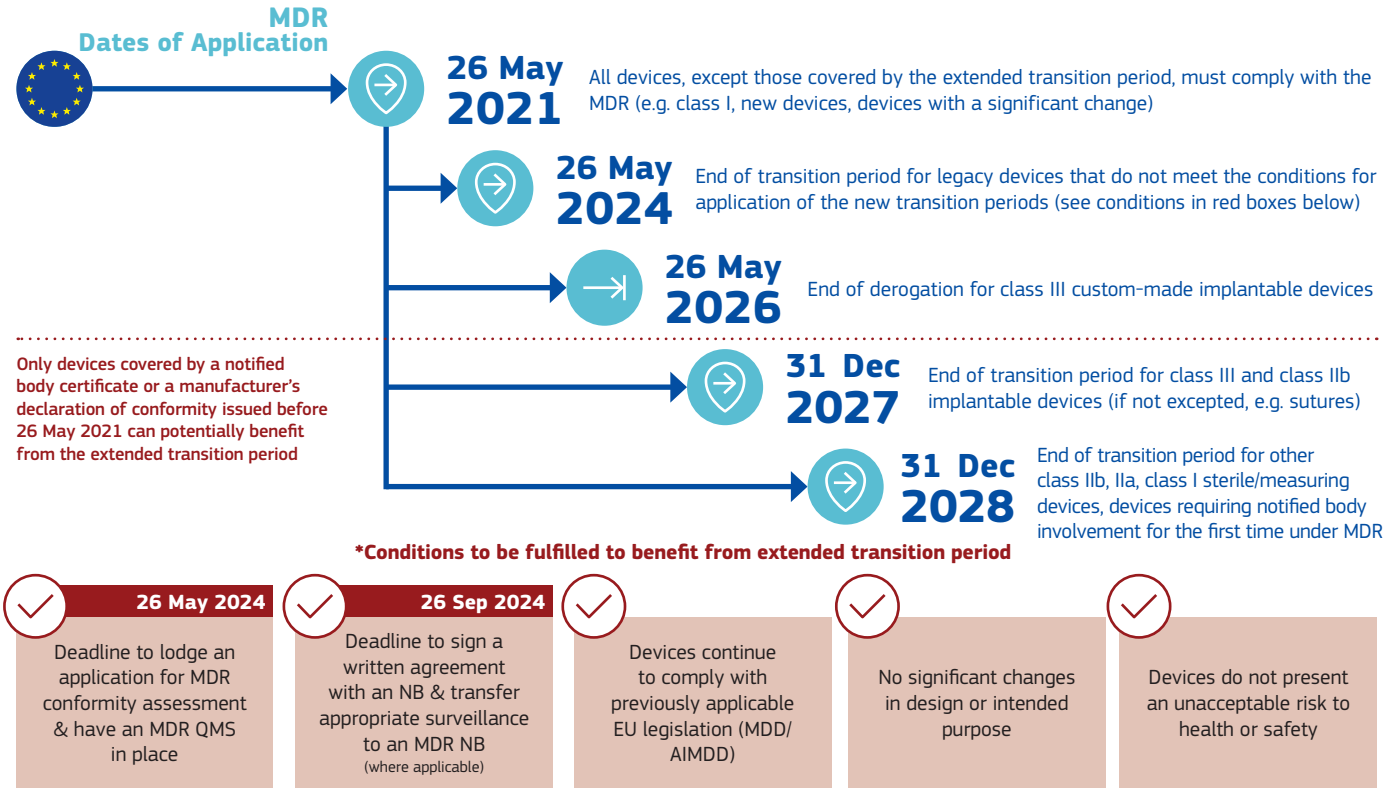
2. Devices placed on the market in sterile condition, to the aspects relating to establishing, securing and maintaining sterile conditions
3. Devices with a measuring function, to the aspects relating to the conformity of the devices with the metrological requirements
4. Reusable surgical instruments, 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
5. http://ec.europa.eu/growth/tools-databases/nando/, NANDO (New Approach Notified and Designated Organisations)

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 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. **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. Manufacturers could also provide evidence of having lodged an application and concluded a written agreement by other means (e.g. copy of relevant documents).** For more information on the extended transition periods of the MDR and its conditions, see the Commission's Q&A[6].



6. 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

Timelines under the IVDR:

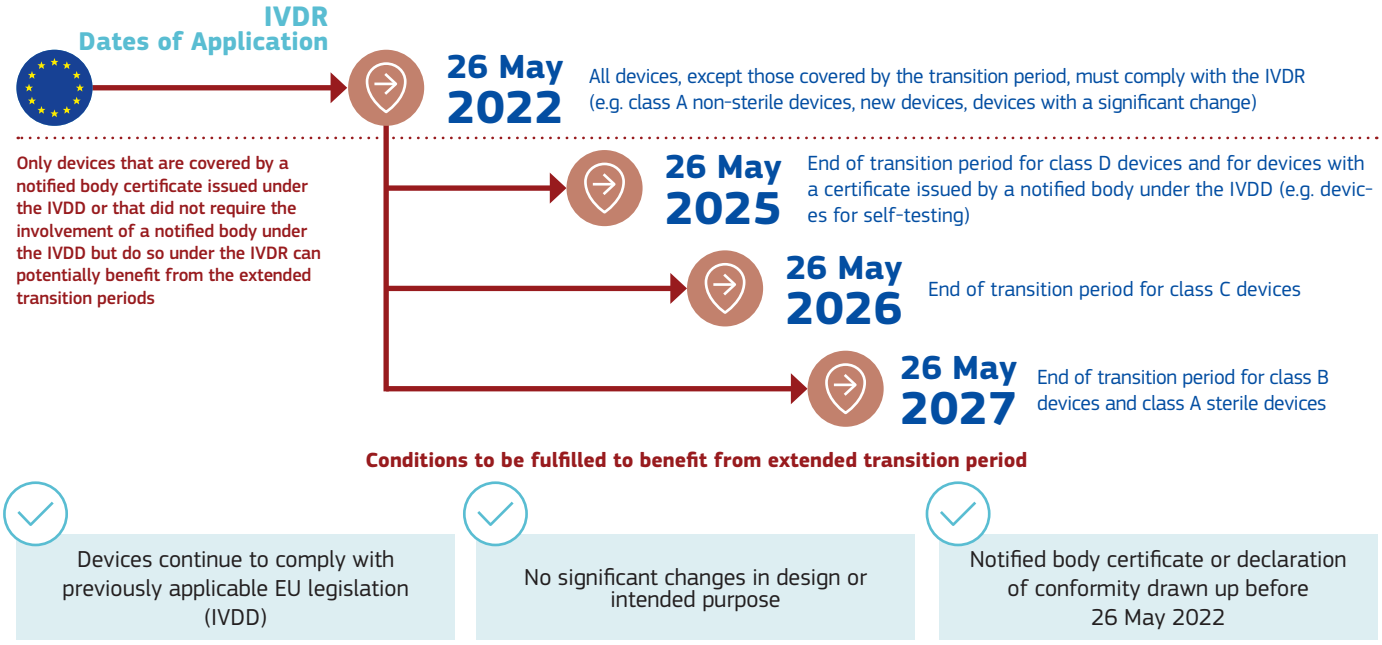
No transition period applies to IVDs that do not require the involvement of a notified body under the IVDR (i.e. class A non-sterile IVDs). These have had to comply with the IVDR since 26 May 2022. Also, all 'new' IVDs, i.e. devices not previously covered by a certificate or declaration of conformity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



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. Competent authorities of all EU Member States may issue certificates of free sale, which all have the same value.

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 medical devices), 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. Please note the extended validity of MDD/AIMDD certificates, as outlined in the timeline section of this factsheet.

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 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.

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 (for medical devices) or performance studies (for 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 (SSCPs) will be made publicly available for implantable and class III medical devices (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 (PSURs) have to be prepared for all medical devices (MDR Article 86) and IVDs (IVDR Article 81), except medical devices 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 statistically significant increase in the frequency or severity of non-serious incidents or expected undesirable effects, when they significantly affect the risk assessment/benefit-risk analysis of the device (MDR Article 88 and IVDR Article 83).

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 assigning the UDI (and Basic UDI-DI), affixing the UDI carrier and entering the required information into the UDI database, which is part of EUDAMED. The UDI carrier should be affixed to the device itself, and all higher levels of device packaging. It should appear in both plain text/human readable information and in a machine readable information format (e.g. barcorde). However, some exceptions exist, allowing either one or the other format to be used.

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.

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**

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

Before these dates, 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.

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European Database on Medical Devices (EUDAMED)

EUDAMED includes UDI related information (Basic UDI-DIs and UDI-DIs), as well as information on economic operators (except for distributors), sponsors, notified bodies, devices, certificates, clinical investigations and performance studies, vigilance, post-market sur-veillance 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 will become fully functional and some modules will be mandatory to use six months after the publication of a Commission notice in the Official Journal of the EU. This applies to obligations and requirements related to 'actors registration', 'vigilance and post-market surveillance', 'clinical investigations and performance studies', and 'market surveillance' modules. Obligations and require-ments related to 'UDI/devices registration' and 'notified bodies and certificates' modules will become mandatory twenty-four months after the publication of the Commission notice in the Official Journal of the EU. Until these dates, 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).

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