In-Vitro Diagnostic Medical Devices Regulation (EU) 2017/746
Transitional periods and requirements

November 2023

The IVDR has officially been in force since May 26th, 2022, replacing the IVDD. To make the transition as smooth as possible, there are different transitional periods for products of the various risk classes. Additionally, some IVDR requirements already apply during the transitional period, even for products that were still certified under the IVDD before or during the transitional period. In this article, Timo Brüggemann discusses what these requirements are and when a notification to the notified body is necessary.

The EU Regulation 2017/746 on in-vitro diagnostic medical devices (IVDR) replaced the Directive 98/79/EC IVDD on May 26th, 2022. The requirements of the IVDR apply to all products placed on the market or put into service from May 26th, 2022, onward.

According to these requirements, a notified body must now be involved in the conformity assessment procedure for most products. However, the number of notified bodies for conformity assessment under the IVDR is still small. To ensure a smooth transition and guarantee the availability of products on the European market, the EU Commission is granting manufacturers extended transitional periods (Regulation (EU) 2022/112). In addition, the sell-off period applicable until the beginning of the year (Regulation (EU) 2023/607) is no longer applicable, while the respective shelf life of the products must be taken into account.

Extension of the transitional period

The extension of the transitional period is limited to existing products for which a declaration of conformity was already issued before May 26th, 2022.

The length of the extension depends on the risk class of the product and whether a notified body was already involved in the conformity assessment under the IVDD.
For devices which already required the involvement of a notified body under the IVDD (List A+B and devices for self-testing), the transitional period will be extended by one year, until May 26th, 2025.
For products still requiring a notified body for the first time for conformity assessment under IVDR, the transitional periods are now defined as follows:

- Class D devices: May 26th, 2025
- Class C devices: May 26th, 2026
- Sterile Class A devices and Class B devices: May 26th, 2027
- For so-called in-house tests, the deadline is extended to May 26th, 2028, if no comparable product is approved on the market.

Non-sterile class A devices and new devices with a declaration of conformity, issued after May 26th, 2022, are excluded from the extended transitional periods.

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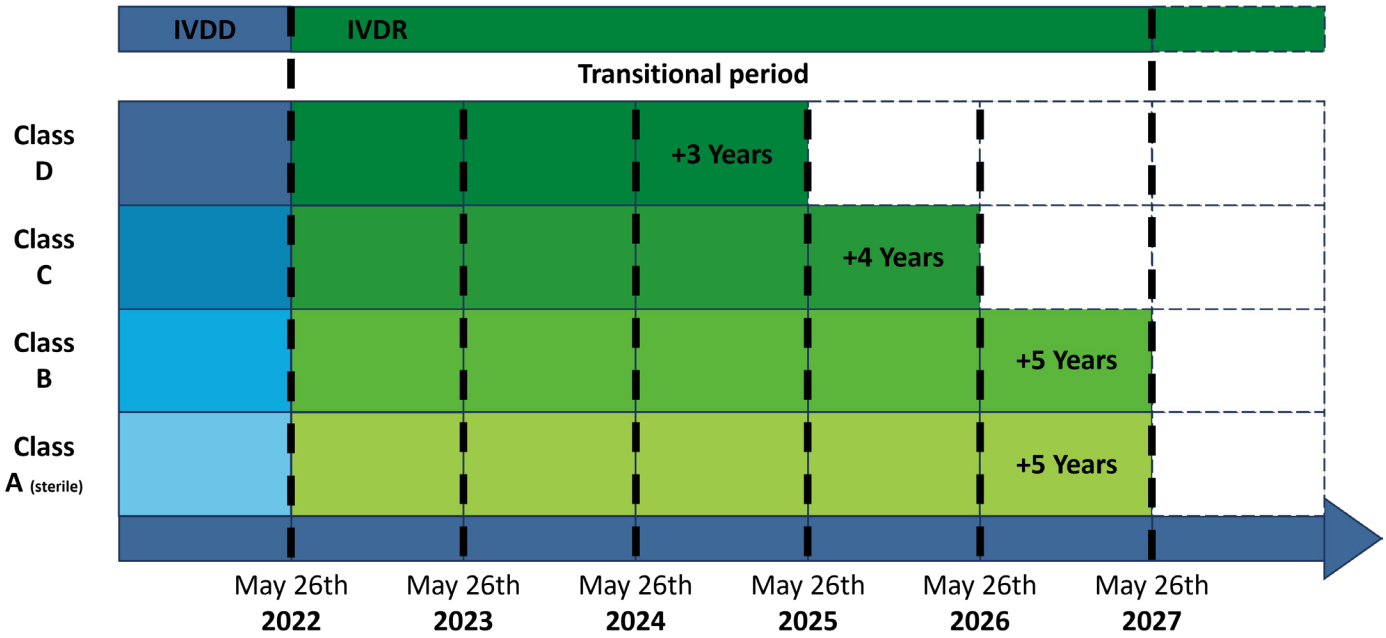

Timeline of the transition from the IVDD to the IVDR, with extended transitional periods for products of the individual risk classes.

Monitoring obligations and vigilance at IVDR level

Regardless of these extensions, manufacturers must fulfill their obligations regarding the monitoring of products on the market and vigilance, even if the products were still placed on the market under the IVDD.

The MDCG document 2022-8, published during May of 2022, provides guidance on how to implement the requirements of the IVDR for existing devices. The MDCG document divides existing products into ‚old' devices and ‚legacy' devices, however, these terms are not mentioned in the IVDR and are only used in MDCG documents.

Depending on whether an existing product is an ‚old' device or a ‚legacy' device, different requirements apply up to the specified cutoff date.

‚Legacy' Devices

‚Legacy' Devices are devices that are placed on the market between May 26th, 2022, and the end of the transitional period mentioned above, provided that they do not undergo significant changes in terms of their intended purpose and design. These may be devices for which a certificate was already issued by a notified body in accordance with the IVDD before May 26th, 2022, or devices with an issued declaration of conformity in accordance with the IVDD before May 26th, 2022, without the involvement of a notified body and for which the involvement of a notified body is now required under IVDR.

'Legacy' devices are also subject to the market surveillance (PMS) and vigilance requirements of the IVDR (Chapter VII, IVDR). A PMS system based on a PMS plan is mandatory, as well as a Post-Market Performance Follow-Up (PMPF), which is part of this PMS system. Regardless of the risk class, every 'legacy' device requires a PMS report (Art. 80, IVDR); if the device is a class C or D device, a periodic safety update report (PSUR) can instead be prepared voluntarily (Art. 81, IVDR).

Additionally, the economic operators of ‚legacy' devices have obligations they must fulfil, this concerns manufacturers (Art.11, IVDR), authorized representatives (Art.11, IVDR), importers (Art.13, IVDR) and distributors (Art.14, IVDR). In principle, the registration of products (Art. 26, IVDR) and the registration of economic operators (Art. 28, IVDR) must also be compliant with the IVDR. As EUDAMED is not yet fully operational, special transitional provisions apply as described in Articles 112 and 113(3) of the IVDR.

‚Old' Devices

‚Old' Devices are devices that were placed on the market before May 26th, 2022, with a valid certificate issued before May 26th, 2022, in accordance with the IVDD, or the applicable national provisions before the IVDD came into force. The IVDR does not apply to these products per se, but manufacturers must fulfill their obligations regarding market surveillance of the products. Therefore, after May 26th, 2022, the articles on market surveillance (Art. 88 to 95, IVDR) by competent authorities will also apply. To further ensure all reports and analyses of serious incidents and field safety corrective actions (FSCAs) are processed as part of the PMS, the articles on serious incidents and resulting measures (Art. 82 and 84, IVDR) also apply.

What if changes to the product occur during the transitional period?

The extensions and the limited IVDR requirements for 'legacy' devices only apply if there have been no significant changes to the device in terms of intended purpose and design during the transitional period.

If changes occurred, it must be recorded whether these changes are significant.

‚Legacy' Devices	‚Old' Devices
Manufacturers' obligations, authorized representatives, importers obligations, distributors' obligations (Art.10, 11, 13 and 14, IVDR)	---
Registration of devices and registration of economic operators (Art. 26 and 28, IVDR) in accordance with Art.112 and 113(3)	---
PMS System and PMS-Plan (Art. 78, 79, IVDR)	---
PMS Report (Art. 80) OR a PSUR (Art. 81, IVDR)	---
Vigilance (Art. 82 to 87, IVDR)	Reporting of serious incidents and analysis of serious incidents and FSCA (Art. 82 and 84, IVDR)
Market surveillance (Art. 88 to 95, IVDR)	Market surveillance (Art. 88 to 95, IVDR)

Applicable IVDR requirements during the transitional period for ‚legacy' and ‚old' devices.

If the changes are non-significant, the product can remain certified under IVDD during the transitional period until the respective transitional period expires.

If the changes are significant, the product cannot remain on the market under the IVDD and must be recertified under IVDR requirements. The responsible notified bodies verify and document the changes in writing and decide on the validity of the product during their surveillance work.

The MDCG document 2022-6, also published during May of 2022, provides guidance on which changes are considered significant and which are not. In general, only certain changes of intended purpose and design are considered significant.

Changes to the intended purpose

For instance, an extension of the intended purpose or other important changes (such as intended users or changes to the method of operation) are considered significant changes to the intended purpose. Only the limitation of the intended purpose is considered a non-significant change. Consequently, the intended purpose may be restricted but not extended or changed.

Changes to the design

Significant changes to the design are changes to the functional principle or changes impairing the risk-benefit ratio, even if the functional principle is unchanged.

The umbrella term for design also includes software, ingredients and materials, as well as sterilization.

If there are no significant changes to the design, it is still required to review whether there are changes to the software, ingredients/materials or sterilization, that change the product significantly. If none of these reviews reveal any significant changes, the product can still be considered an ‚old' or ‚legacy' device. If there is a significant change, then the product must be recertified under the IVDR.

Conclusion

To summarize, the transitional periods have been extended for products of all classes, for different lengths of time depending on the risk class (with the exception of non-sterile class A products). However, market surveillance and vigilance must still be carried out at IVDR level even for ‚old' and ‚legacy' devices certified under the IVDD. If there are significant changes to the intended purpose or design of the ‚old' or ‚legacy' devices during the transitional period, the product must be recertified under the IVDR.