Legacy Devices under IVDR

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What are requirements for devices that were already on the market under IVDD?

Introduction
Regulation (EU) 2017/746 of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices (IVDR) entered into force as of May 25, 2017, with a date of application of May 26, 2022.

Following the publication of amending regulations EU 2022/112, EU 2023/607 and EU 2024/1860, the IVDR requirements will gradually apply to all IVDs to be placed on the EU market and replace the requirements of the Directive 98/79/EC of the European Parliament and of the Council (IVDD).

How long can I sell my IVDD compliant devices?

Do I need additional performance data?

Can I "upgrade" my existing IVDD certificate to an IVDR certificate?

Those or similar questions might arise for you as a manufacturer of In Vitro Diagnostic Medical Devices. This information document will try to answer them and shed some light on the whole issue of so-called Legacy Devices.

What are Legacy Devices?
The term "Legacy Device" is not defined in the IVDR. However, MDCG 2022-8 – "Regulation (EU) 2017/746 - application of IVDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2022", defines legacy devices as devices referred to in the 2nd or 3rd subparagraph of Article 110(3) IVDR (amended to Article 110 (3a) and (3b), respectively, which are placed on the market or put into service after 26 May 2022 (i.e. the IVDR's date of application) and until the end of the respective transition period set out in the 2nd or 3rd subparagraph of Article 110(3), if the conditions laid down in the 1st subparagraph of Article 110(3)3 (amended to Article 110(3c))are fulfilled. Those devices can be:

a. devices covered by a valid CE certificate issued by a notified body in accordance with Directive 98/79/EC on in vitro diagnostic medical devices (IVDD) prior to 26 May 2022; or
b. devices for which a declaration of conformity was drawn up prior to 26 May 2022 in accordance with the IVDD and for which the conformity assessment procedure pursuant to the IVDR (contrary to the IVDD) requires the involvement of a notified body.

What are important Dates with regards to Legacy Devices?
Before looking at timelines, it is important to have a look at some definitions first:

Placing on the market means the first making available of a device, other than a device for performance study, on the Union market. Note: the concept of placing on the market refers to each individual device, not to a type of device, and whether it was manufactured as an individual unit or in series.

Making available on the market means any supply of a device, other than a device for performance study, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.

Putting into service means the stage at which a device, other than a device for performance study, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose.

Amending regulation (EU) 2024/1860 introduced multiple deadlines for legacy devices:

By 26 May, 2025, manufacturers of all classes of devices must put in place an IVDR-compliant quality management system according to Article 10(8).

Manufacturers must make an application for certification with a notified body by the following deadlines:

- 26 May 2025 for Class D devices and devices covered by (a) valid IVDD CE-certificate(s)
- 26 May 2026 for Class C devices not covered by (a) valid IVDD certificate(s)
- 26 May 2027 for Class B and Class A sterile devices not covered by (a) valid IVDD certificate(s)

A signed contract with a notified body must be concluded by the following dates:

- 26 September 2025 for Class D devices and devices covered by (a) valid IVDD CE-certificate(s)
- 26 September 2026 for Class C devices not covered by (a) valid IVDD certificate(s)
- 26 September 2027 for Class B and Class A sterile devices not covered by (a) valid IVDD certificate(s)

Devices may continue to be placed on the market until the following dates:

- 31 December 2027 for Class D devices and devices covered by (a) valid IVDD CE-certificate(s). IVDD certificates become invalid on this date.
- 31 December 2028 for Class C devices not covered by (a) valid IVDD certificate(s)
- 31 December 2029 for Class B and Class A sterile devices not covered by (a) valid IVDD certificate(s)

Note: devices covered by certificates that were valid on 26 May 2022 and expired before 9 July 2024 can only benefit from the extended timelines if an application was filed with a notified body prior to the expiry of the certificate.

The graph below provides a summary of these timelines:

Device continue to comply with Directive 98/79/EC

No significant changes in the design and intended purpose

Devices do not present an unacceptable risk to the health or safety

Obligation	IVDR QMS in Place acc. IVDR Art. 10(8)	Lodge an application for IVDR conformity assessment	Sign a written agreement & transfer appr. surveillance to IVDR NB	End of transition period	Sell-off
IVDD certified or Class D	26th May 2025	26th May 2025	26th September 2025	31st December 2027	No limitation in time other than device expiry date/ stock availability
Class C	26th May 2025	26th May 2026	26th September 2026	31st December 2028	No limitation in time other than device expiry date/ stock availability
Class B & A sterile	26th May 2025	26th May 2027	26th September 2027	31st December 2029	No limitation in time other than device expiry date/ stock availability

What other conditions apply to legacy devices?
Devices must continue to comply with IVDD 98/79/EC, may not undergo any significant changes in the design and intended purpose (as defined in MDCG 2022-6) and must not pose an unacceptable risk to the health or safety of patients, users, third parties or public health.

Legacy devices covered by (an) IVDD certificate(s) continue to be subject to regular surveillance and, where applicable, verification of manufactured product by the notified body. Where application for IVDR certification is made to a notified body that is not the issuer of the IVDD certificate, the surveillance is transferred to the new notified body by way of a transfer agreement.

Are there any IVDR requirements I will need to comply with even if my IVD device is still being placed on the market under the IVDD?
Yes, even if your device is still being placed on the market under the IVDD, you still need to comply with the IVDR requirements for post-market surveillance, vigilance, registration of economic operators and registration of devices. Please refer to MDCG 2022-8 for further details.

How does Conformity Assessment of Legacy Devices work?
There is no difference between conformity assessment of devices that have been previously sold under the IVDD, and for new devices.

Does that mean I have to start from scratch and cannot use any existing data or documentation of a Legacy Device for conformity assessment under IVDR?
No. If you have a device on the market that is compliant to the IVDD, you will be able to use much of your existing documentation and data. Data that was good 20 years ago will be good today. You even have the advantage of having substantial existing post-market data that can be used to support your performance claims and risk management.

Please ensure you evaluate the existing data for any potential gap versus the requirements of the regulation. You will need to perform a thorough gap analysis between the requirements for Technical Documentation for IVDD and those that will be needed for IVDR (there is a separate IVDR Technical Documentation Submission Requirements Document available, please contact us, if you do not have it yet). Keep in mind that the state of the art in medicine may have evolved since the device was first placed on the market. All devices are expected to show adequate safety and performance in relation to the generally acknowledged state of the art.

According to MDCG 2022-2, clinical performance studies conducted under the IVDD should be considered as 'other sources of clinical performance data' per IVDR Annex XIII 1.2.3 or the requirements of IVDR Annex XIII 2.3 should be appropriately justified. This data should be supported by either literature and/or data from published experience gained by routine diagnostic testing.

There is no secret recipe to what you will need, and you will need to go through Annex II and III line by line, but some good questions and hints may be:

- Evaluate the quality and completeness of existing data, rather than the quantity.
- Were relevant standards applied and can a compliance to Annex I be shown?
- Were correct statistical methods used and described?
- Are there plans, protocols and reports available (just having reports is not sufficient)?
- Is generation of additional evidence required (e.g. clinical evidence, performance evaluation report)?

Once all gaps have been identified and closed, you will need to compile a new Technical Documentation for your device and route it through an appropriate conformity assessment procedure; all devices other than non-sterile Class A will need involvement of TÜV SÜD Product Service GmbH.

If you have questions, please do not hesitate to contact us.

How TÜV SÜD can help?
TÜV SÜD is the first Notified Body to issue a certificate under IVDR for Class D devices, and we have issued over 100 Class D certificates to date.

As one of the world's largest EU Notified Bodies for all types of medical devices covered by EU directives and regulations, TÜV SÜD is designated as a full-scope Notified Body under the IVDR.

Our experts' experience and expertise make TÜV SÜD your partner of choice to bring your innovative in vitro diagnostic medical devices to the EU market, providing a full range of certification and testing services to ensure global market access.

We work collaboratively with our partners to ensure access to critical innovative diagnostic technologies for patients and providers.

Contact us to discuss your needs for IVDR certification.

Related services

TÜV SÜD provides the following related services:
- IVDR Certification
- EN ISO 13485 Certification
- Testing services including EMC and NRTL testing
- Medical Device Single Audit Program (MDSAP)

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