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 Devices (IVDR) entered into force as of May 25, 2017, with a date of application of May 26, 2022.

Following the publication of regulation EU 2022/112, the IVDR requirements will gradually apply to all IVDs to be placed on the EU market (see below for a more detailed timeline as well as changes after Regulation 2023/607) 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 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 or any other official document. 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, 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 are fulfilled. Those devices can be:

a. devices covered by a valid EC 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.

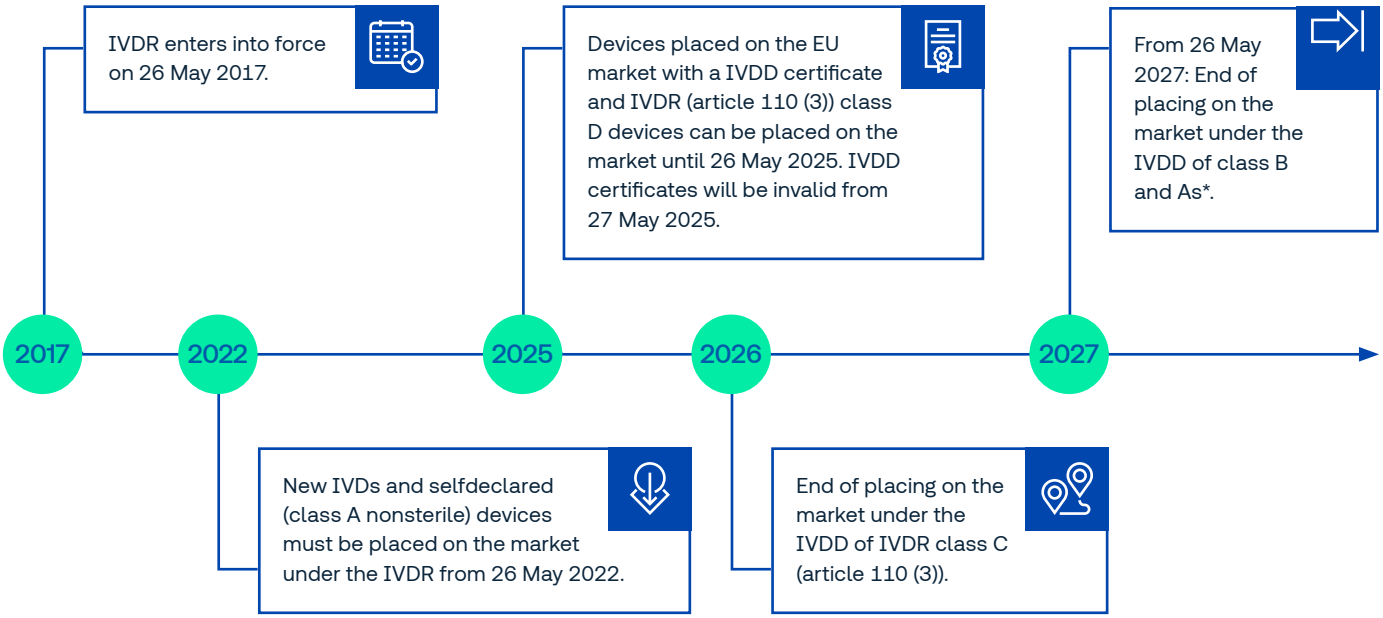
What are important Dates with regards to Legacy Devices?
Before looking at timelines, it is important to have a look at some definitions first:

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.

With these definitions in mind, the following timeline shall be considered:



Accordingly, before May 26, 2022, you as a manufacturer could choose to place devices on the market under the IVDD or IVDR.

Devices covered by (an) existing IVDD certificate(s) valid until May 26th 2025 (this can only be List A, List B or self-testing, "General IVDs" do not have a certificate) still can be placed on the market until the IVDD certificate(s) get invalid and are allowed to be made available or put into service until May 26, 2025.

Those devices have further on to comply with the IVDD provided no significant changes in the design and intended purpose are performed.

All new class A non-sterile IVDs must be placed on the market under the IVDR after May 25, 2022. Those self-declared under the IVDD but requires Notified Body under the IVDR may be able to benefit from an extended transition period. Please refer to the Q&A section on conditions to benefit from the extended transition period.

What are the conditions for extended transition period?
Following the publication of Regulation (EU) 2022/112 and Regulation 2023/607, where the 'sell off' dates in article 110(4) of the IVDR are removed, the transition period depends on the class of the IVD device under the Regulation as well as additional conditions:

Devices with a Declaration of Conformity drawn up prior to 26 May 2022, that did not require notified body involvement under the IVD Directive, may be placed on the market or put into service under the Directive until the following dates:

a. 26 May 2025, for class D devices;
b. 26 May 2026, for class C devices;
c. 26 May 2027, for class B devices and class A devices placed on the market in sterile condition.

Devices with a valid IVDD notified body certificate may be placed on the EU market or put into service until 26 May 2025.

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, 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 sold under the IVDD for 20 years, and for devices that are brand sparkling new.

Does that mean I have to start from scratch and cannot use any existing data or documentation of Legacy Device for conformity assessment under IVDR?
No, of course not. If you have a device on the market that is compliant to IVDD, you will be able to use a lot of your existing documentation and data. Data that was good 20 years ago will be good today. You even have the advantage to have tons of 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 your Client Handler, if you do not have it yet).

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 your Client Handler.

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