Extended IVDR Transition Timelines under Regulation (EU) 2024/1860

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Regulation (EU) 2024/1860 was published in the Official Journal of the European Union on 9th July 2024. This regulation includes an extension of the IVDR transition period, a gradual roll-out of Eudamed, and a new supply chain disruption notification obligation for manufacturers. This document covers the timeline extension, not all aspects of the regulation.

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

Published in early 2022, Regulation EU 2022/112 modified the IVDR requirements to gradually apply to all IVDs being placed on the EU market. In 2023 Regulation 2023/607 removed the sell-off period for "legacy" IVD devices previously placed on the market. The publication of Regulation (EU) 2024/1860 allows for further extension of the transition timelines under certain conditions. This additional extension aims to ensure a continued supply of in-vitro medical devices (IVD) while the implementation of the IVDR is progressing.

Regulation 2024/1860 – questions and answers

a. **From when do the new IVDR transition timelines apply?**
The new IVDR transition timelines became applicable on 9 July 2024.

b. **To what IVD devices does Regulation 2024/1860 apply?**
This additional extension only applies to legacy devices as defined in MDCG 2022-8. New IVD devices, IVDs not requiring a notified body (i.e. class A non-sterile devices), and devices not fulfilling the requirements listed in point c) cannot benefit from the extended transition.
TÜV SÜD's legacy devices infosheet provides additional information.

c. What conditions are required for the extended transition of Regulation 2024/1860 to apply?
For legacy devices to benefit from the extended transition, the following conditions must be fulfilled:

- The IVD device must have been placed on the market prior to 26 May 2022.
- The IVD device must continue to meet the requirements of IVD Directive 98/79/EC (IVDD).
- The IVD device must not undergo any significant changes to the design or intended purpose.
- The IVD device must not present an unacceptable risk to the health and safety of patients, users, other persons, or other aspects of the public.
- By 26 May 2025, the manufacturer has to implement a Quality Management System (QMS) as per article 10 (8) of the IVDR.

d. What are the new deadlines to complete the transition to the IVDR?
The deadlines depend on the device classification under the IVDR and whether these devices were covered by an IVDD certificate (IVDD Annex II List As, List Bs, self-testing devices).

Device risk class	Class D/IVDD certified devices	Class C	Class B/A sterile
Deadline for IVDR compliant QMS	26 May 2025		
Deadline for IVDR application to notified body	26 May 2025	26 May 2026	26 May 2027
Deadline for conclusion of a written agreement	26 Sept 2025	26 Sept 2026	26 Sept 2027
End of transition period	31 Dec 2027	31 Dec 2028	31 Dec 2029

e. How do I lodge a formal IVDR application with TÜV SÜD?
You can register your request for IVDR certification with TÜV SÜD here.
Your local TÜV SÜD representative will contact you and guide you through the next steps.

f. What documents should be included in an IVDR application?
The documents to be included in the application are highlighted in Annex IX or Annex X of the IVDR. In addition, a detailed explanation of the documentation that must be provided to TÜV SÜD for IVDR application can be found here.

g. My device's IVDD certificate expired before 9 July 2024, am I still able to benefit from the extended transition timeline?
Yes. Legacy IVD devices with a IVDD certificate issued after 25 May 2017, and that expired before 9 July 2024, can still benefit from the extended transition timeline if one the following conditions is met:

Option 1: at the time the certificate expired, the manufacturer had already concluded a written agreement with a notified body for the device's conformity assessment.

Option 2: if no contract was signed with the notified body, a national competent authority had granted a derogation from the applicable conformity assessment procedure in accordance with Article 54.

Option 3: if no contract with a notified body was signed, a national competent authority required the manufacturer to carry out the conformity assessment procedure within a specific time period in accordance with Article 92.

If the conditions above are not fulfilled, it will not be possible to benefit from the extended transition and an IVDR conformity assessment process will need to be started.

h. 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 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 and IVDR Article 110 for further details.

i. After the formal IVDR application, will TÜV SÜD issue a confirmation letter?
After the formal IVDR application is complete, TÜV SÜD will issue a confirmation letter upon request. Please contact your local TÜV SÜD representative or contact us via our webpage.

j. Is it possible to have a meeting with TÜV SÜD before I submit the application?
Yes. TÜV SÜD offers the option to have a structured dialogue before an application is submitted. This may include timing, procedural, and regulatory aspects of the application process. The structured dialogue is beneficial for increasing the efficiency and predictability of your IVDR projects. It is not a consultancy service. Find out more about the structured dialogue here.

k. How do I transfer the appropriate surveillance of my IVDD certified devices to TÜV SÜD?
Please contact us via our request for service and select the transfer surveillance option. Your local TÜV SÜD representative will contact you to discuss the next steps.

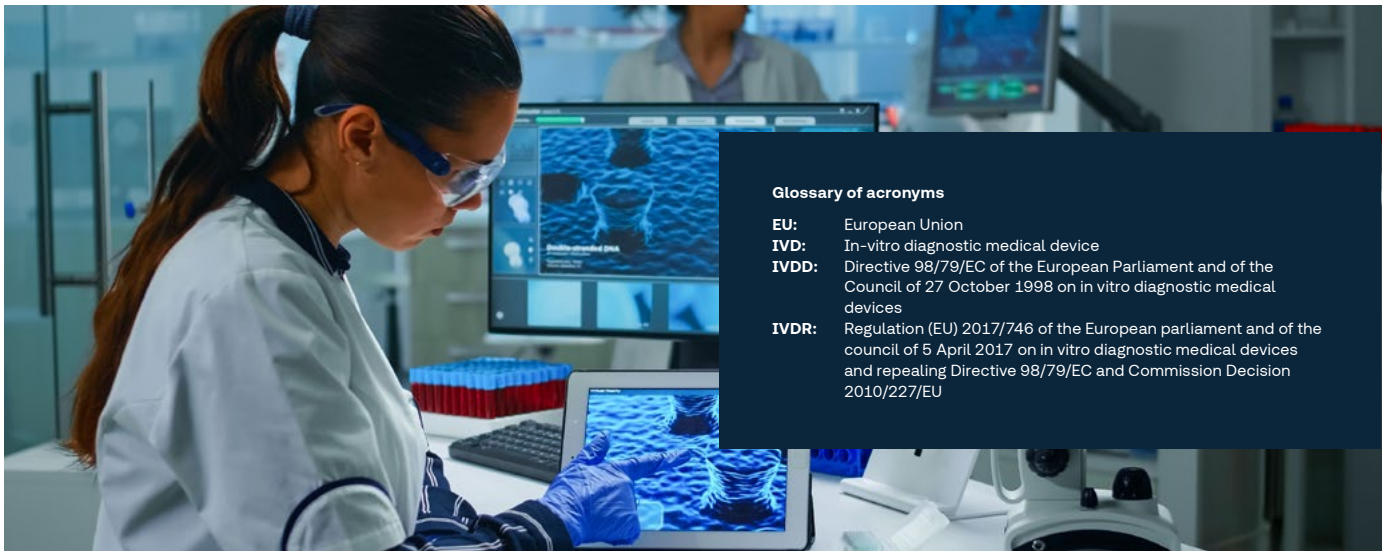
If you have further questions on IVD conformity assessments please do not hesitate to contact your local TÜV SÜD representative or contact us via our webpage.

Why choose TÜV SÜD?
TÜV SÜD is designated as a full scope notified body under the IVDR. We are also one of the world's largest notified bodies for all types of medical devices covered by EU directives and regulations. We were the first notified body to issue an IVDR certificate worldwide. Our global network of more than 750 dedicated professionals includes noted scientists, engineers, and physicians, all recognised as experts in their fields. These capabilities make TÜV SÜD the preferred single source partner for worldwide compliance with medical device regulations.

Add value. Inspire trust.
TÜV SÜD is your trusted partner of choice for safety, security and sustainability solutions. We specialise in testing, certification, auditing and advisory services. Through more than 25,000 employees across over 1,000 locations, the company adds value to customers and partners by enabling market access and managing risks. By anticipating technological developments and facilitating change, TÜV SÜD inspires trust in a physical and digital world to create a safer and more sustainable future.

Related services

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



Glossary of acronyms

EU:	European Union
IVD:	In-vitro diagnostic medical device
IVDD:	Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices
IVDR:	Regulation (EU) 2017/746 of the European parliament and of the council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

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