TÜV SÜD In Vitro Diagnostic Medical Device Regulation (IVDR) Conformity Assessment for Class D Devices

Add value.
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The European Regulation on in vitro diagnostic medical devices (EU) 2017/746 (IVDR) contains provisions for special scrutiny of high-risk Class D devices.

Annex VIII rule 1 & 2 of the IVDR defines Class D devices as those intended to be used for:

- Detection of the presence of or exposure to a transmissible agent in blood, blood components, cells, organs, tissues or their derivatives, to assess their suitability for transfusion, transplantation or cell administration.
- Detection of the presence of, or exposure to a transmissible agent that causes life-threatening disease that is suspected to have or has a high risk of propagation.
- Determining the infectious load of a life-threatening disease where monitoring is critical to patient management.
- Blood grouping or determining feto-maternal blood group to ensure the immunological compatibility of blood, blood components, cells, tissue, organs that are intended for transfusion or transplantation or cell administration, for example: blood and blood components.

Those markers are:

- ABO system [A (ABO1), B (ABO2), AB (ABO3)]
- Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)]
- Kell system [KEL1 (K)]
- Kidd system [JK1 (Jka), JK2 (Jkb)]
- Duffy system [FY1 (Fya), FY2 (Fyb)

The Class D Conformity Assessment process requires the involvement of several stakeholders. This includes notified bodies, EU Reference Laboratories (EURL), and the IVD expert panel for novel devices where no EURL is designated.

European Reference Laboratory (EURL)
The IVDR requires the involvement of a EURL Reference Laboratory in the conformity assessment of Class D devices, if such a laboratory is designated. These EURLs are operational as of October 1, 2024. The Commission Implementing Regulation (EU) 2023/2713 designates EURLs for the following device categories:

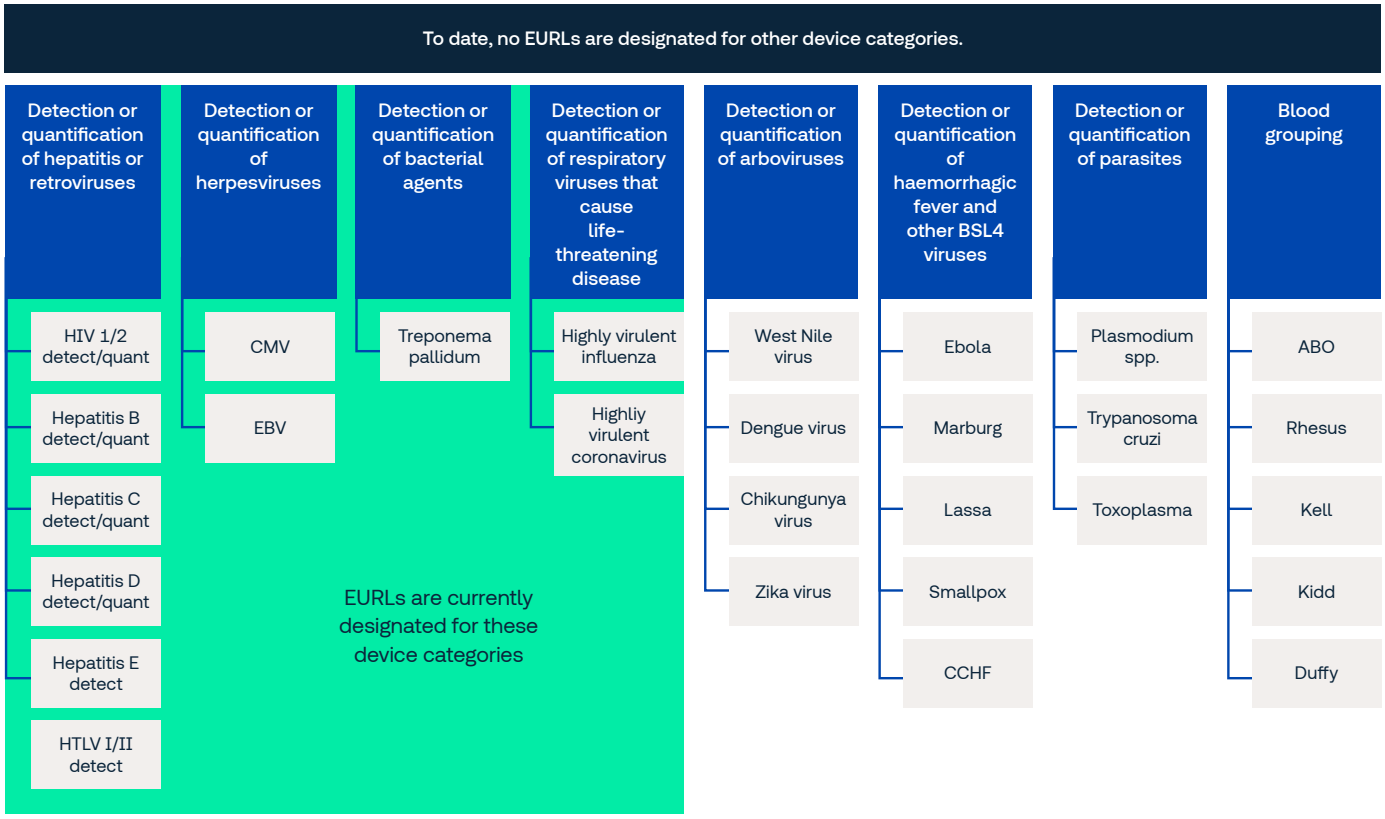

Fig. A Scope of designation of EU Reference Laboratories

According to IVDR Article 100(2) point (a) requirements, a EURL is required to perform performance validation of Class D devices prior to issuance of a CE certificate. According to Regulation (EU) 2023/2713, this requirement applies to applications for conformity assessment made on or after 1 October 2024. For devices in application, undergoing conformity assessment, or already certified before 1 October 2024, the performance validation will be performed prior to renewal of the certificate.

In addition to the initial performance validation, EURLs are also required to verify the performance of each batch of Class D devices produced by the manufacturer as per IVDR Article 100(2) point (b). This requirement applies to all batches manufactured as of 1 October 2024.

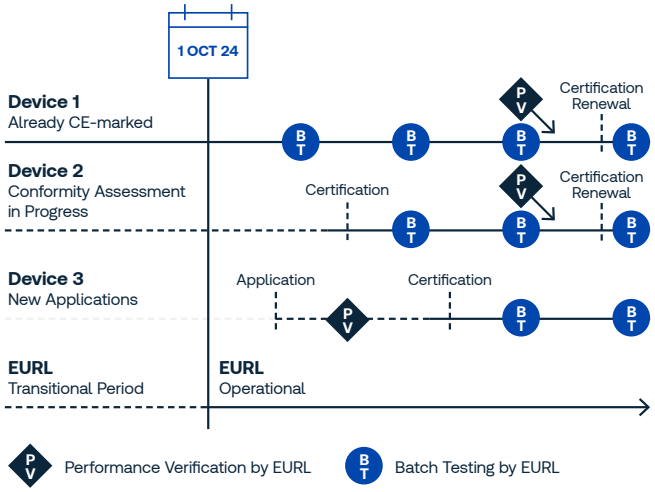

Fig. B Timing of EURL performance verification for new and prior applications

For Class D device certification for which no EURL is designated:

Manufacturers shall:

- Carry out tests on each batch of manufactured devices.
- Provide test results to the notified body.
- Make samples of manufactured devices available to the notified body.

Notified bodies will:

- Set up a batch verification test plan during the initial conformity assessment.
- Release each batch of manufactured devices if quality control results fulfil the test plan criteria.
- Determine the need for additional surveillance activities, e.g.
  - Witness testing during an audit.
  - Proficiency panel testing.
  - Use of specific reference materials.

Common specifications and the IVD expert panel
The IVDR Article 9 calls for the establishment of common specifications (CS) for devices where no harmonised standards exist, or where there is a need to address public health concerns.

Commission Implementing Regulation (EU) 2022/1107 of 4 July 2022 established common specifications for certain Class D devices:

- HIV, human T-cell lymphotropic virus, hepatitis B, C, D
- Variant Creutzfeldt-Jakob disease (vCJD)
- Cytomegalovirus (CMV), Epstein-Barr virus (EBV)
- Treponema pallidum, Trypanosoma cruzi
- SARS-CoV-2
- ABO, Rhesus, Kell, Kidd and Duffy blood groups

As of 25 July 2024, compliance with these CS is mandatory unless a justification is provided. This must demonstrate that the solutions chosen by the manufacturer offer at least an equivalent level of safety and performance. Further CS for additional markers are likely to be issued in the future.

For Class D devices where no CS exists and it is the first certification of that device type, the notified body must consult the IVD expert panel. The IVD expert panel was established by Commission Implementing Decision (EU) 2019/1396 and became operational in September 2021.

The expert panel reviews the manufacturer's performance evaluation report, supplied by the notified body, within five days of receipt and issues its views. The notified body assessment and expert panel review occur in parallel. The notified body must give due consideration to the panel's views.

How TÜV SÜD can help

TÜV SÜD is designated as a full-scope notified body under the IVDR and was the first notified body to issue a certificate for Class D devices. We are one of the world's largest EU notified bodies for all types of medical devices covered by EU directives and regulations.

Our experts provide the full range of certification and testing services to ensure global market access. Their experience and expertise make TÜV SÜD your partner of choice to bring your innovative in-vitro diagnostic devices to the EU market. We work collaboratively with our partners to ensure access to critical innovative diagnostic technologies for patients and providers.

Related services

TÜV SÜD provides the following related services

- EN ISO 13485 certification
- Testing services including EMC and NRTL testing
- Medical Device Single Audit Program (MDSAP)

Contact our experts today

Contact us to discuss your needs for IVDR Class D certification.

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