GMED LNE GROUP Newsletter

N°17 | DECEMBER 2024

Version Française

EUROPEAN UNION REFERENCE LABORATORIES FOR IN VITRO DIAGNOSTIC MEDICAL DEVICES

The involvement of European Union Reference Laboratories (EURLs) is a new requirement described in Article 100 of Regulation (EU) 2017/746 (IVDR) and concerns Class D in vitro diagnostic medical devices (IVDMDs). It is established in order to strengthen regulators' oversight of these devices.
Several tasks, detailed in Article 100, are assigned to EURLs, the aim of this newsletter being to focus on the two main tasks described in points a) and b) with the implementation date of October 1st, 2024.

In addition to assessments of the quality management system and technical documentation, the conformity assessment procedure for Class D devices requires an EU Reference Laboratory (EURL), designated in accordance with Article 100, to carry out performance verification (PV) and batch testing (BT).

a) Verify the performance claimed by the manufacturer and the conformity of class D devices with the applicable common specifications, where applicable, or with other solutions chosen by the manufacturer to guarantee at least an equivalent level of safety and performance, in accordance with the third subparagraph of Article 48(3);

b) Carry out appropriate tests on samples of manufactured Class D devices or batches of Class D devices, in accordance with section 4.12 of Annex IX and section 5.1 of Annex XI.

A PERFORMANCE VERIFICATION (PV) AND BATCH TESTING (BT)

→ 1. Performance verification (PV)

Verification of the Class D device's performance and compliance with the applicable common specifications, or with equivalent

alternatives chosen by the manufacturer, is carried out by means of EURL laboratory tests. These tests focus in particular on analytical and diagnostic sensitivity.

The EURL issues a scientific opinion within 60 days, which determines the certification decision taken by the Notified Body (NB). In the event of an unfavorable scientific opinion, the NB does not issue a certificate.

→ 2. Batch testing (BT)

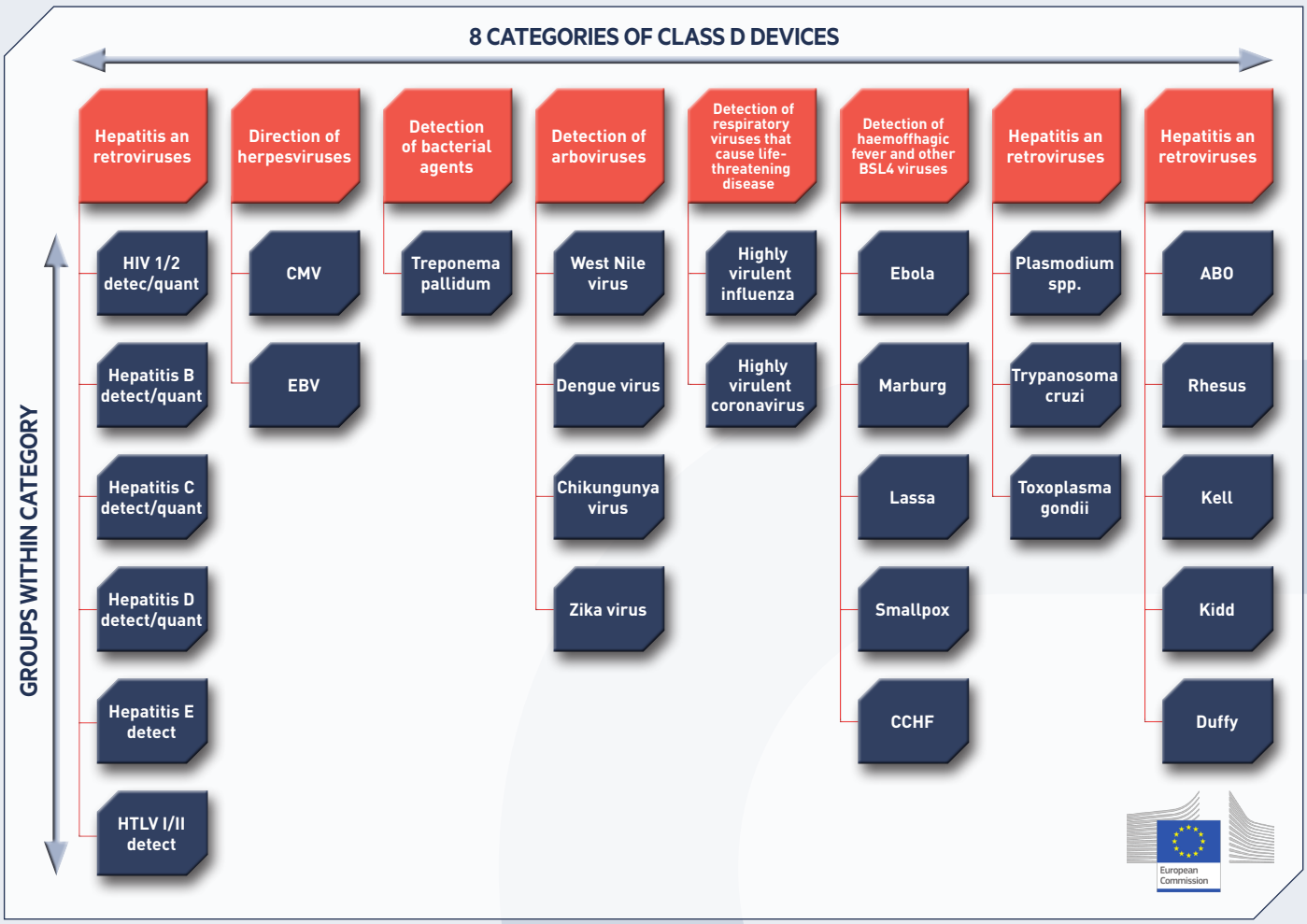
Manufacturers provide to the NB test reports for each batch of Class D devices manufactured, for conformity assessment. In addition, batch testing of Class D devices is carried out by the EURL laboratory in accordance with a test plan approved by the NB and the EURL.

The EURL informs the NB of the results.

Guide MDCG 2022-3 also details the terms and conditions agreed in advance between the NB and the manufacturer for batch testing.

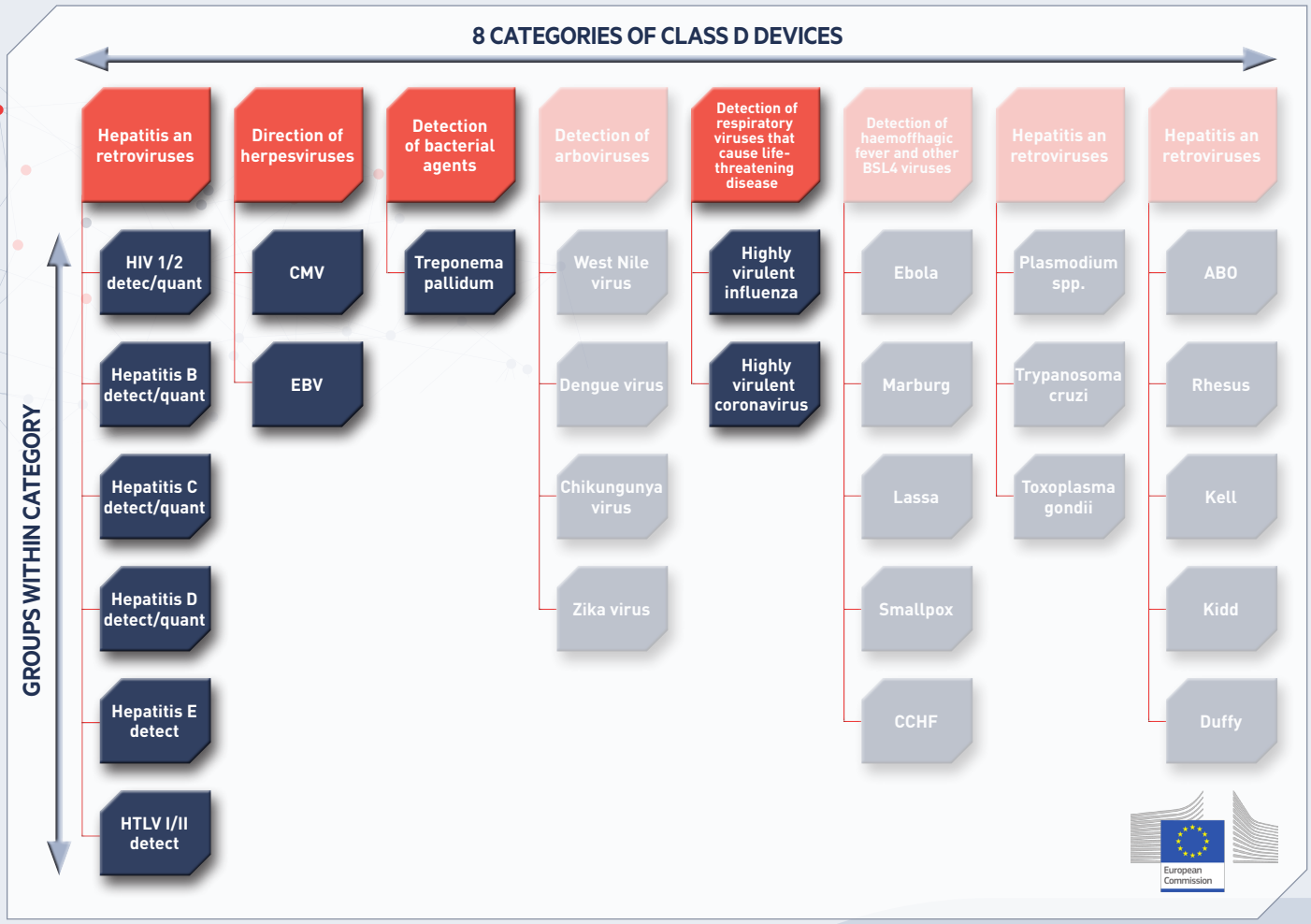
B EURL DESIGNATION

In July 2022, the European Commission launched a process to designate EU reference laboratories for 8 categories of Class D devices, with a first call for applications.



The European Commission, through Implementing Regulation (EU) 2023/2713 of December 5, 2023, designating EU reference laboratories in the field of in vitro diagnostic medical devices, has designated five EURLs covering four of the eight Class D device categories:

- Hepatitis and retroviruses;
- Herpesviruses;
- Bacterial agents;
- Respiratory viruses.



After consulting Member States within the Medical Devices Coordination Group (MDCG), the Commission has launched a second call for applications to cover the remaining categories of Class D devices:

- Arbovirus;
- Hemorrhagic fever and other BSL 4 viruses;
- Parasites;
- Blood grouping.

C IMPLEMENTATION

This implementing Regulation (EU) 2023/2713 applies since October 1ST, 2024, and involves the following actions:

→ 1. Performance verification (PV)

In-vitro diagnostic medical devices (IVDMDs) already covered by an IVDR certificate or in the process of certification (formal application for conformity assessment submitted to a NB) before October 1st, 2024, are not subject to performance verification by an EURL as part of initial certification. This performance verification step will be carried out when their certificate is renewed.

▶ See the diagram "EURL involvement in the conformity assessment of high-risk IVDs": Device 1 - Device 2

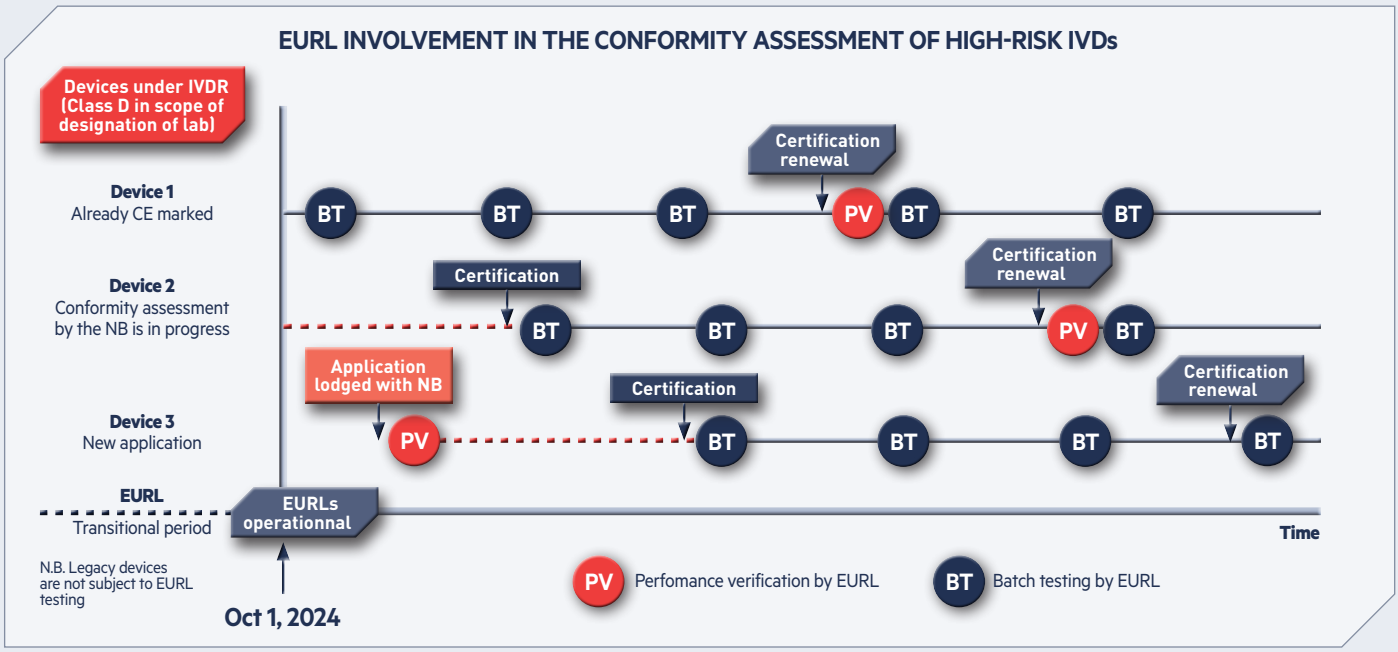
IVDMDs for which a formal application is submitted to a NB after October 1ST, 2024, will have to undergo performance verification by a EURL as part of their initial certification.

▶ See the diagram "EURL involvement in the conformity assessment of high-risk IVDs": Device 3

→ 2. Batch testing (BT)

From October 1st, 2024, samples of manufactured batches of Class D devices must be tested by EURLs, regardless of the date on which they obtained an IVDR certificate.

▶ See the diagram "EURL involvement in the conformity assessment of high-risk IVDs": Device 1 - Device 2 - Device 3



Class D devices for which no EURL is designated can still be certified by Notified Bodies and placed on the EU market in accordance with Regulation (EU) 2017/746. The requirements of Article 100 do not apply to these devices until an EURL is designated. Guide MDCG 2021-4 sets out the arrangements to be followed in the absence of a designated EURL.

Annex II List A devices certified under Directive 98/79/EC and eligible for the transitional provisions of EU Implementing Regulation 2024/1860 are not subject to testing by EURLs from October 1st , 2024. However, they will continue to be subject to batch verification in accordance with the provisions laid down by the NB responsible for their appropriate surveillance.

Conclusion

The establishment of EU reference laboratories marks a significant step in harmonizing compliance with Regulation (EU) 2017/746, ensuring the quality and safety of Class D IVDMDs throughout the European Union.

The organization of a network of laboratories with coordinated methods, procedures and processes, using the same reference materials, common test protocols and adapted test reports will make it possible to contribute favorably to Public Health and patient diagnosis with safe, high-performance IVDMDs.

Manufacturers are invited to keep abreast of the guides published by the MDCG, as well as updates from the European Commission on the progress of EURL implementation, at the following address: **EU reference laboratories (EURLs)**

Sources:

- *MDCG 2021-4 Application of transitional provisions for certification of class D in vitro diagnostic medical devices according to Regulation (EU) 2017/746 (April 2021)*
- *MDCG 2022-3 Verification of manufactured class D IVDs by notified bodies (February 2022)*
- *COMMISSION IMPLEMENTING REGULATION (EU) 2022/944 of 17 June 2022 laying down rules for the application of Regulation (EU) 2017/746 of the European Parliament and of the Council as regards the tasks of and criteria for European Union reference laboratories in the field of in vitro diagnostic medical devices.*
- *COMMISSION IMPLEMENTING REGULATION (EU) 2023/2713 of 5 December 2023 designating European Union reference laboratories in the field of in vitro diagnostic medical devices.*

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Going the extra mile

TRAININGS FOR AMERICA REGION

European in Vitro Diagnostic Devices Regulation (EU) 2017/746
2-day training session | On demand | Virtual classroom

→ CHECK OUT THE PROGRAM

Technical Documentation per In Vitro Diagnostic Devices Regulation (EU) 2017/746
1.5- day training session | On demand | Virtual classroom

→ CHECK OUT THE PROGRAM

TRAININGS FOR OTHER REGIONS

Drafting technical documentation according to Regulation (EU) 2017/746
SA71 | 1-day training session | On demand

Performance evaluation and clinical evidence for in vitro diagnostic medical devices (IVDMs)
SA72 | 1.5-day training session | On demand

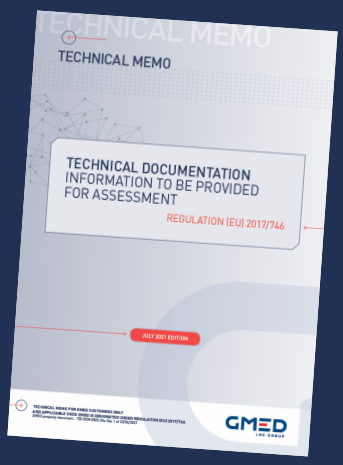
Apply the requirements of European Regulation 2017/746 relating to in vitro diagnostic medical devices (IVDR)
SA50 | 2-day training session | On demand

→ CONTACT GMED TRAINING CENTER

TECHNICAL MEMO

Technical Documentation - Information to be provided for assessment – Regulation (EU) 2017/746

[ONLY FOR GMED CUSTOMERS]



The format and content of the technical documentation to be provided for the assessment of your in vitro diagnostic medical device.

→ REQUEST THE TECHNICAL MEMO FROM YOUR CERTIFICATION PROJECT MANAGER

Newsletter

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