The European Association of
Medical devices Notified Bodies

TEAM-NB A.I.S.B.L.
Rue Bawepuce 20
B – 4140 Sprimont - BELGIUM
Phone: +32 475 85 40 45

E-mail: assistant@team-nb.org
Web: http://www.team-nb.org
IBAN BE09 3401 5174 8757
VAT BE 0864 640 677 - RPM Liège

Editor : Francoise SCHLEMMER	Date : October 1st, 2024

PRESS RELEASE

Transition to the Implementation of Class D oversight by EURLs

1st October 2024 marks the transition to operations for European Reference Laboratories (EURLs) for Class D in vitro diagnostic (IVD) medical devices. From October 1st 2024 the EURLs are intended to carry out tasks referred to in Article 100(2) of Regulation (EU) 2017/746.

What does this mean in practice for the conformity assessment of Class D devices?

1. Background

The conformity assessment of Class D devices under Regulation (EU) 2017/746 on in vitro diagnostic (IVD) medical devices (IVDR) necessitates a specific regulatory infrastructure. This infrastructure includes, among other elements, the involvement of a designated European Union Reference Laboratory (EURL) in the device performance verification and the release of individual batches, as outlined in IVDR Article 100(2)(a) and (b).

Designation of EURLs and Application Date

As of December 2023, five European Union Reference Laboratories (EURLs) have been designated via Implementing Act 2023/2713 covering four categories of Class D devices (Hepatitis and retroviruses, Herpesviruses, Bacterial agents, Respiratory viruses that cause life-threatening diseases).
The application date for this designation is set for 1st October 2024.
At the moment, no EURL has been designated for the remaining technical categories of Class D devices, namely arboviruses, haemorrhagic fever and other biosafety level 4 viruses, parasites, and blood grouping. Therefore, these categories are not within the scope of this press release.

Impact on Performance Verification

For Class D devices with certificates issued or applications received by a Notified Body (NB) before 1st October 2024, performance verification activities will need to be conducted before re-certification. For applications received after 1st October 2024, performance verification activities will be part of the initial conformity assessment of the Class D device before the Notified Bodies (NB) issues the certificate. Refer to the graph in Appendix One for a comprehensive overview of the various scenarios.

Impact on Batch Verification

Batch verification activities for Class D devices should commence as soon as possible after 1st October 2024, or once the device is certified.

2.Transition Efforts

Over the past several months, Notified Bodies (NBs) have actively collaborated with the EURLs to ensure a smooth transition to becoming operational. Significant efforts have been made to standardize the Class D oversight processes and related documents used for both batch release and performance verification, including contract templates, test requests and reports.
While preparation efforts are ongoing, NBs welcome the publication of Revision 1 of MDCG 2021-4, "*Application of Transitional Provisions for Certification of Class D In Vitro Diagnostic Medical Devices According to Regulation (EU) 2017/746."* This revision clarifies the conditions for transitioning to operational status for testing at the European Union Reference Laboratories (EURLs).

The revision specifies that if testing cannot be conducted at the EURL—for example, but not limited to, logistical issues, verification or validation of equipment, training of staff etc. by October 1, 2024—NBs can continue with their current batch release process in place for Class D devices using the alternative methods employed prior to the EURL designation application.

Taking this clarification into account, Notified Bodies (NBs) will continue releasing device batches using alternative methods until testing at the EURL for that specific device can commence. This approach ensures a smooth transition to operational status for EURLs, while preventing shortages of Class D devices in the EU market.

3. **Conclusions**

The transition of EURLs to operational status marks a significant milestone in the development of the regulatory infrastructure for the IVDR. Its implementation demands considerable efforts from all stakeholders involved.

Notified Bodies (NBs) will continue collaborating with all stakeholders to ensure a smooth transition to operations after October 1st.

Appendix 1

Overview of various scenarios for the performance and batch verification process of Class D devices