The European Association of
Medical devices Notified Bodies

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PRESS RELEASE

Important update on the Implementation of Class D oversight by EURLs: endorsement of Multi Services Agreement template

Further to Team-NB press release(1) of 1 October 2024, Notified Bodies are happy to report on the following progress to the full implementation of performance and batch verification of class D devices EURL testing activities.

1. Implementation of Multi Services Agreement

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.

Recently, Notified Bodies that are designated against EU Regulation 2017/746, or the IVDR, have endorsed the consolidated template for the multi services agreement (MSA) with the European Reference Laboratories (EURLs). This document will help setting up a formal agreement and workflow between the Notified Bodies and the EURLs that will support the implementation of EU Regulation, dealing with oversight of Class D devices that are being certified against the IVDR. By agreeing with the document, it will also support the agreed workflow between NBs and EURLs that will, again, facilitate a harmonized and consistent implementation of EU implementing regulations (EU) 2022/944, (EU) 2022/945 and (EU) 2023/2713.

Notified Bodies are now applying the MSA template as soon as possible in order to finalize a quick and compliant implementation of the requirements for Performance Verification and Batch testing activities as been mentioned in article 100 of the IVDR, that are mentioned in Regulation (EU) 2023/2713.

2. Conclusions

The implementation of EURL testing activities marks a significant milestone in the development of the regulatory infrastructure for the IVDR. Its implementation demands considerable efforts from all stakeholders involved. The endorsement and implementation of the MSA template is an important step in the enrolment of the requirements related to article 100, IVDR. This will again help to ensure the availability of safe and compliant in vitro diagnostics that are used in tissue compatibility testing and testing the blood supply in Europe.

Notified Bodies (NBs) are open to and will continue collaborating with all applicable stakeholders to ensure a smooth and complete transition to operations.

(1) https://www.team-nb.org/implementation-of-class-d-oversight-by-eurls-press-release/