



Team-NB/ NBCG Med Position Paper



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Class D measures in the absence of EU Reference Laboratories- Points to consider for Notified Body approach

Disclaimer

This paper is intended for Notified Body use only.

It has been endorsed by members of Team-NB, the European Association for Medical Devices of Notified Bodies and by the Notified Body Coordination Group for Medical Devices (NBCG-Med), as established by Art 49 of Regulation (EU) 2017/745 and Art 45 of Regulation (EU) 2017/746. The NBCG-Med is composed of representatives of all notified bodies for medical devices and IVDs.

The paper is not a European Commission document and cannot be regarded as reflecting the official position of the European Commission, Competent Authorities for Medical Devices (CAMD) or Medical Device Coordination Group (MDCG).

If European Commission, CAMD or MDCG publish new relevant documents or make changes to existing ones, this paper may be updated/withdrawn to align with the position expressed in aforementioned documents.

Scope

The scope of this consideration paper is to provide a framework for the verification process for class D IVD medical devices by Notified Bodies (NB) in the absence of designated EU Reference Laboratories (EURLs).

The scope includes both the verification during the Technical Documentation review prior to certification and of manufactured products post-certification

This position paper reviews possible solutions and/or interim implementation measures, however it is entirely up to a NB to decide what / which methods and solutions are used, if they would like to progress Class D applications in the absence of EURLs.

Background

The regulatory infrastructure specific for the conformity assessment of class D devices may include, among other elements, the involvement of EURLs in the verification of the performance of class D devices. In June 2022, the European Commission launched a call for applications for EURLs in several categories of devices; designation is planned for Q3 2023; however it is currently not known if EURLS will be designated for all categories of devices.

Considerations on possible solutions/interim implementation measures

The IVDR empowers the NBs to request any testing they consider necessary to support their assessment (see Annex IX 4.3 or Annex X 3(a)).

If a NB would like to progress Class D applications in the absence of a designated EURL, it is entirely at the discretion of a NB what measures and solutions are used. This may be specific for particular device and scenario of certification (e.g. market history of the device in question), and therefore 'one rule' may not 'fit all'.

Earlier this year, MDCG 2022-3 Verification of manufactured class D IVDs by notified bodies was published; this document provides guidance on roles, responsibilities, and best practices for the completion of conformity assessment procedures relating to the verification of manufactured class D IVDs. Although MDCG 2022-3 is not within the scope of this position paper and is a provision for when EURLs are designated, it was used as a basis to develop the possible solutions and/or interim implementation measures together with the requirements of Annex VII of the IVDR to operate to the highest standards available for class D devices.

As stated in MDCG 2022-3, the notified body should have documented procedures for:

1. The **verification process**:

The solutions adopted by the NB may vary depending on market status & novelty of a device, as well as the particular analyte under review.

A NB may look to their individual experiences under the IVDD to help support their rationales for their approach.

Pre-market:

Possible solutions pre-market (for all devices regardless of whether they are on the market under the IVDD or other jurisdictions):

- If available, NB could use other sub-contracted labs. Suitable options for this solution are currently being explored
- Use of blinded panel samples¹ or mandatory participation to External Quality Assurance Schemes (e.g. Instand, UK NEQAS or other); a list of on existing EQAS organisations is available at the **European Organisation for External Quality Assurance Providers in Laboratory Medicine (EQALM)** webpage www.eqalm.org; organisations are listed by country name along with their respective websites; further information is available on the European Center for Disease Prevention and Control (ECDC) webpage www.ecdc.europa.eu
- [Witness testing during audits](#)
- Integration of commercial reference materials into final Quality Control testing at Manufacturer's site if such material is available

Additionally, for devices currently on the market under IVDD (or other jurisdictions), the following could be considered:

- Review of historic manufacturing/QC batch records to base future 'release plan'
- Continued used of established IVDD Annex II List A release specifications under the IVDR
- More scrutiny of on-market & vigilance data as part of IVDR conformity assessment

¹ Suitable options for sources of blinded panel samples are currently being explored

- Provision of 'routine diagnostic testing' data

Post market:

Additional measures that may be considered by the NB as part of conformity assessment after initial IVDR certification:

- Witness testing at Manufacturer's site during regular audits; the NB should determine the frequency of witness testing using a risk-based approach. Factors to be taken into account could be, for example, the manufacturer's track record of releasing high risk IVDs. NB could enhance the oversight of post-market data. This could be fulfilled, for example, by requesting the submission of periodic post-market data (e.g. PSUR) with increased frequency during initial certification e.g. every 6 months instead of 1 year
 - Consider proactive notification of change of materials/QCs
 - Proactive PMPF: although Annex XIII of the IVDR allows Manufacturers to provide a justification if they do not consider PMPF appropriate for a specific device, PMPF could be considered necessary for this type of devices
 - The results of earlier unannounced audits of the same Manufacturer could be taken into account
2. The **establishment of a test plan** identifying all relevant and critical parameters which need to be tested for the device, including decision making criteria for success or failure of the batch

The establishment of a testing plan will depend on solutions opted for the verification process and it should be established and agreed upon with the Manufacturer during the initial certification.

3. The **provision for the reaching of an agreement** with the manufacturer concerning when and where the necessary sample or batch testing must be performed

The NB contracts with Manufacturers should include additional requirements or references as needed detailing the scope of interim measure or solutions adopted by the NB until a EURL is appointed for the specific category of class D devices under assessment.

Conclusions

This consideration paper explores possible solutions for performance verification and verification of manufactured class D devices that NB could apply until a EURL is designated for the specific category of device under assessment. The chosen solutions may vary depending on the device under evaluation and should be taken using a risk-based approach.

If possible, for devices classified as Annex II List A under the IVDD, NB should maintain under the IVDR the same testing procedures applied under IVDD.

Further work is ongoing to identify suitable options for independent sub-contracted laboratories and sources of blinded samples.