The European Association
Medical Devices - Notified Bodies

Team-NB Position Paper

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Team-NB Notified Bodies considerations on conformity assessment for class D devices

1. Executive summary

Due to the lack of required regulatory infrastructure, the conformity assessments for class D IVD devices can not currently be completed under the IVD Regulation. Following the publication of MDCG 2021-4 'Application of transitional provisions for certification of class D in vitro diagnostic medical devices according to Regulation (EU) 2017/746 in April 2021', Notified Bodies suggest an approach to performing conformity assessments of class D devices, in the absence of EU Reference Laboratories and consideration of the delay to the IVD Expert Panel becoming operational based on the issued guidance. Some outstanding questions remain and need to be urgently addressed by the Commission.

2. Background

Regulation EU 2017/746 on in vitro diagnostic (IVD) medical devices (IVDR) introduces new rules and a risk-based classification system for IVDs. IVDs are classified in four different classes of increasing risk with class D being the highest risk. Class D includes devices intended to be used for the identification of diseases that are life-threatening and that could present a high risk to public health.

Due to the classification changes, some IVDs that were self-declared IVDs under the IVD Directive are class D under the IVDR. These devices are excluded from the grace period and therefore must be certified under the IVDR by Date of Application (DoA-26 May 2022) or be removed from the EU market.

3. Regulatory Infrastructure for class D devices

The conformity assessment of class D devices requires a specific regulatory infrastructure that includes reference laboratories (EURLs), Common Specifications (CSs) and, if no CS is available and it is the first certification for that type of device, expert panels.

As per IVDR Article 48(6), when consultation of the expert panel is required, Notified Bodies (NBs) must provide the device performance evaluation report to the expert panel within five days of receiving it from the manufacturer.

Based on the publication of MDCG 2021-4 *Application of transitional provisions for certification of class D in vitro diagnostic medical devices according to Regulation (EU) 2017/746 in April 2021*

- Notified Bodies may accept applications and issue certificates for class D IVDs without EURLs, as long as no EURL has been designated. The certificates issued will remain valid until their expiry date.
- Sample and batch testing of IVDR certified class D devices will start once an EURL for a specific device becomes operational; i.e. certification will be made with potentially

alternative arrangements for batch release, which would need to revert to wet-testing when the EURL is operational.

- Additionally, MDCG 2021-4 allows NBs to submit Manufacturer's Performance Evaluation Report within 5 days of the expert panel becoming operational instead of 5 days of receiving it from the manufacturer.
- At the time of drafting this position paper, it is unknown when the IVD Expert Panel will become operational. If consultation of expert panel is required, NB cannot issue a certificate until the consultation is completed.
- The role of EURLs in verification of performance (for initial certification) will be implemented if applicable from re-certification, i.e. if certification has progressed in the absence of EURLs being designated.

Based on the information currently available, CSs will be adopted via two separate implementing acts: the first implementing act will be adopted in 2021, the second will be adopted later. Both implementing acts will have a transition period of at least 12 months during which CSs can be applied on a voluntary basis.

Time required to complete conformity assessment procedures

Based on the experience with other device classes, it is estimated that conformity assessment for class D will require 9-12 months. The time required by manufacturers to prepare the technical file prior to application to the NB and to update the labelling after approval should be added to this timeline.

Further time may be required if the expert panels are involved (i.e. for Class D with no CS) and/or where the EURL is designated and involved in verification of performance prior to certification.

Assessment of general IVDs up-classified to class D

Based on the information available to date, NB expect applications for the following devices are being up classified from self-certified under the IVD Directive to class D depending on their intended purpose:

Babesia	Hepatitis E (screening)
Chagas (T. cruzi)	Highly virulent corona virus (e.g. SARS CoV, SAR-CoV-2 (Covid-19), MERS)
Crimean-Congo Haemorrhagic Fever (CCHF)	Highly virulent pandemic influenza virus
Cytomegalovirus CMV	Lassa
Ebola	Malaria (Plasmodium spp.)
Epstein-Barr Virus (EBV)	Marburg
Hepatitis A (screening)	Syphilis
	Multiplex devices [e.g IVD panels including any of the above]

Applications for additional diseases also up-classified from general to class D cannot be excluded.

Notified Body position on conformity assessment for class D devices

Due to the lack of the required regulatory infrastructure, as described above, and the time constraints associated with expert panel consultation, NB have not been accepting conformity assessments for class D devices until now.

Following the publication of MDCG 2021-4, Notified Bodies will apply the following approach:

1) For class D devices that have CSs, NBs will start accepting applications for conformity assessment for class D devices as soon as the IVD expert panel is operational. To avoid shortage of critical IVDs in the EU market, priority will be given to those devices up classified from self-certified to class D devices i.e. Chagas, Syphilis, EBV and SARS CoV-2 (if available) as these devices cannot benefit from the grace period.
2) For devices up-classified to class D not meeting the CS during the transition period, NBs may still issue a certificate, depending on the type of issue observed, and on the condition that CS requirements are fulfilled by the end of the transition period of the CS.
3) For class D devices that do not yet have CSs (or those devices not covered by the first publication of CS in Q2 2021), Notified Bodies will review the application on a case by case basis versus current State of the Art data including the Expert Panel opinion for that type of device if available. Compliance with CSs will be verified as part of surveillance activities once the CSs become applicable.
4) Validity of certificates: According to Annex VII (4.11) of the IVDR, re-certification needs to occur at least every five years. Considering that the regulatory infrastructure for class D devices is not finalised, individual Notified Bodies may decide to require reduction in validity period of certificates or to enhance post-certification monitoring (e.g. additional Post Market Performance Follow-up, PMPF).

However, to make the above approach work, NBs have identified the following needs for information, clarification and guidance:

- For **Class D devices with no CS**

  - A clear definition of 'first certification of that type of device' for expert panel consultation.

  - A process to communicate to NBs that a certain type of device is already being reviewed by the expert panel and the timing associated with this communication.
    - **Proposal**: have the Expert Panel Secretariat immediately inform the applying NB that a 'first type of device' is already under assessment

  - If a Class D device with no CS is **not** the first of its type, clarification is needed on the expectations for review and certification. Specifically, how will the expert panel output and recommendation(s) on this type of device be communicated e.g. will the output be encompassed in a new CS? Will these mean that there is time prior to the DoA for certification of the 2nd, 3rd type of these devices?

- **Proposal**: Class Ds with no CS (2nd or 3rd of its type) can be certified, with a transition period to meet the expert panel recommendation(s).

❖ For **Class D devices certified without EURL**:

➢ The expectations around the process for batch release wet testing to verify each batch released to market need to be clarified.
- **Proposal**: Batch verification will be completed as documentation release by the NB.

➢ The process to implement batch release wet testing when EURLs become operational should be defined to minimise the risk of accumulation of devices requiring testing.
- **Proposal**: establish a transition period for EURL requirement for batch release: this phased approach will help prevent device shortages.

❖ For **conformity assessments** conducted **without CS or if CS application is voluntary**

➢ Agreement on how to establish state of the art
- **Proposal:** draft CS proposals will be made available to NBs and could be used to guide reviews by NBs.

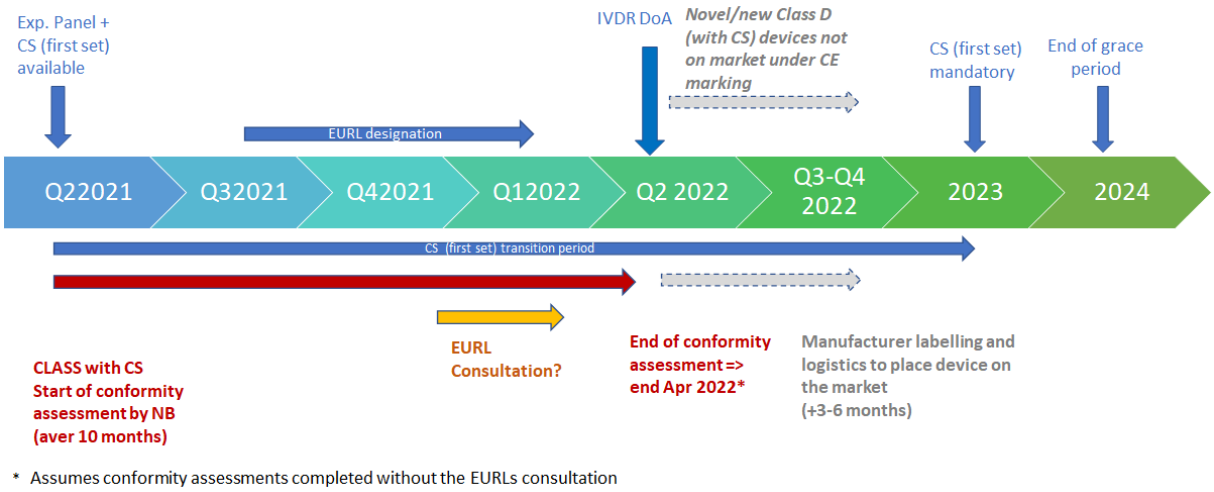
❖ For **Class D devices undergoing conformity assessment at the time the EURL becomes operational**

➢ Definition of criteria for the involvement of the EURL performance

Conclusions

To support the implementation of the IVDR and to ensure EU patients do not suffer any shortage of critical IVDs in the market, Notified Bodies are eager to start processing conformity assessment for class D devices. It should be noted, however, that due to the time required by all stakeholders to perform all the tasks related to conformity assessments, meeting the IVDR DoA for these devices will be challenging even without the time required for the EURL consultation (60 days) as shown by Figure 1.

Figure 1: Estimated timelines for conformity assessments for class D devices



* Assumes conformity assessments completed without the EURLs consultation

Due to the lack of regulatory infrastructure for the conformity assessment process, it is envisaged that there may be scenarios where a Notified Body will not be able to certify certain types of devices. The worst-case scenario may mean certain types of devices are not available to the market after the DoA.

Furthermore the lack of EURLs and of Common Specifications for certain class D devices will reduce the extent of the regulatory assessment of these devices, therefore Notified Bodies call to the Commission to answer the key outstanding issues highlighted above as a matter of urgency to prevent devices coming off the market and a risk to public health.