MDCG 2021-4 Rev. 1

Application of transitional provisions for certification of class D *in vitro* diagnostic medical devices according to Regulation (EU) 2017/746

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MDCG 2021-4 revision 1 changes	
Introduction	Clarifications on scope
Q1	Indication that question is obsolete
Q2	Minor revision
Q3	Introduction of reference to MDCG 2021-22 Rev 1
Q4	Editorial change
Q5	Minor revision
Q6	Revision
Q7	New question

Application of transitional provisions for certification of class D *in vitro* diagnostic medical devices according to Regulation (EU) 2017/746

According to Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (the IVDR), as part of conformity assessment of class D *in vitro* diagnostic medical devices (IVDs), the manufacturer must submit an application to a notified body. In addition to the assessment by the notified body, under certain conditions particular elements may be reviewed by an expert panel and/or tested by an EU reference laboratory (EURL). This document provides indications for how to apply the IVDR provisions related to expert panels and EURLs before the IVDR application date, i.e. 26 May 2022, as well as around the time when the first EURL designations become applicable for the purpose of EURL tasks (1 October 2024 according to Commission Implementing Regulation (EU) 2023/2713).

Q1. Before 26 May 2022, may notified bodies accept applications from manufacturers for certification of class D IVDs, and issue the corresponding certificates, if the IVD expert panel is not yet operational?

Notified bodies may accept and begin the assessment of applications for class D IVDs. However, the notified bodies may not issue the certificate before the expert panel is operational and, for the devices that require consultation of the panel, before the panel has provided its views (see also Q2 and Q3).

[This question is obsolete as the IVD expert panel is operational, see the relevant Commission webpage.]

Q2. For devices to which this requirement is applicable, when must the notified body submit the performance evaluation report of the manufacturer to the expert panel?

According to IVDR Art 48(6), "*the notified body shall provide the performance evaluation report of the manufacturer to the expert panel within five days of receiving it from the manufacturer*".

Q3. How should the notified body determine whether the device will have to undergo consultation of the expert panel prior to issuing the certificate?

According to IVDR Article 48 (6), "*where no CS are available for class D devices and where it is also the first certification for that type of device, the notified body shall consult the relevant experts referred to in Article 106 of Regulation (EU) 2017/745 on the performance evaluation report of the manufacturer*". Guidance on what constitutes a "type of device", as well as on the process that the notified bodies should follow to determine whether a given certification is the first one for that type, is available in MDCG 2021-22 Rev 1.

Q4. When can the notified body expect to receive the views of the expert panel?

According to IVDR Article 48(6), "*The experts shall provide their views to the notified body within the deadline for delivery of the scientific opinion by the EU reference laboratory*". Regardless of whether or not an EU reference laboratory (EURL) is designated for the device in question, the expert panel should provide its views within 60 days, in line with the time available for the EURL to issue its opinion according to Annex IX Section 4.9 and Annex X Section 3 (j).

Q5. May notified bodies accept applications from manufacturers for certification of a class D IVD, and issue the corresponding certificate(s), if an EURL is not designated for that device?

Yes. Notified bodies may accept applications for a class D IVD and issue the corresponding certificate(s) if an EURL is not designated for that device.

Q6. What will happen to devices certified under the IVDR in the absence of an EURL if an EURL is designated for the corresponding scope at a later time point?

The certificate will remain valid until its expiry date established by the notified body and according to the IVDR. On sample or batch testing, the notified body and manufacturer should follow the EURL-related provisions of Section 4.12 of Annex IX or Section 5 of Annex XI from the time that the EURL becomes operational (see Q7). For performance verification, the notified body should follow the EURL-related provisions of Section 4.9 of Annex IX or Section 3 (j) of Annex X in the course of the renewal of EU technical documentation assessment certificates and EU type-examination certificates in line with Section 4.11 (f) of Annex VII. The provisions on consulting the EURL in case of changes (second paragraph of Section 4.11 of Annex IX or Section 5.4 of Annex X) apply if the initial performance verification by an EURL has been carried out.

Q7. What does the date of application of the designation of EURLs (1 October 2024) mean in practical terms for EURL tasks, and in particular for sample or batch testing according to Article 100(2)(b) IVDR and performance verification according to Article 100(2)(a)?

The Commission Implementing Regulation (EU) 2023/2713 states that, for the purpose of the tasks referred to in Article 100(2) of the IVDR, the designation of the EURLs shall apply from 1 October 2024. The activities that are part of fulfilling the tasks are laid down in Commission Implementing Regulation (EU) 2022/944. When the designation of the EURLs becomes applicable for these tasks on 1 October 2024, the EURLs are required to engage in the activities described in Articles 10-16 of Commission Implementing Regulation (EU) 2022/944.

In particular for batch testing, as of 1 October 2024, for all class D devices for which notified bodies have issued a certificate under the IVDR, and which fall within a scope of a designated EURL, notified bodies are obliged to contact an appropriate EURL and engage in the activities described in Articles 10, 11 and 13 of Commission Implementing Regulation (EU) 2022/944.

More generally, notified bodies should engage with an appropriate EURL as regards preparation for batch testing in advance of the issuance of the certificate for all class D devices for which they are involved in conformity assessment activities under the IVDR, and which fall in scope of the designated EURLs.

For each device testing, there are preparatory elements to complete, such as: signing of contracts, shipping of equipment, shipping of device samples, installation activities etc. As the EURL is required to support and carry out these activities as of 1 October 2024, it may not be possible to start the testing itself on this date. Testing should take place, on a case-by-case basis, as soon as all the arrangements such as proper installation and validation of any equipment are in place. While these preparatory elements of the task are being put in place, the notified body can request other testing or evidence from the manufacturer to ensure appropriate batch verification in line with the provisions in Annex IX 4.3, 4.12 or Annex X 3(a) and 5 and Annex VII 4.5.3 IVDR, especially if such arrangements were in place before the application of the EURL designation.

For performance verification, for all class D devices for which a formal application is lodged with the notified body from 1 October 2024, and which fall in scope of the designated EURLs, notified bodies are obliged to contact appropriate EURLs to engage in activities described in Articles 10-12 of Commission Implementing Regulation 2022/944 as part of the conformity assessment procedure. For class D devices for which a formal application is lodged with the notified body before 1 October 2024 but a certificate was not yet issued by that date, the notified body should follow the EURL-related provisions of Section 4.9 of Annex IX or Section 3 (j) of Annex X in the course of the renewal of EU technical documentation assessment certificates and EU type-examination certificates.