

MDCG 2021-4

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

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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). The establishment of EURLs for a range of class D devices has been identified as an important priority by the Medical Device Coordination Group. The European Commission is preparing the implementing acts on tasks and criteria of the EURLs and fees they may levy, referred to in Article 100(8) of the IVDR, as well as the first call for applications to be submitted by the Member States. This document provides indications for how to apply the IVDR provisions related to expert panels and EURLs during the transition period, i.e. before 26 May 2022.

Q1. During the transition period, 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).

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*”. If the panel is not yet operational, the notified body should submit the performance evaluation report of the manufacturer within five days of the panel becoming operational¹.

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*”. MDCG guidance is in preparation on what constitutes a “type of device”, as well as on

¹ As announced on the European Commission’s website:
https://ec.europa.eu/health/md_expertpanels/overview_en.

the process that the notified bodies should follow to determine whether a given certification is the first one for that type.

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*”. If no 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 Section 4.9 of Annex IX and Section 3 (j) of Annex X.

Q5. During the transition period, 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?

During the transition period, as long as no EURL has yet been designated for that specific device, category or group of device, the notified bodies may accept applications for a class D IVD and issue the corresponding certificate(s).

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. 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 at the time of the re-certification in line with Section 4.11 (f) of Annex VII. So, the procedure set out in paragraph 5 of Article 48 involving an EURL will be applied at the time of the re-certification.

