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Clarification on "*first certification for that type of device*" and corresponding procedures to be followed by notified bodies, in context of the consultation of the expert panel referred to in Article 48(6) of Regulation (EU) 2017/746

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Introduction

For class D devices, Article 48(6) of Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (the IVDR) establishes the conditions to be applied by the notified body to determine whether it has to consult the expert panel on the performance evaluation report of the manufacturer. These conditions are:

(1) the absence of common specifications for the class D device in question, AND
(2) where it is also the first certification for that type of device.

This guidance provides clarification on the meaning of these conditions and on the corresponding procedures to be followed by the notified body.

1. What is the meaning of "*the first certification for that type of device*" in accordance with Article 48(6) of Regulation (EU) 2017/746?

As mentioned in recital (53) of the IVDR, notified bodies should consult the expert panels where it is the first certification for that specific type of device and there is no similar device on the market having the same intended purpose and based on similar technology. Therefore, "*first certification for that type of device*" in Article 48(6) of the IVDR should be understood as the first certification under either Directive 98/79/EC or under Regulation (EU) 2017/746 by any notified body in relation to a product with a specific[1]:

- intended purpose, including all of the following:
    1. what is detected and/or measured,
    2. the function of the device such as screening, monitoring, diagnostic, *etc.*,
    3. the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate,
    4. whether it is automated or not,
    5. whether it is qualitative, semi-quantitative or quantitative,
    6. the type of specimen(s) required,
    7. where applicable, the testing population,
    8. intended user,
- analysis technology and process used, including:
    1. the principle of the assay method or the principles of operation of the instrument.

Once a device with a specific set of elements listed above has been certified either under Directive 98/79/EC or under Regulation (EU) 2017/746, any other device to be certified for the first time under Regulation (EU) 2017/746 with a similar set of

[1] Taking into account Section 1.1 of Annex II to IVDR

elements will be considered the same "type of device" irrespective of the manufacturer and therefore will not need to be subject to a consultation with the expert panel.

2. What procedure should a notified body follow to determine whether a given certification is the first for that type of device?

It is the notified body who has to decide whether the certification of the device in question is a first certification of its type. This means that the notified body should judge whether the above elements of the definition of "type of device" are similar to an already certified device for it to be considered of the same type. For its decision, the notified body should:

- use its own knowledge and expertise;
- consider information provided by the manufacturer, including relevant research (e.g. scientific and market research);
- consider the information on type of device for the already completed and ongoing consultations of the expert panel, referred to in question 3.

If the notified body comes to the conclusion that no device of that type has been certified yet (either under Directive 98/79/EC or under Regulation (EU) 2017/746), and if no common specifications are available for that device, the notified body has to consult the expert panel.

The notified bodies should document their assessment of whether a given certification is the first of that type of device, and their corresponding conclusion.

3. How should the notified body indicate the type of device in its submission to the IVD expert panel?

When consulting the IVD expert panel, the notified body should provide, as part of the documents submitted to the Secretariat, the information requested in the template below describing the type of device.

The template duly completed by the notified body will be published on the website of the expert panel for the ongoing consultations of the expert panel. Once the expert panel has issued its views, the template will be part of the views.

Table 1: Template for description of the type of device for the purposes of expert panel views according to Art 48(6) of Regulation (EU) 2017/746

Intended purpose (P)		
P1	what is detected and/or measured *please specify the analyte(s) or marker(s), e.g. SARS-CoV-2 spike protein, Kel1 (K)*	

P2	function of the device *e.g. diagnosis, aid to diagnosis, monitoring, determining the infectious load, tissue typing etc*	
P3	the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate *e.g. hepatitis C infection, exposure to SARS-CoV-2, risk of HIV transmission in blood transfusion etc.*	
P4	whether it is automated or not	
P5	whether it is qualitative, semi-quantitative or quantitative	
P6	type of specimen(s) *e.g. whole blood, serum, saliva etc*	
P7	where applicable, the testing population *e.g. persons with specific health conditions, persons with specific symptoms, children in a certain age range*	
P8	intended user	
Technology (T)		
T1	principle of the assay method or principles of operation of the instrument *e.g. real-time PCR, qualitative PCR, digital PCR, sandwich immunoassay, competitive immunoassay, immunoturbidimetric assay etc.*	

4. What is the meaning of the phrase "*where no CS are available*" in Art 48(6)?

This should be understood as the case where no common specifications have been adopted and published in the Official Journal of the European Union for that type of device. After publication, the CS are considered "available", so the consultation of the expert panel is not required.

5. If a notified body identifies that a consultation of an expert panel is currently ongoing for that type of device, what should it do regarding the certification process?

This question does not concern the notified body that consults the expert panel on the first certification for that type of device, but rather the notified bodies that might be dealing with a second, third certification *etc*. while the consultation on the first certification is still ongoing. These notified bodies should not issue the certificate until the consultation of the expert panel on the first certification for that type of device is completed and the views are published. It is highly recommended that the notified bodies should give consideration to the views of the expert panel in its decision to issue the certificate.