The European Association of
Medical devices Notified Bodies

TEAM-NB A.I.S.B.L.
Rue Bawepuce 20
B – 4140 Sprimont - BELGIUM
Phone: +32 475 85 40 45

E-mail: assistant@team-nb.org
Web: http://www.team-nb.org
IBAN BE09 3401 5174 8757
VAT BE 0864 640 677 - RPM Liège

Editor : Francoise SCHLEMMER	Date : 12/03/2025

PRESS RELEASE

Certificates with Conditions – Team NB Statement

The EU Medical Device Regulation (MDR) 2017/745 Annex VII section 4.8 allows the possibility of notified bodies to issue certificates with specific conditions, provisions or limitations.

The notified body shall have documented procedures for decision-making including as regards the allocation of responsibilities for the issuance, suspension, restriction and withdrawal of certificates. Those procedures shall include the notification requirements laid down in Chapter V of this Regulation. The procedures shall allow the notified body in question to…

- *decide whether specific conditions or provisions need to be defined for the certification,*
- *issue a certificate or certificates in accordance with the minimum requirements laid down in Annex XII for a period of validity not exceeding five years and shall indicate whether there are specific conditions or limitations associated with the certification,* [1]

The EU In-Vitro Medical Device Regulation (IVDR) also has similar clauses in Annex VII section 4.8 [2]

Issuing certificates with specific conditions, provisions or limitations had been a possibility under the Medical Device Directives 93/42/EEC and 90/385/EEC. The MEDDEV Guidance 2.7/1 revision 4[3] published in June 2016 recommends the possibility of increased notified body surveillance for '*breakthrough*' products and devices with an '*unmet medical need*'. Section A8 of this guidance considers that the notified body should conduct annual assessments of devices that are considered breakthrough to ensure that Post Market Clinical Follow Up (PMCF) results are monitored closely, these activities would have typically been conducted outside of a usual conformity assessment timeline or process.

Specific conditions, provisions or limitations on certificates provide opportunities for the manufacturer and the notified body to support innovation within Europe but also ensuring the controlled release of medical devices by safeguarding patients against the unknown risks that may typically exist with novel devices.

Use of such specific conditions, provisions or limitations can also provide an opportunity to gather additional fast paced real-world evidence to compliment the clinical evaluation.

[1] REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

[2] REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

[3] CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC June 2016 Revision 4

Examples of specific conditions, limitations or restrictions on a certificate could include (non-exhaustive):

- Ensuring that there is an agreement between the manufacturer and the notified body that interim surveillance of PMCF activities may be required e.g. on a 6 monthly basis outside typical scheduled activities such as technical file surveillance or evaluation of Periodic Safety Update Reports (PSURs).
- Limiting the intended purpose of the device, ensuring that when the device is used in certain population groups, (e.g. paediatrics) additional PMCF data is required to be generated to complement the clinical evaluation.
- Limiting the validity of the certificate e.g. reducing the certificate validity from the typical 5 years to 3 years.
- Ensuring that there is an agreement between the manufacturer and the notified body that the device is limited to the sale of certain medical institutions where appropriate resource, experts or trained individuals are employed to use the device.
- Mandatory input of safety and performance data for all devices used into a registry.

In August 2022, the EU Commission published guidance MDCG 2022-14[4], on exploring the use of certificates of specific conditions, provisions or restrictions noting that '*the possibility for notified bodies to issue certificates under conditions or combined with the requirement to carry out PMCF / PMPF studies'.* This work is still ongoing, and TEAM NB remains committed to supporting this initiative.

A reference to the use of certificates with conditions and how this can be pragmatically applied was recently published in EU Commission guidance MDCG 2024-10 for the clinical evaluation of orphan medical devices[5], the guidance encourages notified bodies to consider this option for such devices.

CORE-MD Research and Publication of Conditions on Certificates.

A recent publication from the Co-ordinating Research and Evidence for Medical Devices (CORE-MD) titled '*Reports on conditions on certificates by notified bodies Deliverable 3.3*' [6] has highlighted the low volume use of certificates with conditions by notified bodies under the medical device directives, but also highlighted the value of this mechanism to support innovation and encouraging increased use of such conditions under the MDR.

TEAM NB is grateful and thankful to the exceptional work and research conducted by the CORE-MD group on this important subject and has seriously considered the recommendations of the report.

TEAM NB therefore encourages all members in line with this published report and in addition to point 17 on the guidance MDCG 2022-14, to continually consider the possibility of issuing certificates with specific conditions, provisions, or limitations under Annex VII section 4.8 of both the MDR and IVDR. Applying specific conditions, provisions or limitations to certificates can ensure that innovative, novel and orphan medical devices continue to be accessible to healthcare professionals and patients in the EU with appropriate surveillance safeguards in place.

[4] MDCG 2022-14 MDCG Position Paper Transition to the MDR and IVDR Notified body capacity and availability of medical devices and IVDs August 2022

[5] MDCG 2024-10 Clinical evaluation of orphan medical devices June 2024

[6] CORE-MD Report on Conditions on certificates by notified bodies, deliverable 3.3, Lopez, Dobrzynska Lozano et al. March 2024. Version 1.0

- **About Team-NB**

Team-NB is the European Association for Medical Devices of Notified Bodies, Team-NB is dedicated to ensure a high level of patients' safety and confidence.

Our three main areas of focus, have been and will remain:

- ❖ The promotion of innovation, but innovation that is backed by solid safety and effectiveness data. The certification of manufacturers' products is essential to continue the confidence in Medical Devices and In-Vitro Diagnostic products.
- ❖ Our support to notified bodies, through our detailed and state of the art guidance documents, ensures a consistent standard is achieved by our members throughout Europe.
- ❖ Ultimately, Team-NB works to ensure continuous improvement of products, leading to increased patient access to safe innovative products.

Our main objectives, have been and will remain:

- ✓ To improve communications with the European Commission, Industry, Competent Authorities and User Groups by acting as a focal point and the single voice of Notified Bodies
- ✓ To promote high technical and ethical standards in the functioning of Notified Bodies
- ✓ To increase competences in decision making processes
- ✓ To make available to the sector a competent work forces as quickly as possible
- ✓ To protect the legal and commercial interests of Notified Bodies in their vital role in the functioning of the three medical device directives.

Team-NB set up **Mirror MDCG-working groups** to allow the members the opportunity to support development of European guidance and enable comments on draft documents in order to coordinate and consolidate input.

Team-NB also set up **task forces** to address specific items in order to harmonise views and come with best practice guides. Today there are 27 tasks forces working on topics such as article 117, classification interpretation, cybersecurity,…

Moreover, the **Team-NB academy** organised several trainings related to the new MDR/IVDR with the aim to help notified bodies deal with new requirements in their assessments. Another purpose is to achieve a better harmonisation among notified bodies thanks to the exchanges that will be favoured during the presentations and the cases studies sessions.
Moreover, **session for harmonisation** has been set up at the senior experts' level to share their experience on burning clinical (MD) and performance (IVD) evaluation topics. The objective is that attendees cascade the info into their organisation to reach all reviewers.
The Team-NB academy has also held several **trainings for manufacturers** on both IVD and MD technical documentation in aim to help them to meet the regulations requirements.

In case of any further clarification needed, please contact : schlemmer(at)team-nb.org.