The European Association of Medical devices Notified Bodies

Team-NB Press Release

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TEAM-NB Notified Bodies call to action to manufacturers to apply. October 2023

1. Background

The In Vitro Diagnostic Medical Device Regulation (EU) 2017/746 (IVDR) has repealed and replaced the previous directive 98/79/EC (IVDD) that applied to in-vitro diagnostic medical devices. The IVDR either increased or introduced new requirements along with requiring notified body certification of many more IVDs compared to the IVDD. The increased requirements under the IVDR, the slow pace of designation of the notified bodies to the IVDR and the Covid-19 pandemic meant that the transition to IVDR from IVDD has been slower than expected. In order to address the slow transition and prevent shortages of IVDs, the amending regulation (EU) 2022/112 of 25 January 2022 introduced staggered extension of transition periods based on the classification of the IVDs. While the amending regulation has provided additional transitional time, the first deadline of 26 May 2025 for Class D devices is approaching quickly. However, the survey results published by the European Commission (as of end of June 2023),https://health.ec.europa.eu/medical-devices-topics-interest/notified-bodies_en, indicate that only 1155 applications have been received by NBs with 500 certificates issued so far. Moreover, only 231 applications have been received for Class D devices with 62 certificates issued so far. Also, it is worthwhile to mention the recent publication by the IGJ that also appeals to manufacturers to take action: https://english.igj.nl/documents/publication/2023/09/05/appeal-to-manufacturers-take-action-to-meet-ivdr-requirements

2. Call to action

This press release is a call to action to raise awareness with the device manufacturers and other economic operators to apply with notified bodies in time. The survey referred to above, also showed that the initial conformity assessment process may take 6-12 months for low to medium risk devices (covered by quality annex certificates) and between 13-18 months for high-risk devices (covered by a product annex certificate). With the deadline for Class D devices fast approaching, and the current timelines for conformity assessment, it is of the utmost importance that manufacturers contact a notified body now and submit their applications as soon as possible.

Notified bodies have the capacity to accept applications under IVDR and complete the conformity assessment process in time if the applications are submitted **without delay**. For class D devices, it is strongly recommended to submit the applications no later than the **end of 2023**, that will allow technical documentation assessments to start in time.

Notified Bodies that are members of TEAM-NB have jointly committed themselves to make time and resources available to process the device applications and complete the conformity

assessments being mindful of the implementation dates mentioned in the transitional provisions of EU 2022/112 if the applications are submitted in good time.
This call to action also means that when applications are not submitted in time, a notified body cannot guarantee that the conformity assessments and certification will be processed successfully before the transition timelines end, leading potentially to problems in the supply chain and access to IVDs in the EU.

3. Recommendations

Notified Bodies that have jointly committed to this call to action give the following recommendations to device manufacturers:

- Contact a notified body of your choice that has been designated to carry out the conformity assessment for the types of devices you have in your portfolio without any further delay. You can find the scope of notified bodies on the NANDO website. https://webgate.ec.europa.eu/single-market-compliance-space/#/notified-bodies/
- Prepare the application making use of the forms, tools, and guidance available and submit them to the notified body on time, including best practice guidance documents representing the views of notified bodies: https://www.team-nb.org/team-nb-documents/

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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 EC 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 25 tasks forces working on topics such as article 117, classification interpretation, cybersecurity, Lifetime,…

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, Experts session for harmonisation has been set up at the senior experts' level to share their experience on burning evaluation topics. The objective is that attendees cascade the info into their organisation to reach all reviewers.

In case of any further clarification needed, please contact schlemmer@team-nb.org