The European Association of
Medical devices Notified Bodies

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PRESS RELEASE

Team-NB views on implementation of MDR/IVDR Regulations

At the Team-NB general assembly meeting, held on October 9th, the members aligned on a strategy including operational aspects to respond to the concerns regarding the difficulties encountered with the implementation of the MD and IVD Regulations (MDR and IVDR).

Notified Bodies play a critical role in the implementation of the MDR and IVDR by ensuring the safety and performance of medical devices and IVDs that are placed on the EU market. Team-NB members have increased their staff significantly within the last decade in preparation for, and to be able to respond to the additional demand on resources created by the MDR and IVDR. Today, most NBs have capacity to accept applications and undertake conformity assessment activities quickly for most types of devices with some capacity restrictions for a limited number of device types. However, some NBs are facing difficulties in planning of their work and keeping their resources occupied due to delays in technical documentation submissions by manufacturers and in receiving responses to questions raised during the conformity assessment process. If such delays persist, it could lengthen the overall certification timelines and lead to potential bottlenecks in the future towards the end of the transitional timelines in 2027 and 2028. Any modification of regulation and associated guidance should prevent to increase such delays.

In recent communications with European Commission and Competent Authorities in answering questions on Notified Bodies priorities to help the implementations of MDR and IVDR, Team-NB emphasised the need to simplify and consolidate divergent approaches associated with a given legislative process/requirement. For example, improved efficiency and transparency could be expected from clear and consistent process of resolving and immediate publication of decisions reached on qualification and classification of devices via mechanisms such as Classification Dispute and the Helsinki Procedure. Team-NB are also in favour of reviewing the data once during a life cycle process and eliminating the need to review and report on the same data as part of different processes, such as technical documentation, PSUR, PMC(P)F, CEAR/PEAR assessments. This would eliminate additional burden and costs associated with reviewing the same data multiple times.

Notified bodies are in favour of consistent, binding clarification of requirements, such as on classification and qualification, criteria for the application of MDR art 61.10, and clarifying the definition of Well-established technologies including consideration to expand the list of such device types via delegated acts. In addition, we think the already existing tool of Common Specifications should be used more broadly, especially in the clinical area to specify

the types and levels of clinical evidence required for various types of devices including the Well-established technologies. Further, Team-NB believes that the use of modern IT-tools could help improve the efficiency of the conformity assessment processes, so that in the end, notified bodies will assess data directly, and not documents.

Team-NB members endorsed an updated version of the Code of Conduct a month ago. This updated version adopted typical durations for various parts of the conformity assessments and surveillance processes. These rules adopted by Team-NB for its members is a testament to our commitment in improving harmonisation, transparency, and predictability of the certification processes for manufacturers. Team-NB are also in support of any efforts to harmonise the rules and their interpretation by Competent Authorities associated with designation and monitoring of notified bodies.

Notified Bodies are conscious of the importance of the SMEs in the sector (up to 77% of clients of Team-NB members), and Team-NB are in favour of increasing the EU level financial support available to the SMEs for the certification process, as it exists in some Member States today.

As stated in former position papers, members of Team-NB are in favour of harmonised, fast-track pathways across EU for breakthrough and life-saving products (orphan, rare disease) to enhance early access to such devices and to promote public health while backed and supported by measures such as EU registries or the monitoring of the market via tools such as EUDAMED.

Team-NB looks forward to working with various stakeholders in improving the implementation of the MDR and IVDR.

- **About Team-NB**

Team-NB is the European Association for Medical Devices of Notified Bodies, Team-NB is dedicated to ensuring 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 to coordinate and consolidate input.

Team-NB also set up **task forces** to address specific items 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, etc.

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.