The European Association of
Medical devices Notified Bodies

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PRESS RELEASE

IVDR Technical Documentation Training for Manufacturers

Team-NB has organized a training for manufacturers of in vitro diagnostics medical devices on the content of technical documentation with the objective of meeting regulatory requirements of the IVDR.

This training has been established with the goal to meet the MDCG Position Paper Transition to the MDR and IVDR (MDCG 2022-14), while incorporating the recently published TEAM-NB Best Practice Guide on IVDR Technical Documentation (on the Team-NB web site https://www.team-nb.org/team-nb-documents/#55820824170d7fee2 dated February 25, 2023). Two aspects have been taken into consideration when drafting this training; namely the strengthening of the communication with manufacturers by means of webinars, workshops, targeted feedback and informative sessions and the specific help to SMEs.

The content was elaborated by IVD experts of 7 notified bodies, namely BSI, Dekra B.V., Dekra GmbH, GMED, NSAI, TÜV Rheinland LGA and TÜV SÜD. The topics were presented by IVD experts of IVDR designated notified bodies.

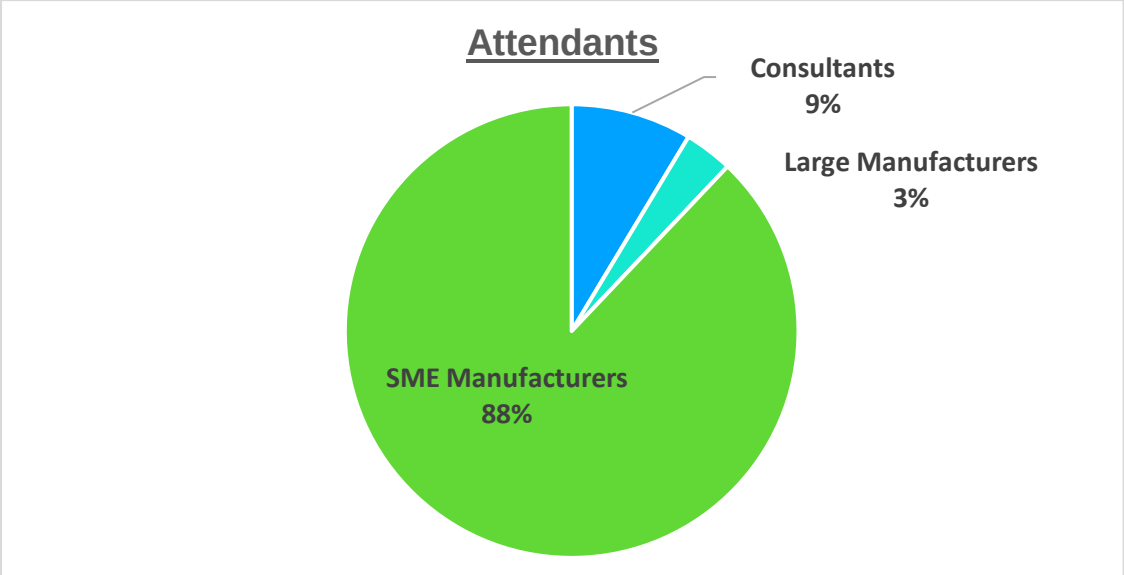
The first session took place on June 14 th.

The session was fully booked leading to Team-NB to set up a 2nd session in September which is now also fully booked. Currently, we are consulting to plan a 3rd session.

The aim of this training is to review the IVDR requirements related to Technical Documentation and share notified bodies insights; it is also planned to review the Team NB Technical Documentation Best Practice document for IVDR (published on March 1st 2023 in the News - All News - Welcome to Team NB | Team NB (team-nb.org)).

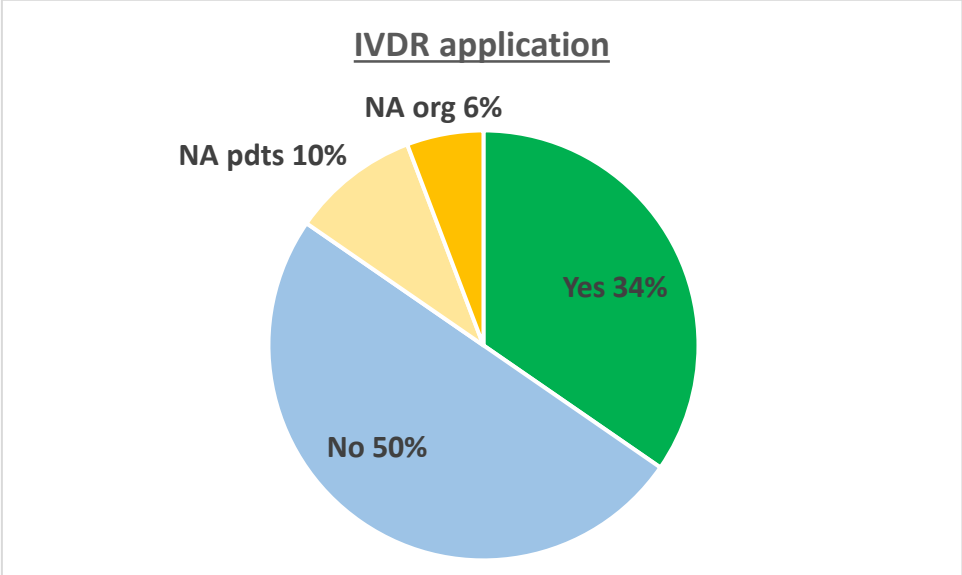
In order to evaluate the outputs of this 1st training session, a questionnaire was sent round to the participants through ZOOM; you will find below the responses of the participants to some questions asked, below.

At the question what type of IVD manufacturer / others are you?
Thanks to the responses put in form into the below graph, we can see the objective to inform the manufacturers and more specifically the SMEs is clearly ~~not~~ met.



To allow an estimation of organisations that have sent in an IVDR application with a Notified Body, it was proposed the below possibilities of answers :

- Yes, an application was sent to a Notified Body;
- No, an application was not sent to a Notified Body;
- not applicable for our products;
- not applicable for our organisation;

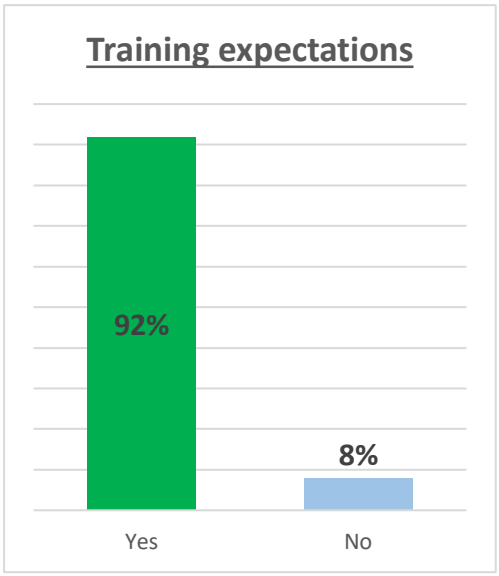


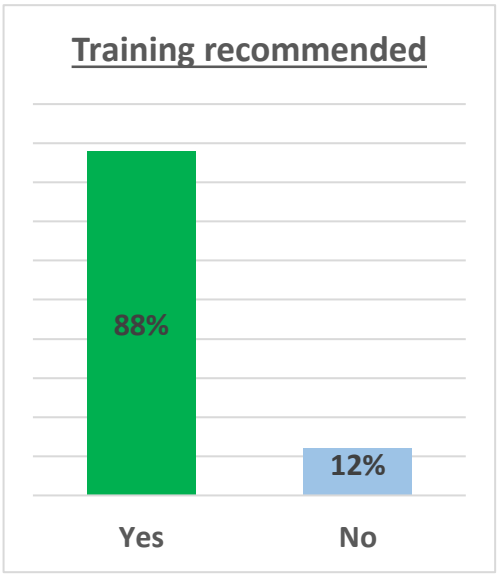
It is interesting to see the information regarding the repartition among the attending IVDR manufacturers when excluding the consultants from the attendees and accounting to 94% as a total which gives:

- 11 % of organisations which have products not requiring Notified Body certification
- 36 % of organisations which applied to a Notified Body
- 53% of organisations which have products requiring Notified Body certification, but have not applied yet

Of course, it should only be considered as an indication as the sample size is too small.

Concerning the achievement of the expectations of the attendants and the recommendation to follow this training to colleagues the responses shows that Team-NB reached a very good level of satisfaction with:





Thanks to the evaluations of the participants, the feeling of success of this 1st training can be better substantiated. The goal is to continue our effort in order to best help manufacturers to meet the requirements of the IVDR.

- **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