The European Association of
Medical devices Notified Bodies

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PRESS RELEASE

MDR Technical Documentation Training for Manufacturers

Team-NB is pleased to announce the results of participation in the eighth training session regarding the requirements related to Technical Documentation of the Medical devices Regulation (EU) 2017/745.

Team-NB has developed and is delivering training courses for manufacturers in response to some of the actions associated with Notified Bodies from MDCG 2022-14 and to specifically support Small and Medium Enterprises (SMEs) by enhancing their understanding of the legislative requirements.

Team-NB has also supported this initiative in MDCG 2022-14 by making freely available to all manufacturers best practice guides for Technical Documentation.

Team-NB intends to further strengthen its communications and support of manufacturers via other means such as publication of other best practice guides, webinars, workshops, targeted feedback and informative sessions in the future.

The MDR Technical Documentation course and its content were developed by medical devices experts from 11 notified bodies, namely BSI, CeCert, CeCertiso, Dekra B.V., DNV, ECM, GMED, NSAI, SGS, TÜV Rheinland and TÜV SÜD with the main aim of helping manufacturers to better understand the requirements and prepare/establish technical documentation that is compliant to the requirements of MDR. The course was also delivered by notified body experts who have real world experience conducting conformity assessment.

The objectives of the training course were to:

- Explain the technical documentation related requirements from MDR;
- Cover aspects of the recently updated Team-NB Best Practice Guide on MDR Technical Documentation towards guidance on preparing technical documentation submissions;
- Share notified body interpretations, insights and first-hand experiences from technical documentation assessment

The course also included an interactive “Questions and answers” session to provide more practical guidance on topics of interest from the attendees.

The course that took place on February 12th was the eighth training on this topic. There were 95 attendees from 54 different organisations with more than a half being SMEs who also benefited from reduced pricing for the course.

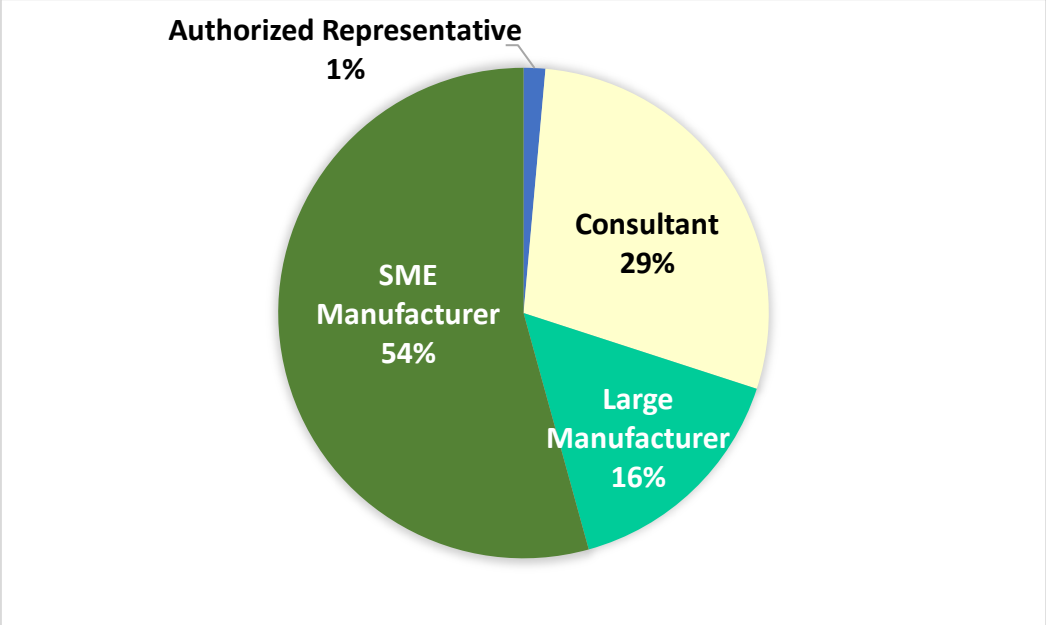
In total, as part of this initiative, Team-NB organized 8 trainings in 14 months for medical device manufacturers on the topic of MDR technical documentation. During these 8 trainings, we trained 625 participants from 353 organizations.

Feedback was requested from the participants via a questionnaire to evaluate the outcomes of the course and also to understand the progress of the manufacturers towards their transition to MDR.

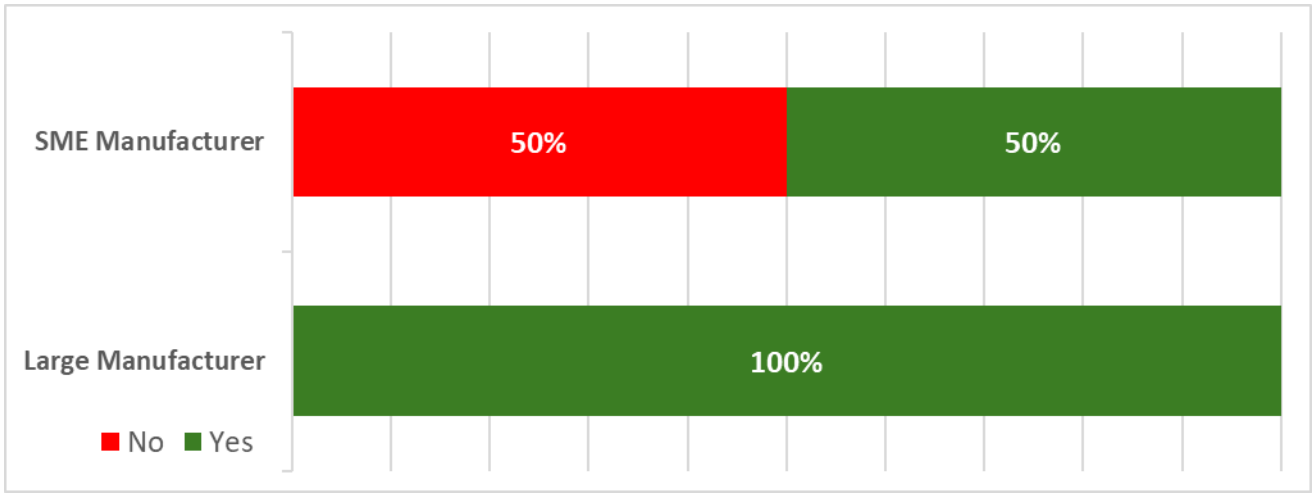
Key highlights from the feedback provided are shared below:

Our 1st question was intended to have a better view on the distribution of the course participants and the question was: “what type of MDD manufacturer / others are you?”

The responses (N=70) showed that most of the participants were manufacturers and more specifically SMEs, fulfilling one of the aims of this Team-NB initiative to support SMEs.

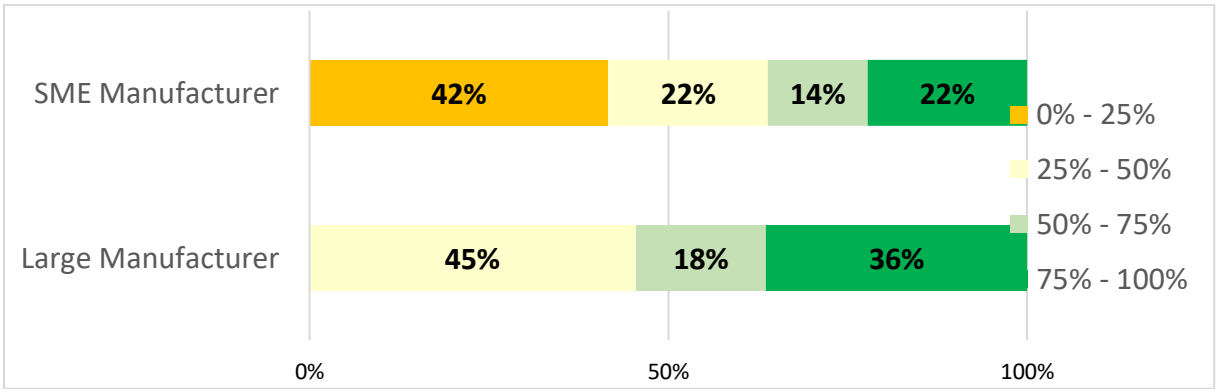


Responses received to the question (posed to manufacturers only; N=44) “Have you already submitted your MDR Technical Documentation to a Notified Body?” indicate that all large manufacturers have submitted at least one technical file/documentation to their Notified Body while only half of SMEs had submitted at least one.



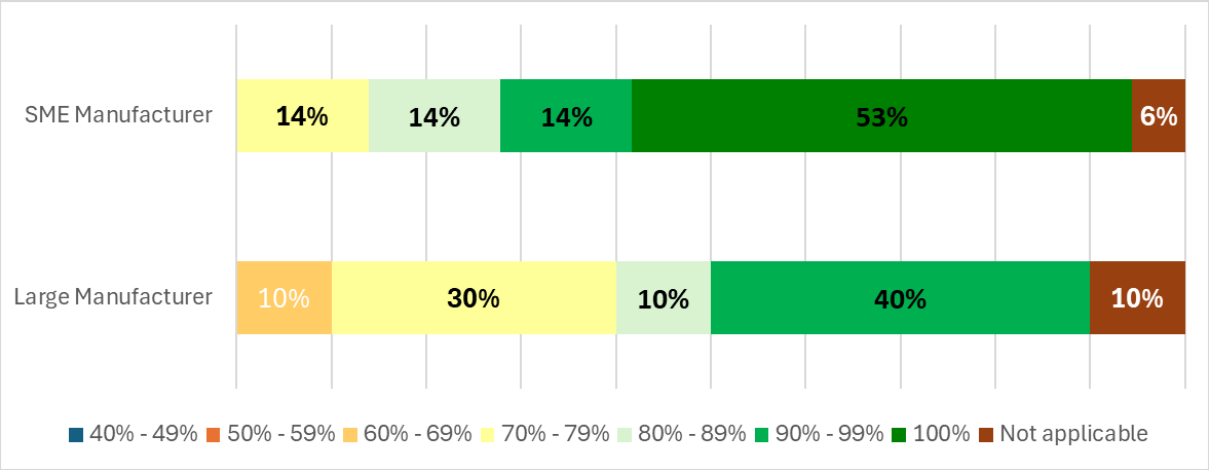
A follow-up question “What percentage of your technical documentation files have you updated for MDR?” was posed to manufacturers only to understand the progress of manufacturers in updating their technical documentation towards MDR compliance.

The responses (N=47) generally indicate that 54% of large manufacturers have updated half of their technical documentation compared to 36% of SMEs who have updated half of their technical documentation. However, this should be considered as an indication only as the sample size is too small to draw firm conclusions.



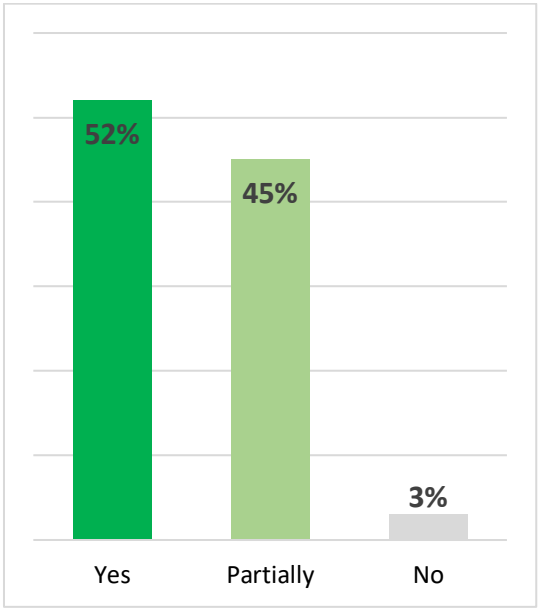
That said, these results demonstrate that there is still a significant effort to be made so that the technical files can be submitted to the notified bodies for certification. It should be remembered that the certification process according to the MDR is longer than before. These figures and the postponement of submissions identified by the notified bodies make us fear that regulation EU 2023/67 will simply have postponed the problem and that we will be faced with a new bottleneck in 2 years.

Furthermore, we thought it would be interesting to have answers to the question: What percentage of the medical device portfolio does your company intend to certify in accordance with the new MDR regulations and thus continue to market?



When you consider only manufacturers responses, you get the above results based on manufacturer size.
It is interesting to note that more than 50% of SMEs will continue to market their entire product portfolio and that 95% of these SMEs will continue to market almost 3/4 of their product portfolio. As for large companies, they will continue to bring 60 to 99% of their product portfolio to market.

The training course was considered a success with 97% of the attendees indicating that their expectations were at least partially met and that majority of the attendees would recommend the training to others.



Based on the success, Team-NB's goal is to continue our efforts to help manufacturers to meet the requirements of the MDR and IVDR.

The next meeting regarding technical documentation is scheduled for June 17th.

In addition, in response to requests, an additional half-day training session dedicated exclusively to clinical aspects will be organized on May 7th.

- **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