One Year of Application

Starting on November 26, 2017, organisations seeking notification status as Notified Body for the MDR and/or IVDR were allowed to send their applications to the responsible national competent authority. One year has gone by and this is the time to provide both a brief overview of the current status and thoughts about the near future until the date of application of the MDR.

In July 2018 NB-Med has started a survey asking existing Notified Bodies some details about their application process. 37 Notified Bodies responded at that time providing detailed information about their status as well as the scope of their application. As a summary of this survey:

- The clear majority of the existing Notified Bodies have decided to apply for the new regulations
- Not all Notified Bodies seeking notification status have submitted their application at that time
- Very few Notified Bodies have not decided whether they are going to apply for the new regulation
- All scopes, MDR and IVDR, are covered by the applications. Not a single product scope stays untouched
- Most Notified Bodies reported a significant increase of their resources.

Starting with the first Joint Assessment in April 2018 discussions are mounting regarding this designation process and the possibility that all applicants can become a Notified Body in time. In time is often seen as a time well in advance before May 2020 to allow the new Notified Bodies to conduct audits and certify manufacturers and products according to the new MDR.

Many manufacturers, healthcare professionals and other stakeholders fear that insufficient number of Notified Bodies will be designated on time enabling them to start managing the waves of submissions for initial certification according to the new legislative framework. There are also doubts about the capacities of already designated Notified Bodies under the current system (MDD/AIMDD/IVDD). Those doubts about insignificant capacities are also based on the fact that the expectations of the Joint Assessment Teams on resource qualification is dramatically increased compared to the requirements laid down by previous directives.

With this paper Notified Bodies would like to express their concerns on the future and to clarify the situation from their point of view.

What are the main concerns of Notified Bodies?

- Implementation period, May 2017 until May 2020, is too short for all stakeholders, taking into account that many details for both, manufacturers and Notified Bodies, are still under discussion
- Missing Guidance Documents enabling clear interpretation of specific requirements
- Unclear process behind the divergent opinions from the Joint Assessments
- Unharmonized interpretations of the Joint Assessment Teams and the various member states
- Capacity shortage for some medical device codes
- Workload for two legislative frameworks running in parallel for a period of time, from May 2020 until May 2024

Very important: we need to sharpen the questions we are experiencing

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Question:	Is it possible that all manufacturers and all products will be certified according to the new MDR before May 2020?
Our answer:	Most likely not - because the “new” Notified Bodies will not be able to assess and take certification decisions for all applications before May 2020!

Why do we not believe that this is possible?

Reason #1:	Notified Bodies will be designated step by step, and some Notified Bodies will be designated just few days before the date of application in May 2020 - or even later.
Reason #2:	The time left for Notified Bodies between the publication in the NANDO database and the date of application in May 2020 is well too short.
Reason #3:	Notified Bodies have to implement completely new procedures and have to hire, train and develop additional new resources for the new regulation(s) which cost time and efforts that are not available. Additional resources are necessary as the new regulations put much more duties on the shoulder of Notified Bodies (e.g. assessment of SSCP and PSUR).
Result:	Most of the manufacturers need to make use of the extended grace period until May 2024. For manufactures of other than class I devices this makes it absolutely necessary to have valid MDD/AIMD-certificates available after May 2020 by applying from now on for renewal of the currently available certificates. This step will lead to additional workload on notified bodies desks and will hinder the acceptance of new product applications leading to a bottleneck in the whole approval process.

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Question:	Will Notified Bodies be able to certify all class I R devices before May 2020?
Our answer:	Notified Bodies are fully aware about a number of these devices through their current customers. Many class IR manufacturers or software manufacturers do not use a notified body at this moment of time and will submit surprisingly applications which are not planned by the Notified Body. This process will lead to additional problems and will not enable a soft assessment and certification of these products. Moreover, the time remaining to assess and certify these kind of devices is getting less every day we do not have a designated notified body leading to additional capacity problems.

Big Waves Are Coming!

How do Notified Bodies predict the future work load? The graph below shows our prediction of the future waves coming, as can be seen, it is not only the initial audits according to the new regulations that will place burden on the shoulders of the Notified Bodies. There are more waves coming, e.g. SSCP, PSUR, ISO 13485, MDSAP etc.