The European Association Medical Devices - Notified Bodies

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	Position paper : Debriefing of General Assembly of Team-NB of October 11, 2016	

On October 11th took place the General Assembly meeting of the Team-NB (The European Association for Medical Devices of Notified Bodies) association with the presence of 90% of the members.

First it has to notice that as promised at the last NB-Med meeting of April, due to the situation of the process of re-designation of notified bodies, we have asked our members (currently 22 in number) which organizations are intended to submit for the re-designation and for which Regulation.
All the members have responded and the results have been published on our website.
We expect that the publication of this list is reducing the uncertainty for manufacturers on which number of notified bodies is intended to be in business in the future.

At the yesterday evening meeting, we have reviewed also the best allocation of our resources to meet our goals of harmonization of working methods among notified bodies. With the upcoming draft MDR and IVDR we face much more and more stringent requirements for notified bodies and their work practices.

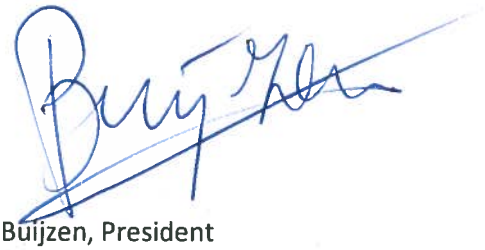
As we have mentioned during the April meeting, we have started before the summer the project to review, interpret and harmonize the content of the draft MDR and IVDR for our members. We have a lot of committed participants in the meetings and tele-conferences. Those meetings are taking a lot of our resources.

In this framework, it is clear that the current Code of Conduct has served our members in the recent years to harmonize defined best work practices. But we have concluded that it is logical to focus now on the working groups as mentioned before and to allocate for the coming timeframe our resources for working on those goals. As a consequence, we decided to suspend the current Code of Conduct audits till we can re-start those against the new set of the requirements of the MDR / IVDR.

As far as our interpretation / harmonization project is concerned, we achieved in the MDR / IVDR working groups our first goal to review the Chapter IV and Annex VI and come to common understanding of that.
The next target is to have preparation of the set of documents needed for the submission for the re-designation; beginning tomorrow!

We have the intention to set up an overall type of handbook with high level "process flowcharts and checklists" to support our members in their implementation to pass the re-designation and the associated joint audits.

Some of the documents on the proposed interpretation in a harmonized way regarding MDR/IVDR will be publicly available to all stakeholders. It looks that the Commission acknowledges our initiative as far as they are themselves very short on time to prepare interpretation. In this framework they agree on a process following which the proposed harmonized notified bodies interpretation documents will be sent to the Commission for possible review. In case they have comments, they will inform us about potential problems on reasonably short notice. In any case, under our responsibility we will be able to make them publicly available on the Team-NB web site knowing that they could also be available on CIRCABC under NB-Med flag.



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