



The European Association
Medical Devices - Notified Bodies

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15th Anniversary Press Release	

On this April 11th, 2016, Team-NB, The European Association of Notified Bodies in the Medical devices had its 15th anniversary.

The association formed in 2001 has today 22 members representing 11 countries. At the end of 2001 we counted 23 members with a peak of 35 members in 2012. In 2013, some members made the choice not to implement the Code of Conduct that had become mandatory and 6 of them left the association. Our 22 members today is the result of this decrease and the present trend of-decreasing numbers of Notified Bodies following merges or de-notifications.

The Code of Conduct is considered as a useful tool to prepare the Members to answer-the forecasted requirements in the framework of the new Regulations. It is also a good indicator for the outside world of the fact that the Members who fulfilled the Code of Conduct requirements are in a better position to pass the MDR / IVDR designation audit.

As in the past, it is estimated that the Team-NB members represent about 80% of the world-wide medical device Notified Body certification activity.

At the occasion of our 15th anniversary, a reception took place in Brussels at the Metropole Hotel with a panel of representatives of the Commission, Industry, and of course of Notified Bodies represented respectively by Erik Hansson, Sabina Hoekstra and Guy Buijzen.

The main theme of the panel presentation was information on the state of the new regulations. Although, Mr Hansson was not in position to speak about on-going negotiations and so he focused on “the importance of the role of notified bodies and the current developments and the role of Team-NB in this”.

Amanda Maxwell, a journalist specializing in EU Medtech regulations accepted the role of mediator to introduce the speakers and ensuring a lively discussion with the audience.

The participants had the pleasure to listen to the presentations of the VIP panel and to challenge them with questions.

Team-NB, the European association of notified bodies in the medical devices sector is dedicated to ensure a high level of patients’ safety and confidence.

This year Team-NB celebrates its 15th Anniversary, and we are proud of the achievements we have driven in the global medical device regulatory world. Our three main areas of focus, have been and will remain:

- The promotion of innovation, backed by solid safety and effectiveness data.
- Our support to notified bodies, through our detailed and state of the art guidance documents.
- Continuous improvement of products, leading to increased patient access to safe innovative products.

Team-NB is going to stay at the disposal of all stakeholders in this objective of ensuring a high level of patients' safety and improving patient's welfare.

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