



The European Association Medical
Devices - Notified Bodies

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PRESS RELEASE Team-NB sector survey 2016 April 14 th , 2017	

For the seventh time, all members provided their data to the now annual TEAM-NB survey.

For information, at the time of the data collection, there was 21 members. Today, we have welcomed a new member.

Team-NB, The European Association for Medical Devices of Notified Bodies 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 harmonious 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 areas of focus, have been and will remain:

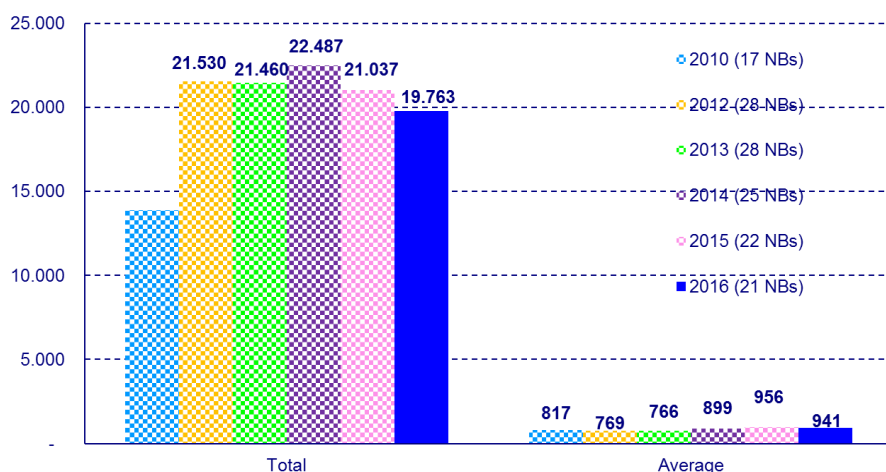
- To improve communications with the EC Commission, Industry, Competent Authorities and User Groups by acting as a focal point and the single voice of Notified Bodies
- To promote high technical and ethical standards in the functioning of Notified Bodies
- To increase competences in decision making processes
- To protect the legal and commercial interests of Notified Bodies in their vital role in the functioning of the three medical device directives.

Moreover, there is 1 year that Team-NB working groups are working on the new regulations in order to help the members to identify and interpret the impact of the new requirements on the notified bodies. The aim is that the members will be ready to submit their applications and pass their designation audit against the new regulations in the quickest time.

You will find below some commented graphs of our 2016 survey.

❖ Evolution of the number of valid EC certificates

Valid certificates issued 2010-12-13-14-15-16



For the 3rd consecutive year, the total number of valid CE certificates **decreased by 6%**

Today, the repartition of the NBs size within the members are:

- 29% big
- 24% medium
- 47% small

The size is defined by the number of certificated delivered with

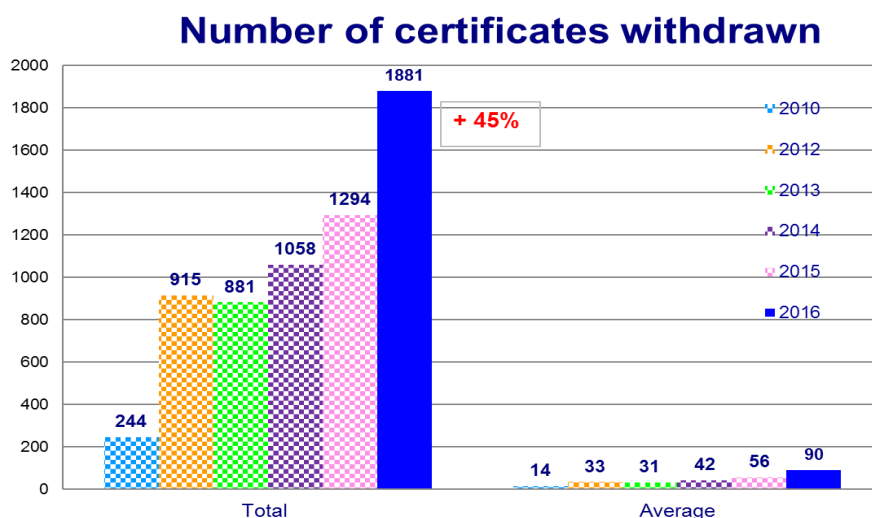
- Big: above 1000 certificates
- Medium: between 350 and 1000 certificates
- Small: less than 350 certificates

As in the past, the vast majority of certificates are issued under MDD with the same repartition as the previous year.

❖ Recent increase in the withdrawal of EC certificates

This year, the key element is the **significant increase - by 45% - of the withdrawn certificates.**

That increase in withdrawn certificates could indicate the regulatory expectations are increasing and TEAM-NB members are toughening up.

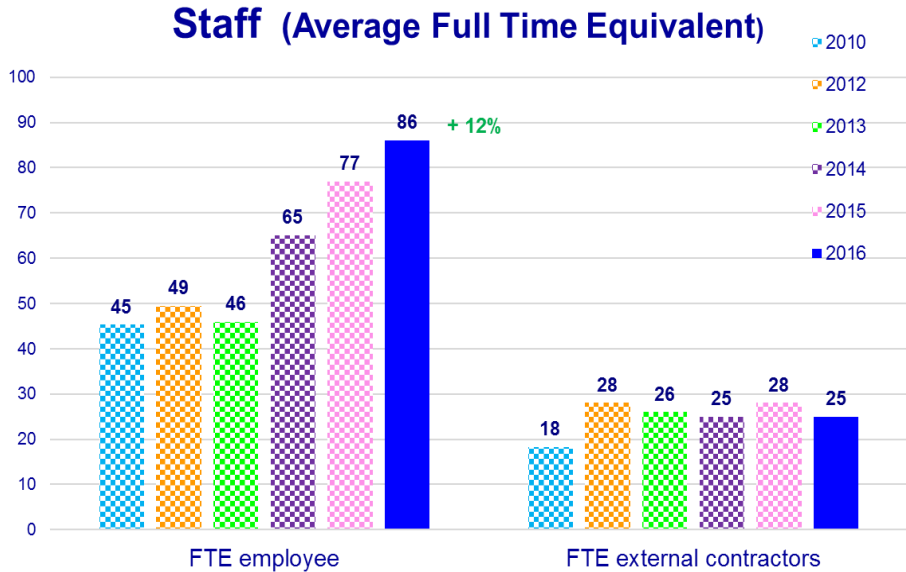


The reasons for the withdrawing identified by the members are:

- reduction number of « OBL » certificate,
- company reorganisation, including closure of location or bankrupt
- lack of payment and/or certification too expensive
- voluntary cancellation and transferred NB,
- requirements not met and/or non-conformities not closed

Total number of ISO 13485 certificates have as the 2 previous years significantly grown - additional 16%. The analyse is the same, manufacturers that could be impacted by a request of certification against the new regulations could be preparing themselves.

❖ **Continuing increase in the number of full time employees**



As for staff, the full time employees are **increasing by 12%**.

There is a small decreased for the external contractors. That could be interpret as the wish of NBs to reach a greater involvement and control in reaching compliance of the staff.

That is the 4th year in a row that the full time employees are growing. This is peculiarly significant knowing that, between 2013 and 2016; on one side the members number decrease by 25% (from 28 to 21) and the full time employees grew by 87%. If we calculate the increase at constant members' number, it would make 149% of increase!

Definitely that shows the concerns of members to meet and anticipate the request for additional work forces to meet the new requirements.

The full survey is available on our web site <http://www.team-nb.org/...>

In case of any further clarification needed, please contact secretary@team-nb.org