



The European Association Medical
Devices - Notified Bodies

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PRESS RELEASE Team-NB sector survey 2017 April 26 th , 2018	

For the eighth time, all members provided their data for the annual TEAM-NB survey.

For information, the current number of members is 24. It has increased by 14% in comparison with 2016.

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 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:

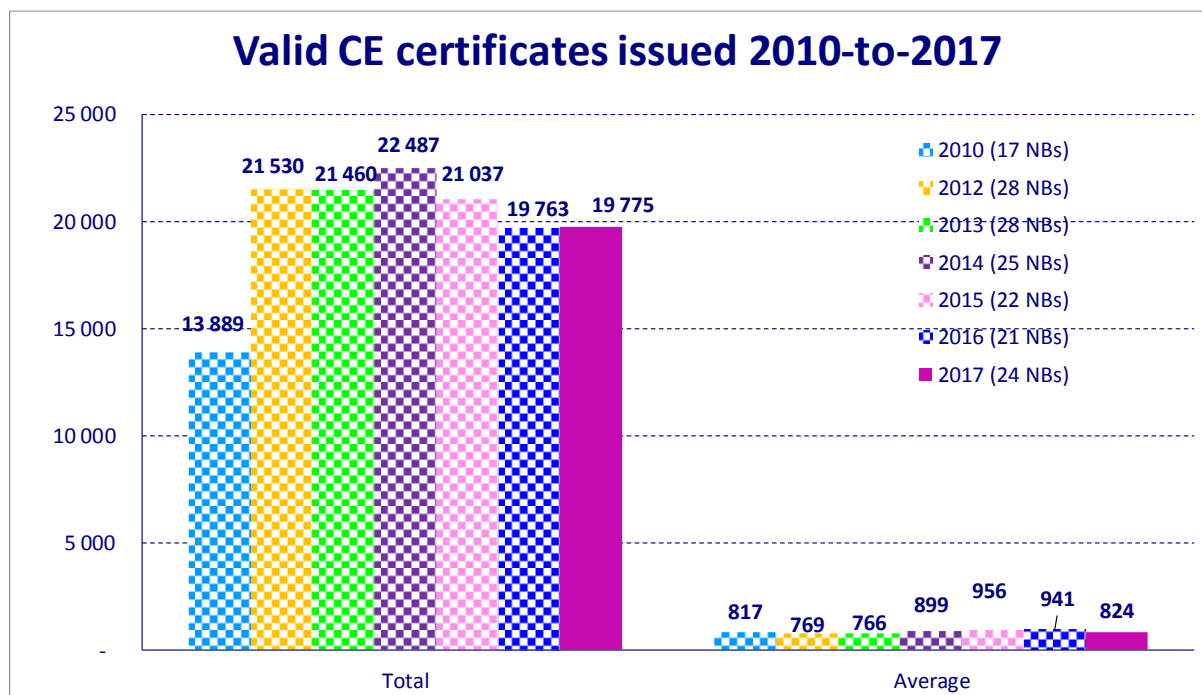
- To improve communications with the EC Commission, Industry, Competent Authorities and User Groups by acting as a focal point and the single voice of Notified Bodies
- To promote high technical and ethical standards in the functioning of Notified Bodies
- To increase competences in decision making processes
- 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.

To have the members designated at the earliest opportunity, Team-NB set up working groups on the new regulations in order to help their members to identify and interpret the impact of the new requirements on notified bodies. The aim was that the members were ready to submit their applications and pass their designation audit against the new regulations in the quickest possible time. Thanks to this preparation, 80% of the members submitted their applications in 2017 and the others planned to do so at the beginning 2018.

You will find below some explanatory graphs of our 2017 members survey.

❖ Evolution of the number of valid EC certificates

After 3 consecutive years of decrease, the total number of valid CE certificates **has stabilised**



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

- 25% “big”
- 17% “medium”
- 58% “small”

The size is defined by the number of certificates delivered with

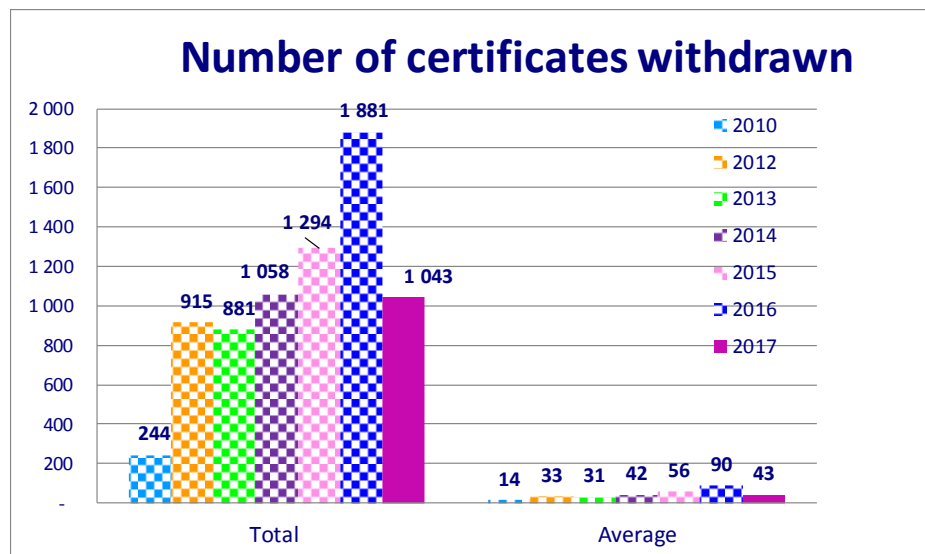
- Big: above 1000 certificates
- Medium: between 350 and 1000 certificates
- Small: less than 350 certificates

The **size breakdown of NBs** evolved from the previous year. In absolute numbers, the number of “big” NBs is unchanged although, it has a small decrease in percentage following the increase of members. On the side of “medium” sized NBs, we note a reduction of both absolute and relative numbers and on the “small” size ones, we note an increase of both absolute and relative (> 10%) numbers.

The **breakdown of issued certificates in 2017** is reasonably the same as last year with the vast majority of certificates issued under MDD (90%), and for the 2 other directives respectively 8% for in vitro diagnostics with a small increase and 2% for active implantable.

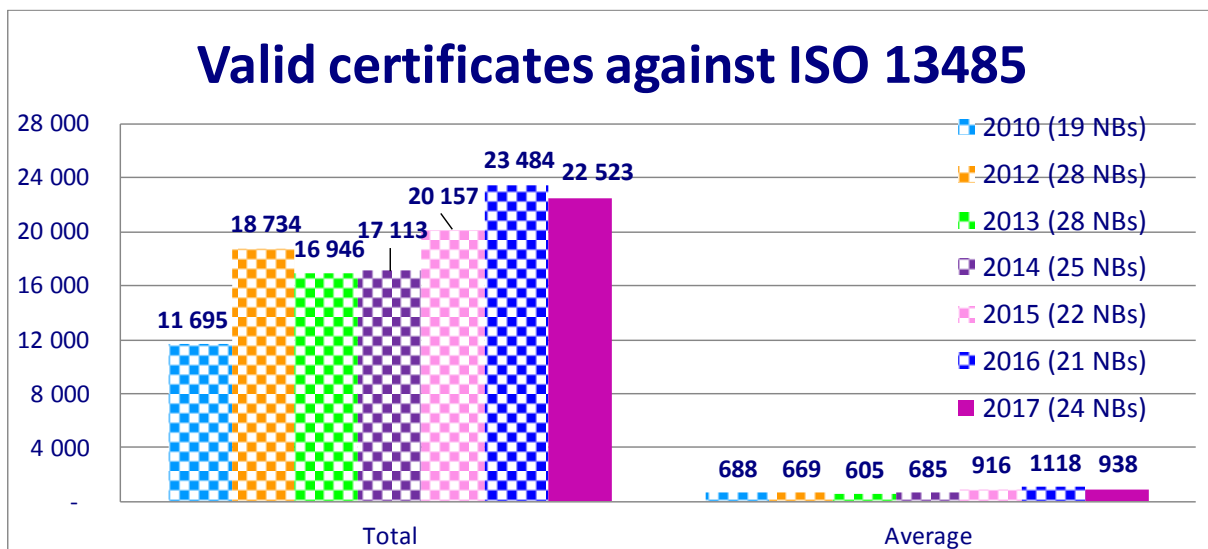
❖ **Decrease in the withdrawal of EC certificates**

After last year increase -by 45% - the withdrawn certificates have decreased to stabilise at the level of the 4 previous years.

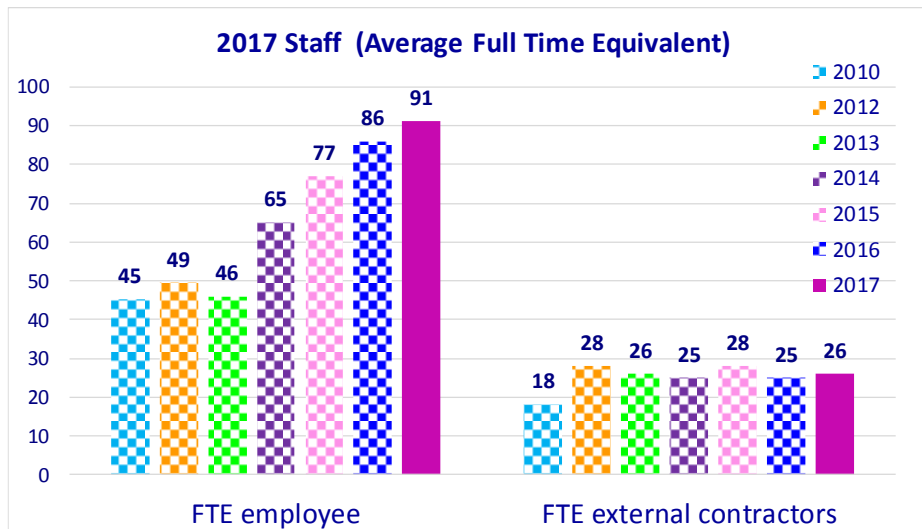


❖ **ISO 13485 certificates**

Number of *ISO 13485 certificates* have decreased by 4% in the total of the members and by 16% in relative figures. Nevertheless, the ISO 13485 certificates number remains at higher level than the CE certificates, because apart from the legal manufacturers there are also suppliers and/or distributors who require an ISO 13485 certificate.



❖ Continuing increase in the number of full time employees



That is the 5th year in a row that the full time employees have increased.

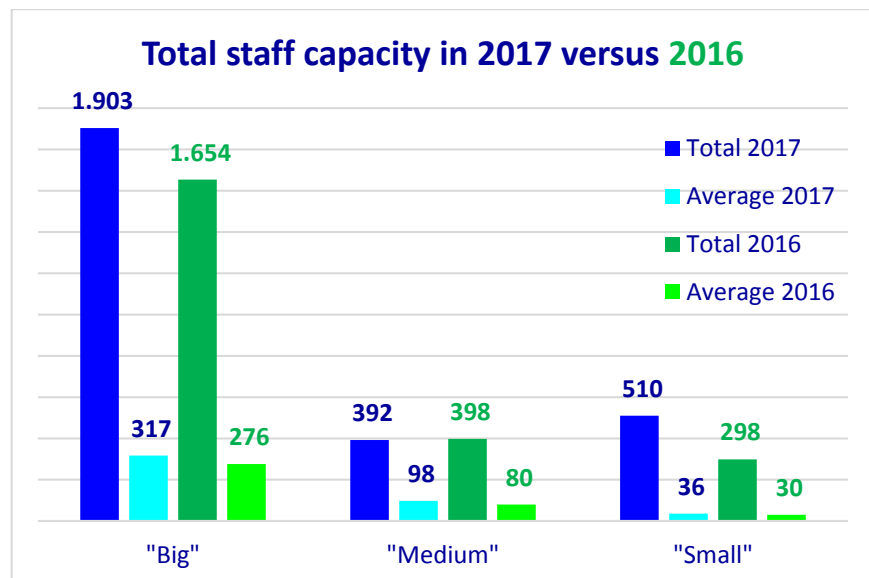
In 2017, the total number of employees of the members are **increasing by 20%**. (with only 6% in average thanks to the increase of members)

The **staff capacity growth** in comparison with last year is relevant to all sizes of NBs.

The “**small**” NBs level of increase is 21%.

At the “**medium**” size NBs level, the level is even more significant with an increase of 23%.

And, for the “**big**” size NBs the level has increased by 15%.



This increases in staff and with the significant percentage of applications against MDR / IVDR submitted definitely show the concerns of Team-NB members to meet and anticipate the request to meet the requirements of the new regulations.

The full survey is available on our web site <http://www.team-nb.org/documents-2018/>

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