

Editor : Françoise SCHLEMMER (FSC)	Date : May, 24 th , 2019
PRESS RELEASE Team-NB sector survey 2018	

Recurrently, since 2008, in order to identify trends, all TEAM-NB members provides their data for the annual sector survey.

The survey compiled the data of the 23 notified bodies, members at the end of 2018. It's one less member than in 2017. That said, it has to be noticed that at the April General Assembly meeting, the members welcomed 3 more members which is bringing the current membership number to 26.

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:

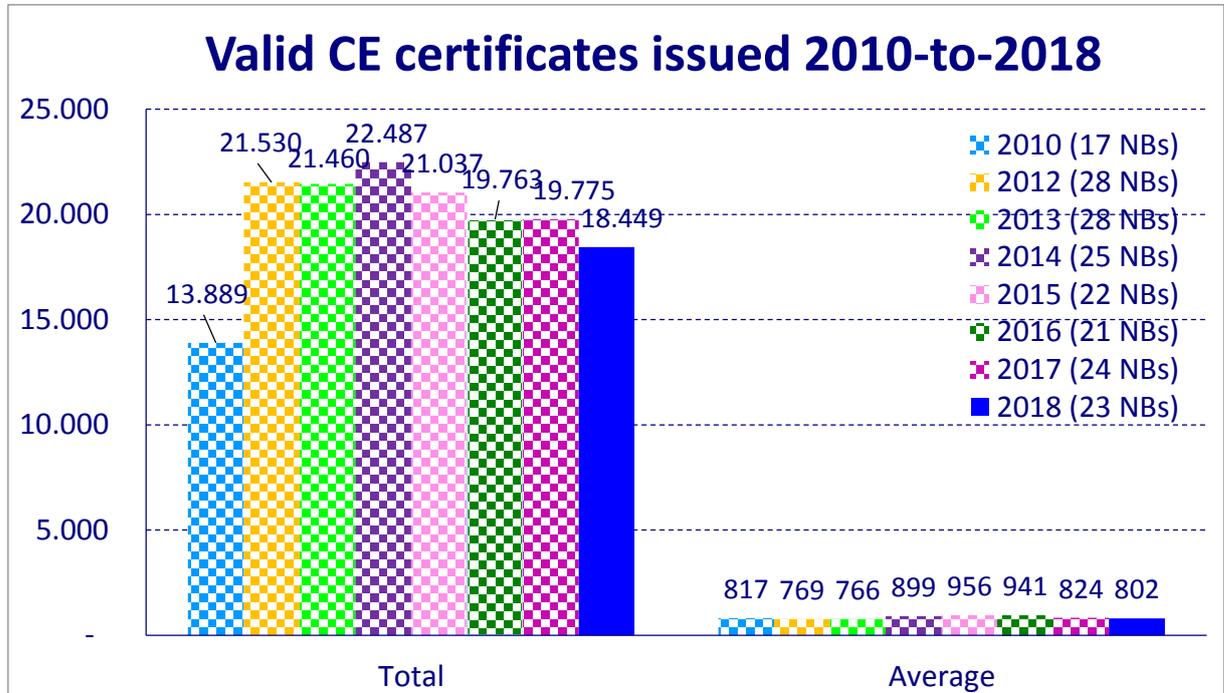
- To improve communications with the EC Commission, Industry, Competent Authorities and User Groups by acting as a focal point and the single voice of Notified Bodies
- To promote high technical and ethical standards in the functioning of Notified Bodies
- To increase competences in decision making processes
- 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. Today 10 of our members are in the last phases before designation.

You will find below some explanatory graphs of our 2018 members survey.

❖ Evolution of the number of valid EC certificates

After last year stabilisation in terms of valid certificates, the downward trend, begun in 2015, continues with a decrease of 6%.



Today, the breakdown of the notified bodies size within the members are:

- 22% “big”
- 26% “medium”
- 52% “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

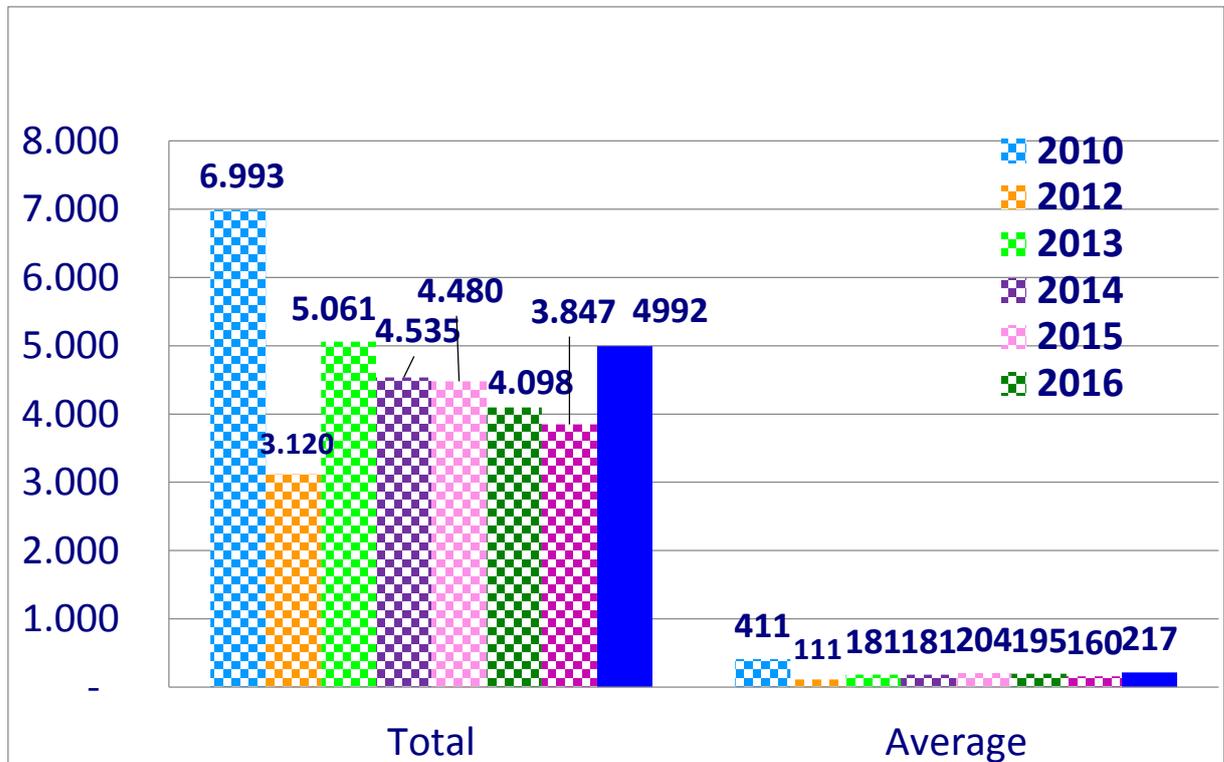
The **size breakdown of notified bodies** evolved from the previous year. In absolute numbers, the number of “big” notified bodies decreased from one unit. Conversely, on the “medium” notified bodies size, there has been an increased form 2 units which has increased the percentage from 17 to 26%. And on the “small” size ones, we note a decrease of 2 units in absolute numbers.

The **breakdown of issued certificates in 2017** is reasonably the same as last year with the vast majority of certificates issued under MDD (91%), and for the 2 other directives respectively 7% for in vitro diagnostics with a small decrease and 2% for active implantable.

❖ **New CE certificates issued this year**

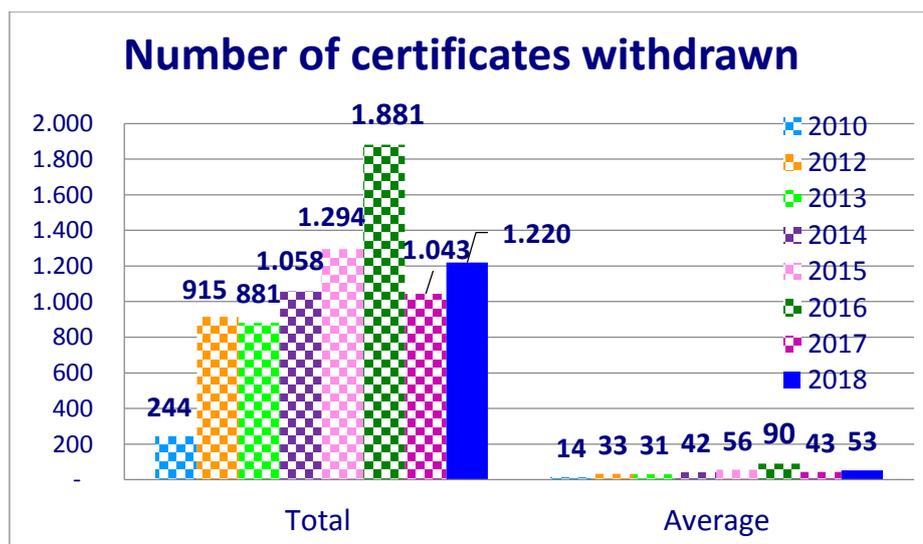
We noticed an increase in new issued certificates with a jump of 30% after several years of decline.

This surely in line with the anticipation of industry in the renewal of their certificates against current MDD legislation in order to avoid the uncertainties of the future.



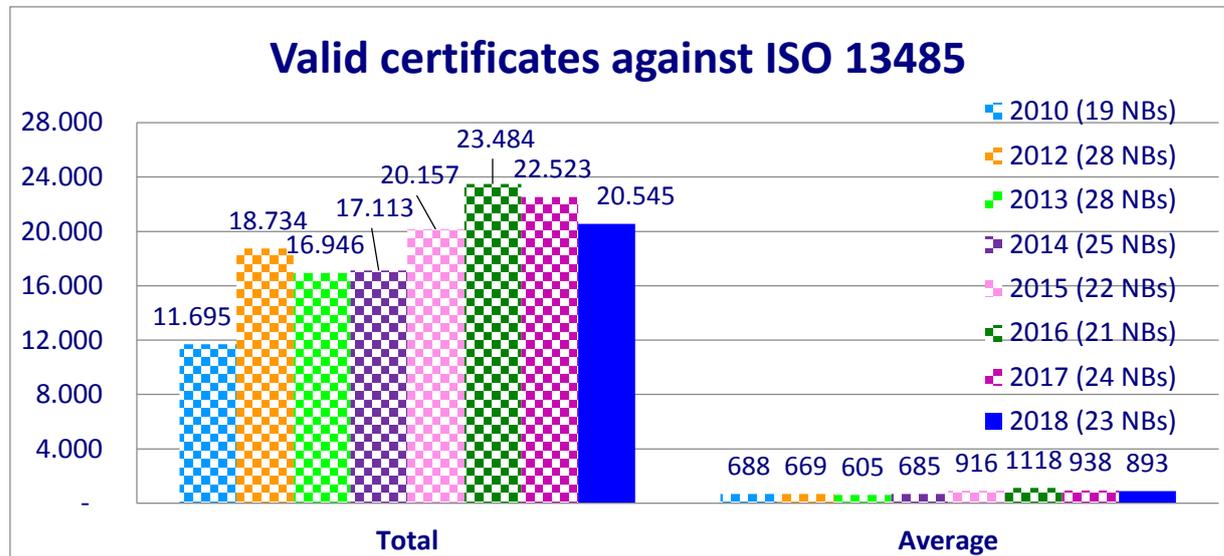
❖ **Decrease in the withdrawal of EC certificates**

After last year decrease - by 45% - the withdrawn certificates have increased by 17%.

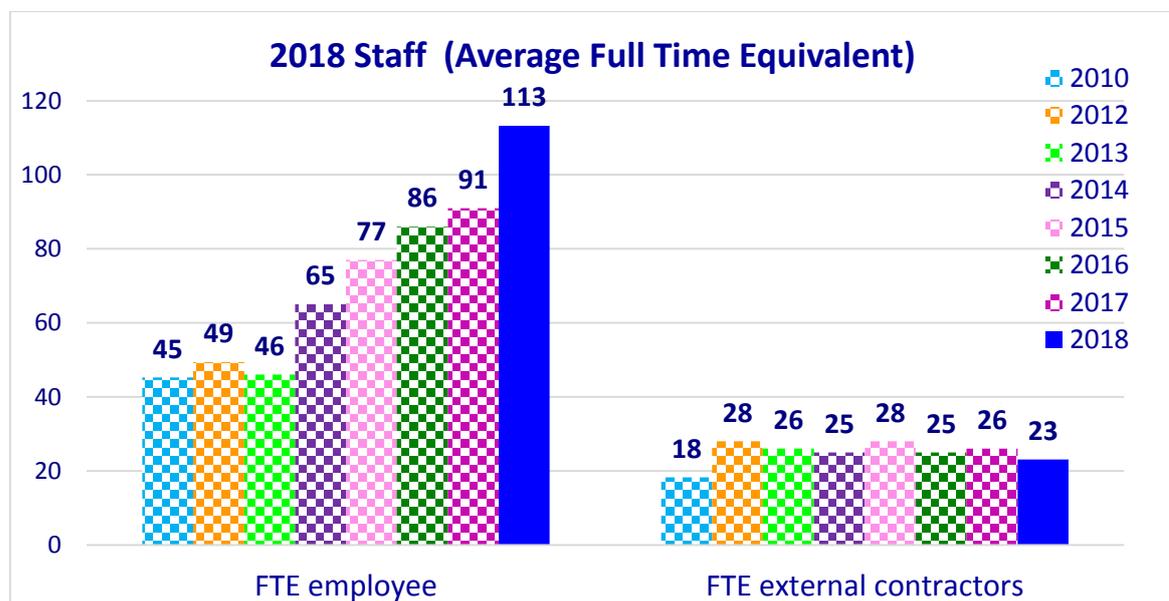


❖ ISO 13485 certificates

The number of *ISO 13485 certificates has decreased* as last year. 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

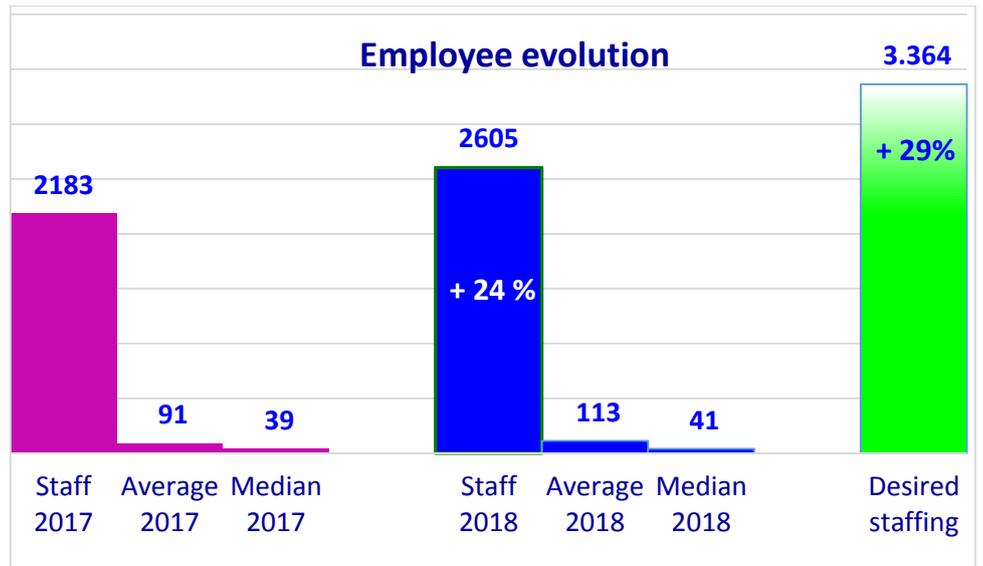


That is the 6th year in a row that the full time employees have increased and thus even in higher proportion than in the preceding years.

In 2018, the average number of employees of the members are **increasing by 24%**.

On the contrary, the number of subcontractors tends to stagnate or even decrease probably to better respond to the regulations requirements.

If we combine, this annual survey with the survey performed in February 2019 on the intention to hire new personnel, the **employee capacity-growth** is definitely in growing increase.



Employee growth, continued effort to hire new recruits as well as the significant percentage of applications against MDR / IVDR submitted (see our former surveys on designations) definitely show the concerns of Team-NB members to meet and anticipate the requests to meet the requirements of the new regulations and the sector needs.

The full survey is available on our web site <http://www.team-nb.org/documents-2019/>

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