

Editor : Françoise SCHLEMMER

Date : May 5<sup>th</sup>, 2020

**PRESS RELEASE**

**Team-NB sector survey 2019**

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

The survey compiled the data from 23 notified bodies, members at the end of 2019. This is the same number as in 2018. Please note that during 2019 all members from the UK resigned their membership. These reductions did not impact the associations total membership as new applications from sister's organisations established in an EU 27 member states were received.

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.

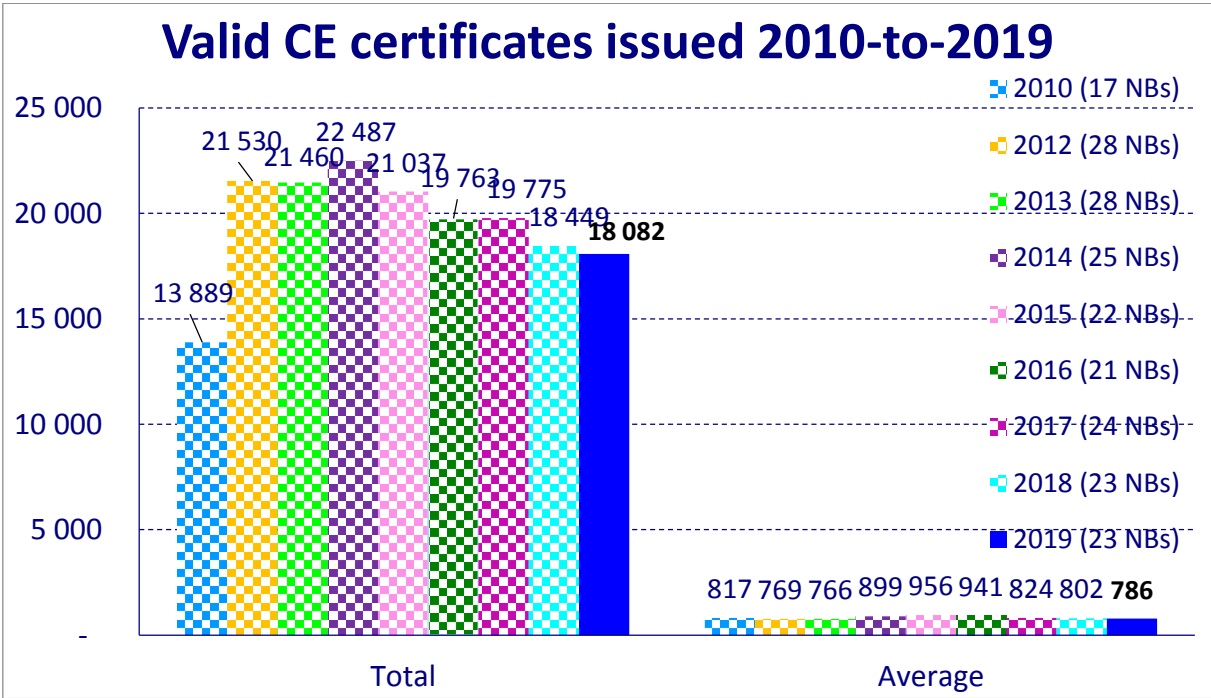
To give the members the opportunity to support development of European guidance and allow comments on draft documents, Team-NB set up **MDCG mirror working groups** in order to coordinate and consolidate input.

Team-NB also set up a **training academy** in order to give training on several topics related to the new MDR/IVDR requirements.

You will find below some explanatory graphs of our 2019 members survey.

- **Evolution of the number of valid EC certificates**

The downward trend in terms of valid certificates, begun in 2015, continues with a small additional decrease of 2 %.



Today, the breakdown of the notified bodies size within the members are the same as last year with the following distribution:

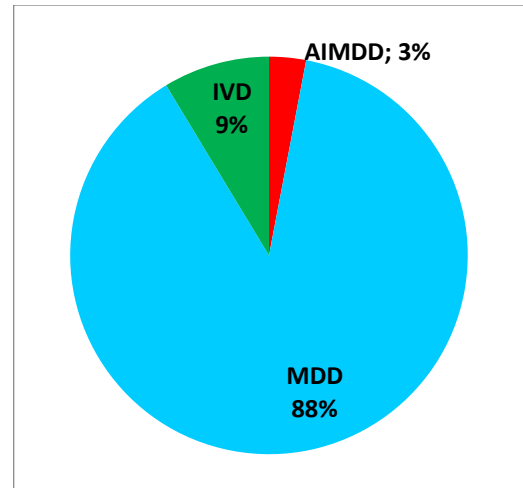
“big”	“medium”	“small”
22%	26%	52%

With the size defined by the number of certificates issued as

above 1000 certificates	between 350 and 1000 certificates	less than 350 certificates
-------------------------	-----------------------------------	----------------------------

The **sharing of issued certificates in 2019** is reasonably the same as last year with

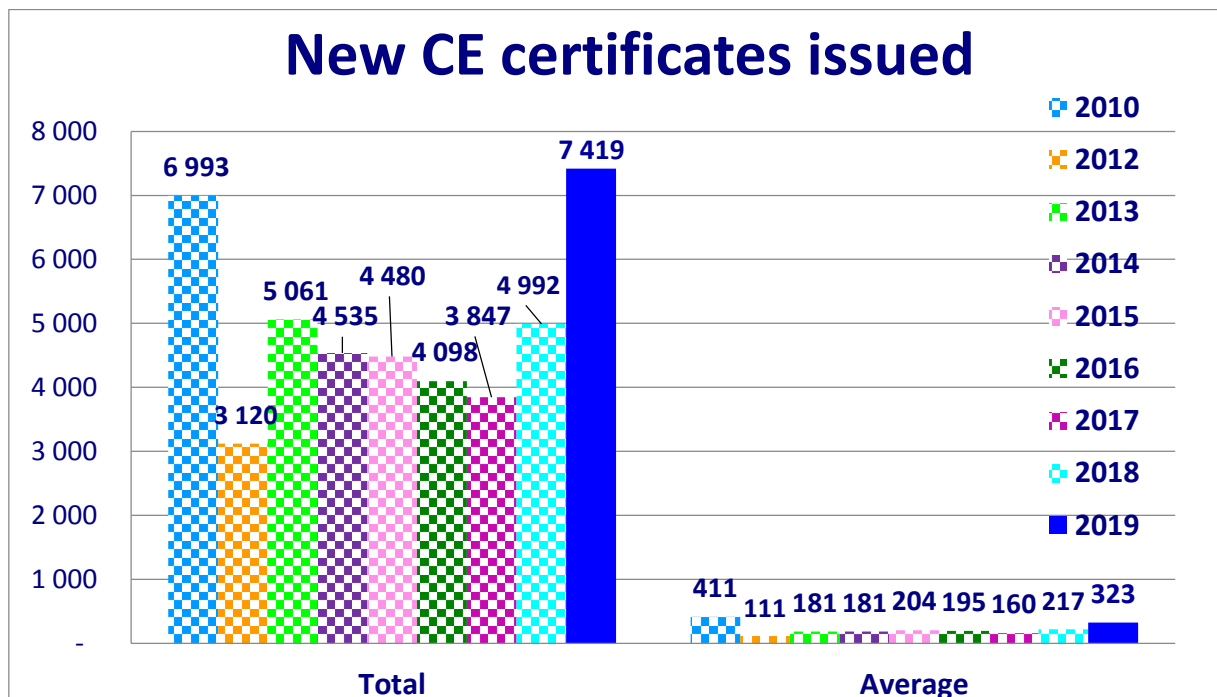
- the vast majority of certificates issued under MDD (minus 2%),
- and for the 2 other directives respectively
- 9% for in vitro diagnostics with a small increase (+ 1%)
- and
- 3% for active implantable (+ 1%).



• **New CE certificates issued this year**

We noticed an important increase in certificates issued in the year with a jump of nearly 50% after 30% jump in the preceding year 2018. This adds to a significant increase in the workload in these 2 years.

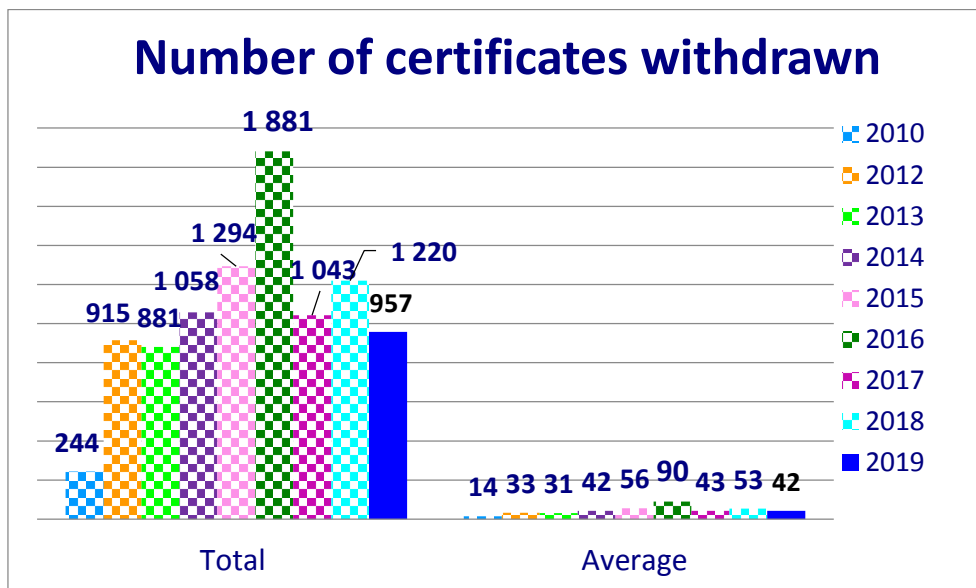
This is surely in line with the wish of industry to renew their certificates against current MDD legislation in order to avoid the need to adapt to the new legislation at short notice.



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

After last year increase, the withdrawn certificates have decreased by 21%.

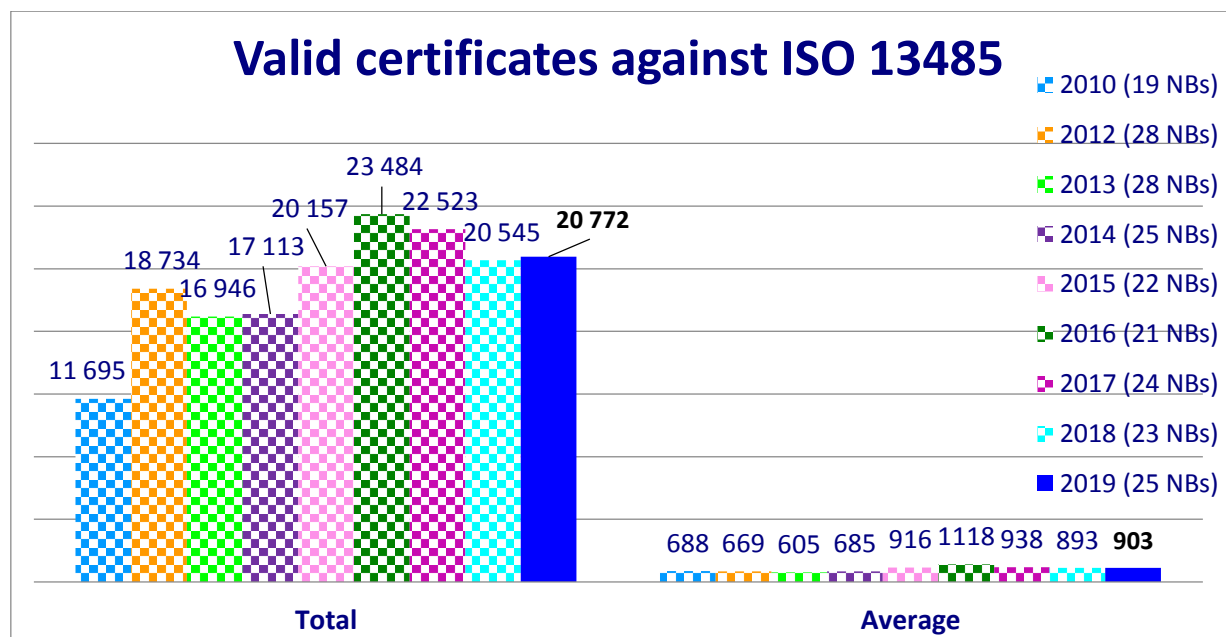
The decrease could be due to manufacturers strategy to maintain devices under current MDD legislation.



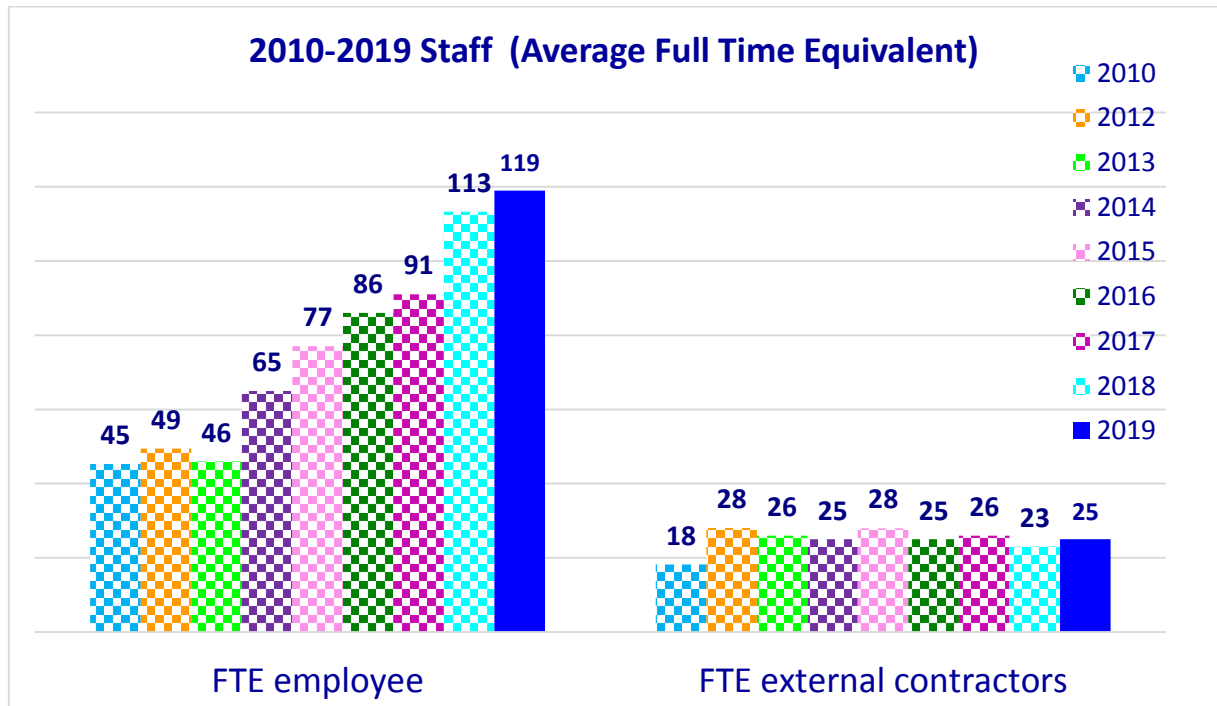
- **ISO 13485 certificates**

The number of *ISO 13485 certificates is stabilised* (increase of 1%) after 3 years of decreased.

We notice, as these last years, 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 7th year in a row that the full time employees have increased. The average number of employees of the members is **increasing by 5%**.

The small increase in number of employees in comparison with the wishes of notified bodies is mainly related to the difficulties to find people with the requested competencies on the market. It is a real problem the notified are facing. That certainly explains, the small increase in number of subcontractors although the trend was a decrease in order to nevertheless respond to the need of the market.

The full survey is available on our web site as a graphical presentation <http://www.team-nb.org/documents-2020/>

In case of any further clarification needed, please contact [schlemmer@team-nb.org](mailto:schlemmer@team-nb.org)