The European Association Medical Devices - Notified Bodies

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PRESS RELEASE

Team-NB sector survey 2020

Annually since 2010, all Team-NB members provided data in order to present figures on the sector for the past year and comparisons with previous years in order to identify trends.

The survey compiled data from 26 notified bodies, members at the end of 2020. This is an increase of 3 members in comparison with the previous year which make a 13% increase in membership. It is a follow up of the increase trend after a stagnation year in 2019 where UK resigned their membership and were replaced by applicants from sister's organisations established in an EU 27 Member States.

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 task forces to address specific items in order to harmonise views and come with best practice guides.

Moreover, the Team-NB **training academy** organised several workshops on different topics related to the new MDR/IVDR requirements. The aim is to allow the auditors of notified bodies to get updated theoretical information as well as practical exchanges in order to help them in their audits.

You will find below some explanatory graphs of our **2020 members survey**.

- **Breakdown of the notified bodies size**

As a piece of information, in the recent years, Team-NB proposed a breakdown of the notified bodies size defined by the number of certificates issued as follow:

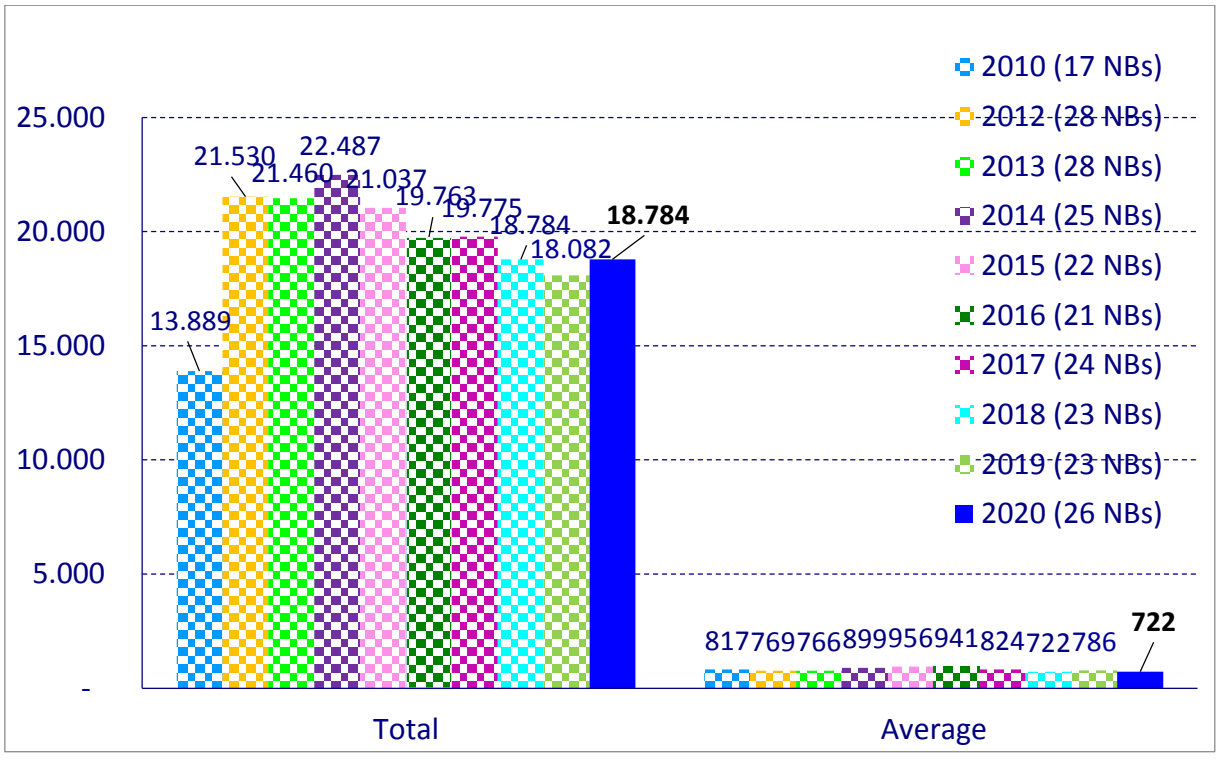
"big"	**"medium"**	**"small"**
above 1000 certificates	between 350 and 1000 certificates	less than 350 certificates

The 2020 distribution is

"big"	**"medium"**	**"small"**
23%	19%	58%

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

The downward trend in terms of valid certificates, has stopped, probably due to the pandemic which pushed Manufacturers to request a re-certification against the directives, with the benefit of a remote audit. Without this opportunity some Manufacturers would have been trapped in a situation without valid certification and no ability to place products on the market.



- **Certificates split among the 3 directives**

The ***sharing of issued certificates in 2020*** is reasonably the same as last year with

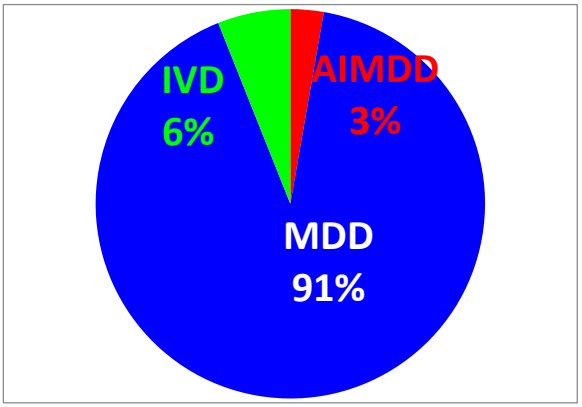
- the vast majority of certificates issued under MDD (plus 3%),

and for the 2 other directives respectively

- 9% for in vitro diagnostics as last year (equal)

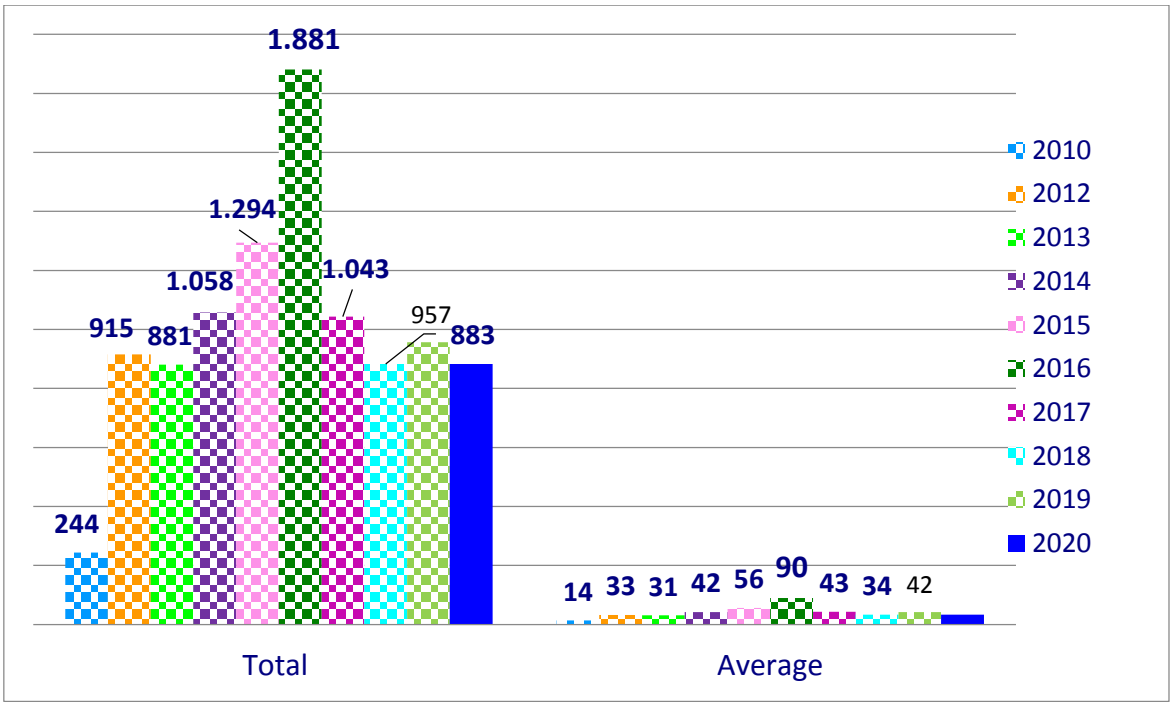
and

- 3% for active implantable (equal).



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

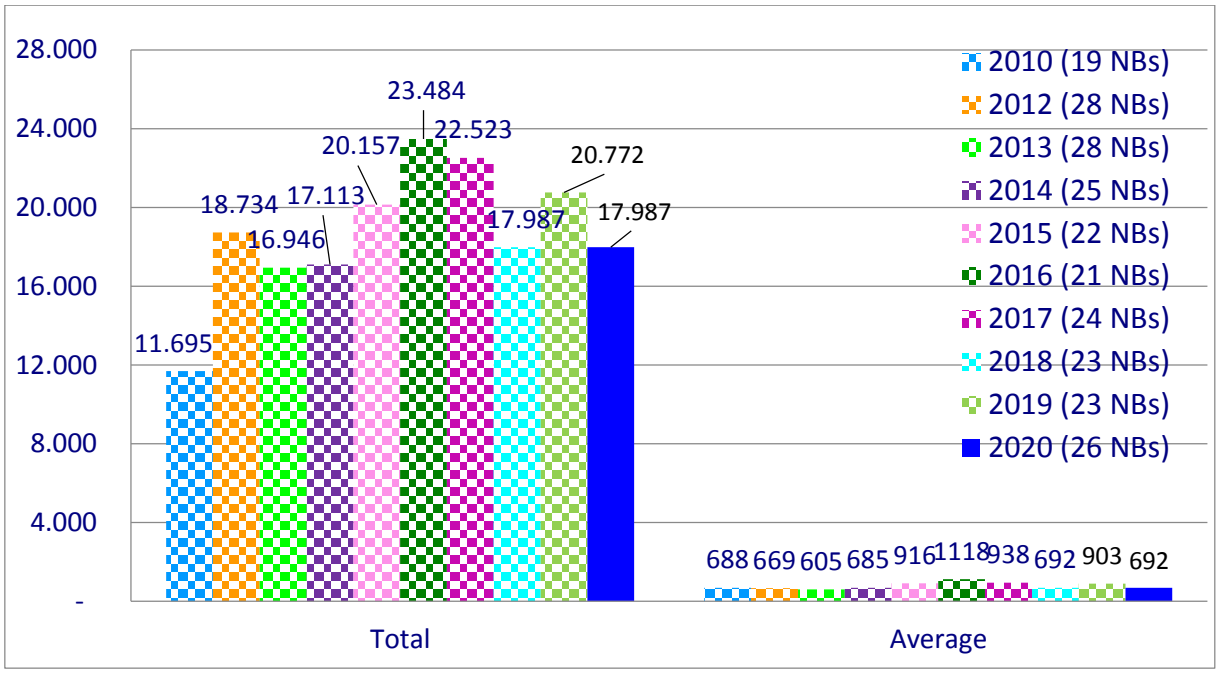
The withdrawn certificates continue its slow decline arguably in line with learning how to respond to new clinical data requirements. Perhaps as well due to the imposed strategy to maintain devices under current MDD legislation.



- **ISO 13485 certificates**

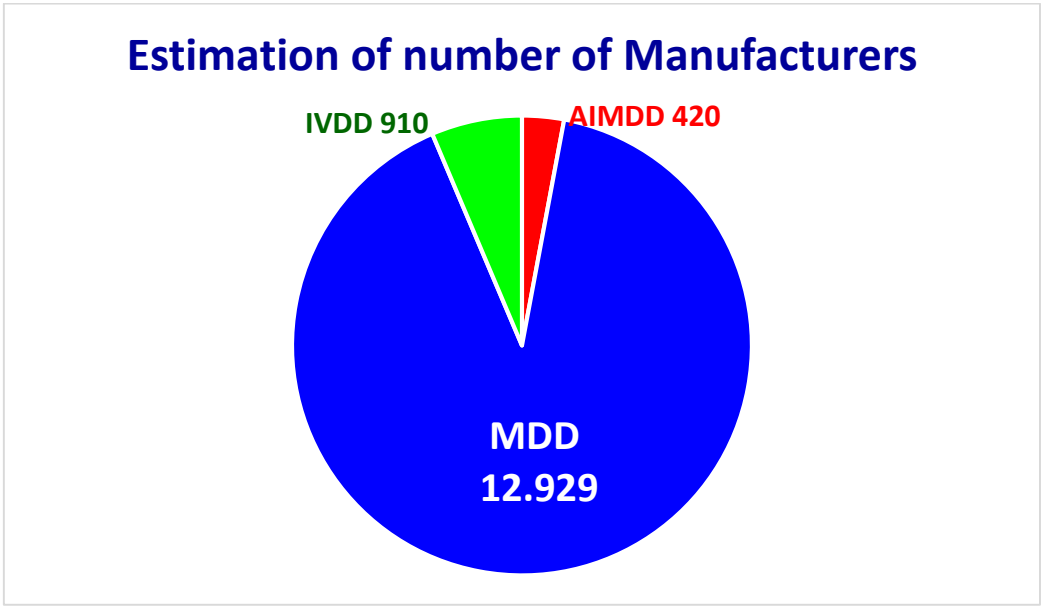
After 1 year of stabilisation, the trend to the decrease of the number of ***ISO 13485 certificates*** has returned.

The number of ISO 13485 certificates is now very similar to the number of CE certificates. Manufacturers holding CE certificates do not require ISO 13485 certificates, however subcontractors, suppliers and/or distributors often hold ISO 13485 certification.

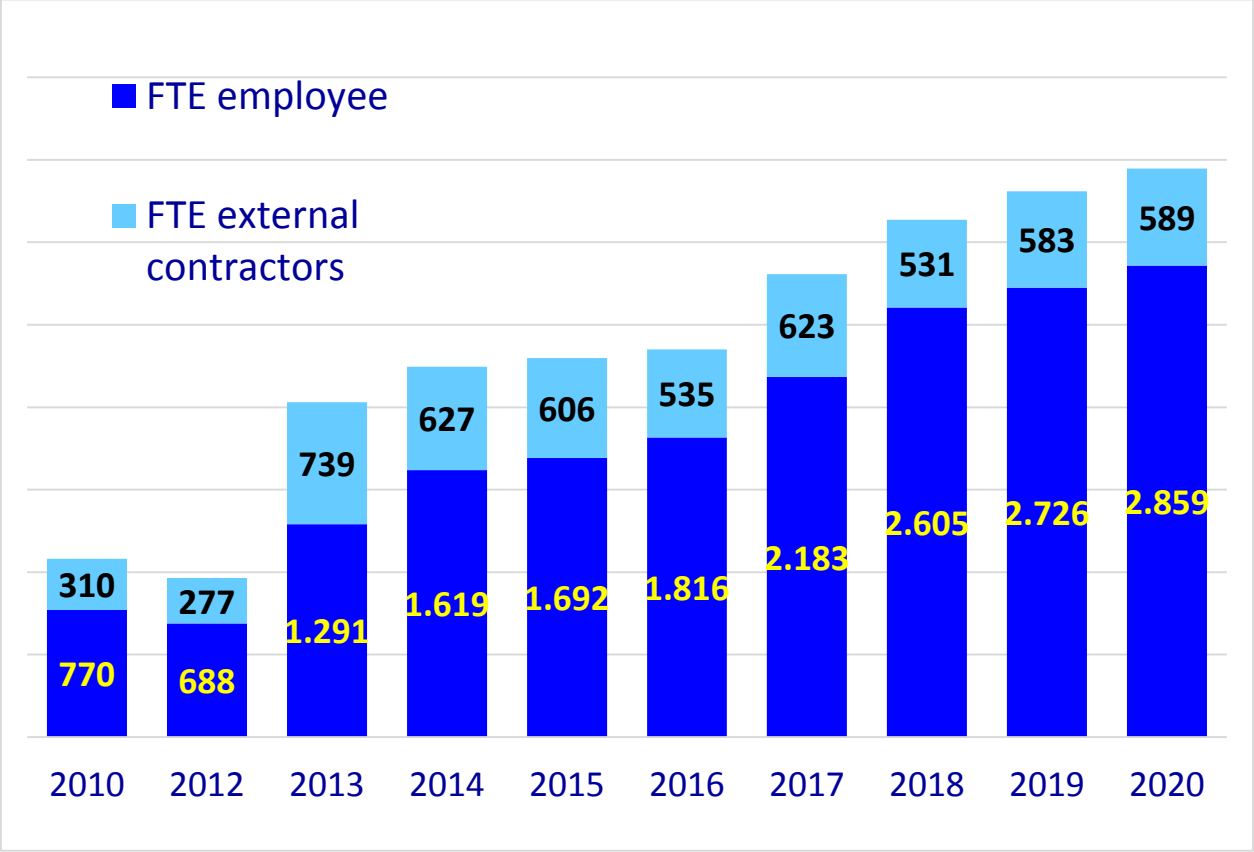


- **Number of Manufacturers**

In compiling the number of quality system certificates, (namely AIMDD – Annex 2 & 5, MDD = Annex II, V & VI and IVDD = Annex 4) under the Directives, we get a good estimation of the number of manufacturers.
This is making a total number of 14 259 medical devices manufacturers



- **<u>Continuing increase in the number of full time employees</u>**

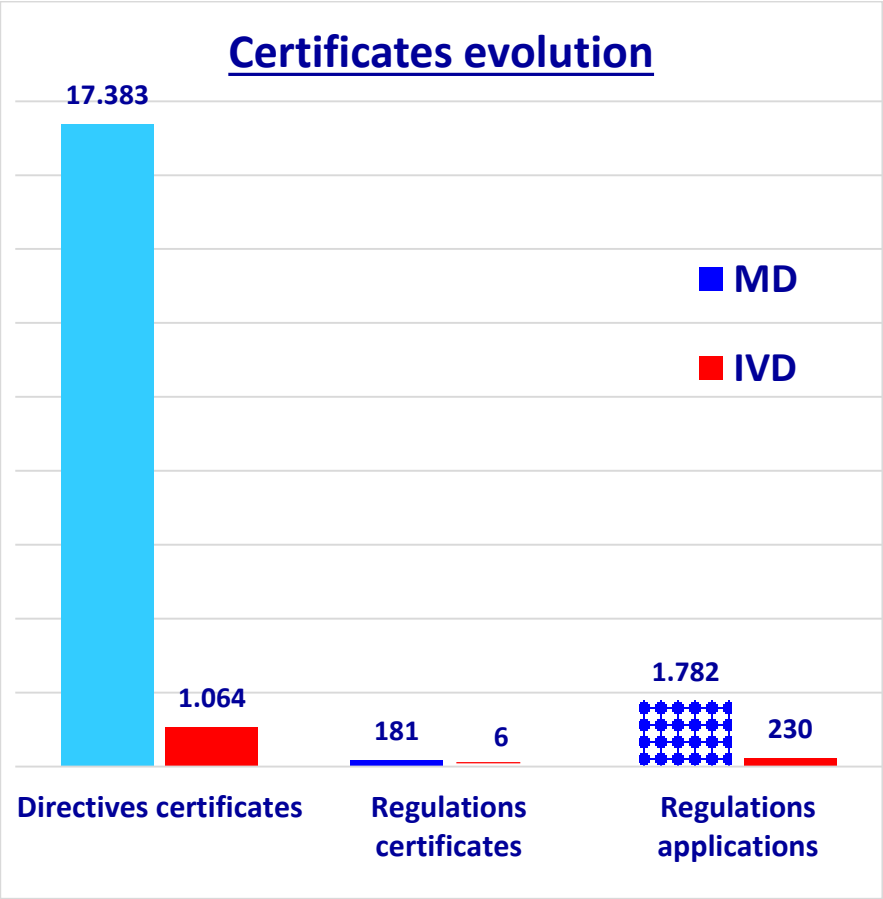


That is the 8th year in a row that the full time employees have increased. The average number of employees of the members has **increased by 5%.**

The increase in number of employees is small in comparison with the wishes of notified bodies to hire personnel. The difference is mainly related to the difficulties to find people with the required competence on the market. Notified Bodies are facing stiff competition with manufacturers and consulting companies to hire people with previous work experience in medical devices.

The number of subcontractors is quite stable. Some notified bodies had to reduced reliance on subcontractors due to impartiality requirements.

- **Transition process form directives to regulations**



We can see in the next graph that only 1% of MDR certificates has been issued.

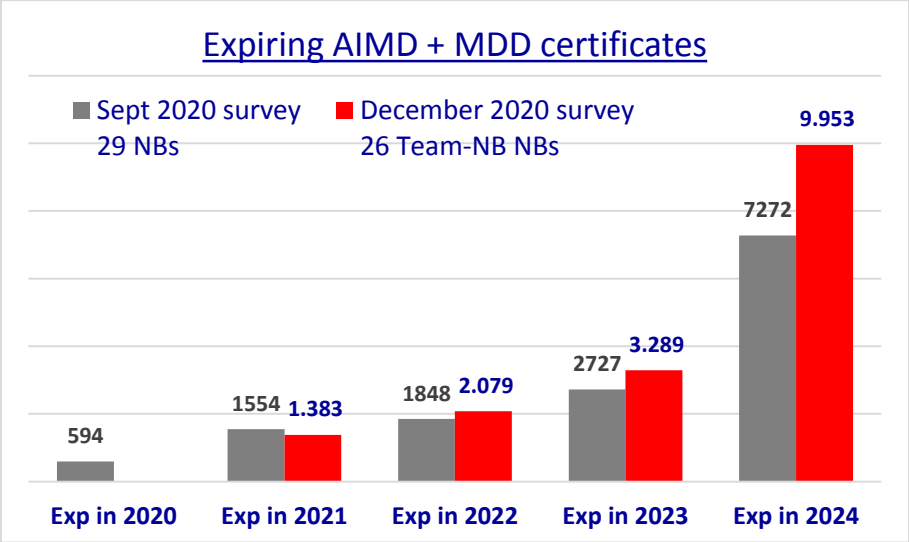
Applications represent 10% of MDD and AIMD certifications. Most of them are in the certification process. Some of them being at the final step and awaiting permission to perform the initial certification audit.

- **Expiration of directives certificates**

  - **AIMD + MDD expiring certificates**

    Sources: September survey: CIRCABC with 29 responses – all NBs
    December survey: All Team-NB members - 26 responses

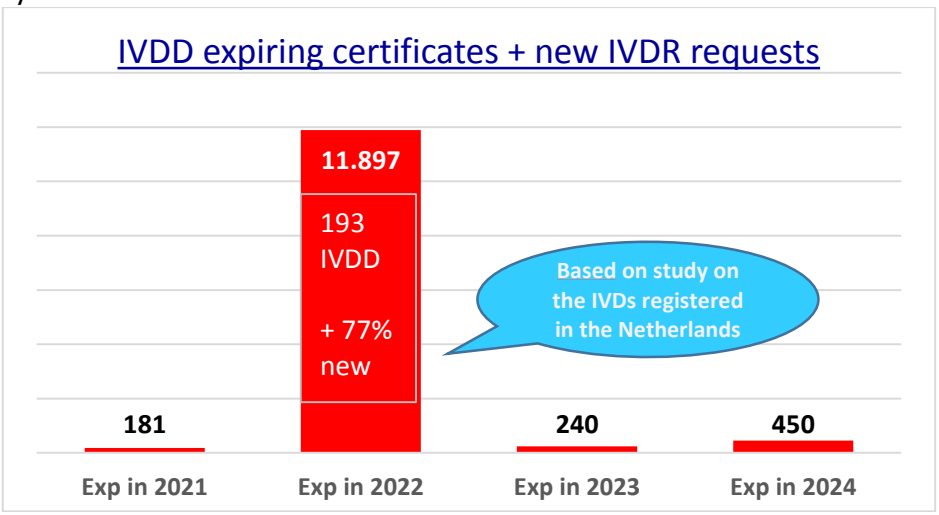
    From the September survey to the one of December, thus in 3 months, NBs did their best to re-certify against AIMD/MDD to allow access to devices necessary during the pandemic. Thanks to the remote audits authorised by the COM, in 3 months there has been an additional 2700 certifications that are valid until 2024.



It has to be added that this increase is surely more important as we compare 26 notified bodies to 29 notified bodies (members and non-ones who responded to CIRCABC survey).

  - **IVDD expiring certificates and new IVDR requests**

    As far as IVD devices are concerned, the expiring directive certificates is only a small percent of the required number of regulation certificates.
    The number of devices requiring new certification to the IVDR has been estimated thanks to a 2018 study on IVDs registered in the Netherlands. If these results can be extrapolated to the EU, there will be a 77% increased request for NB certification. This also assumes that there has not been an increase of IVD placed on the market in 3 years.



In any case, there will be a large need for certification to be completed prior to May 2022.

The full survey is available on our web site as a graphical presentation
http://www.team-nb.org/documents-2021/

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