The European Association Medical Devices - Notified Bodies

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PRESS RELEASE

Team-NB sector survey 2022

Since 2010, all Team-NB members contribute to the annual Team-NB survey. This allows Team-NB to provide data on the sector over the past year and to identify trends by comparison with data from previous years.

The 2022 survey compiled data from 33 notified bodies, the total number of Team-NB members at the end of 2022. This is an increase of 3 members in comparison with 2021, a 10% increase in membership.

Below some explanatory graphs of our **2022 members survey**.

• Breakdown of the notified bodies size

Team-NB applies 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 2021 distribution is

"big"	**"medium"**	**"small"**
15 %	27%	51%

Noteworthy trends are an increase of the small size notified bodies with 10% of growth and a decrease of both medium and big size notified bodies, in contrary to 2021.

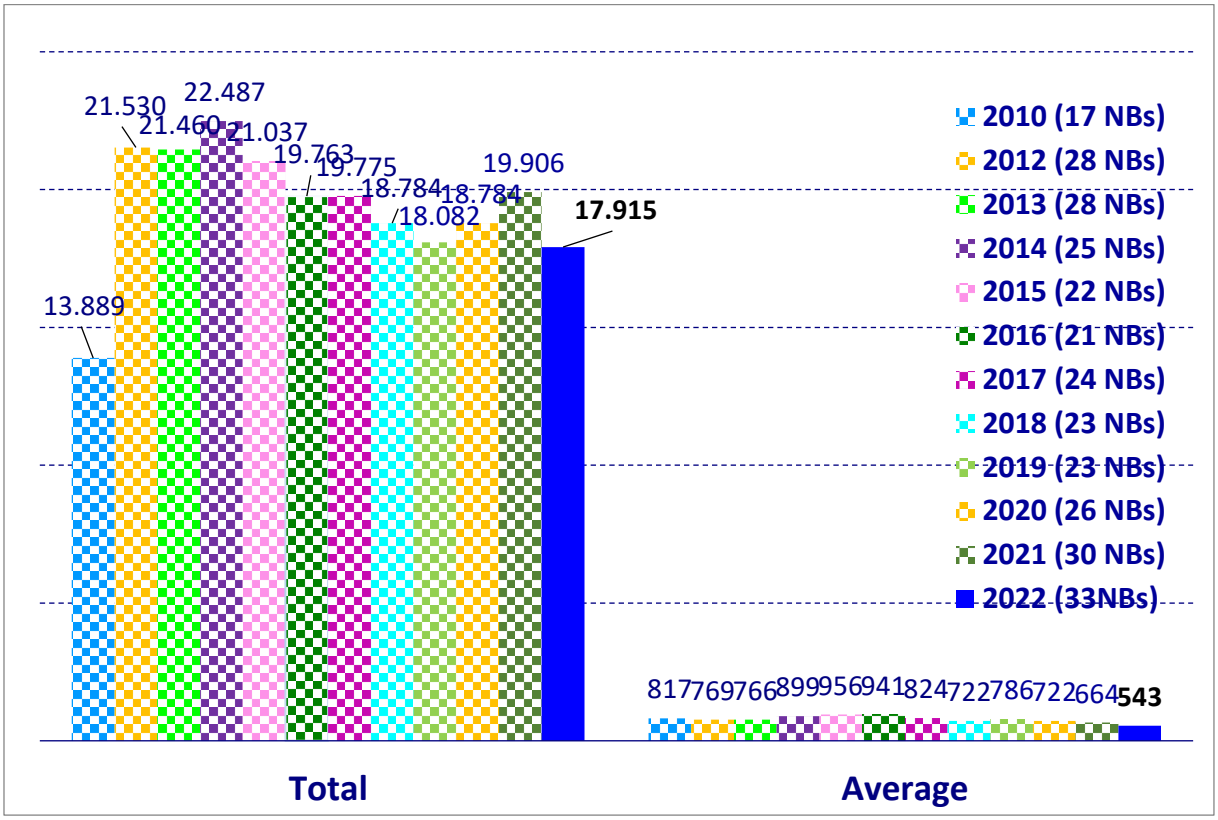
• Evolution of the number of valid EC certificates

Unlike previous years, we see a significant decrease of 10% in the number of valid certificates over last year.

To explain part of this decrease, consider the number of certificates that have been cancelled by Manufacturer or withdrawn by Notified Bodies between 26 May 2021 and December 31st, 2022 which is of 1301 certificates.

For the remaining part, this decrease could be linked to the certificates that expired in 2022 and for which the manufacturers either have decided not to continue the putting on the market of the devices or have not found a solution to prolong the validity of the certificates which in both cases explained the decrease of valid certificates.

Survey responses were provided prior to EU 2023/607, which may allow already expired Directive certificates more time to place product on the market.



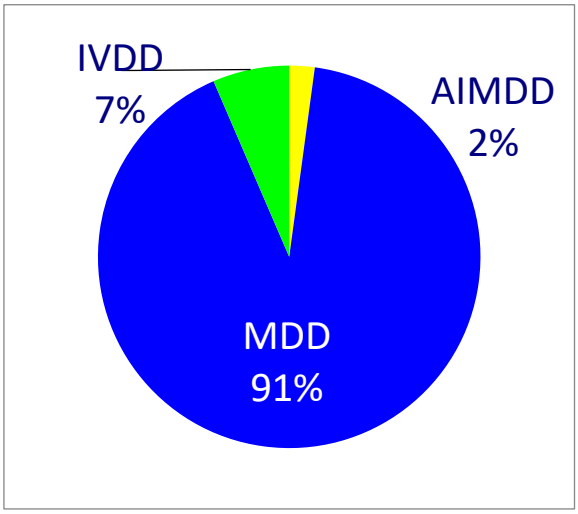
- **<u>Certificates split among the 3 directives</u>**

The ***Distribution of valid certificates in 2022*** has not significantly changed from last year:

- the majority of valid certificates in 2022 are still under MDD (91% to be compared with 92% last year),
- the "*In Vitro*" diagnostics certificates stayed comparable (7% to be compared with 6% last year)

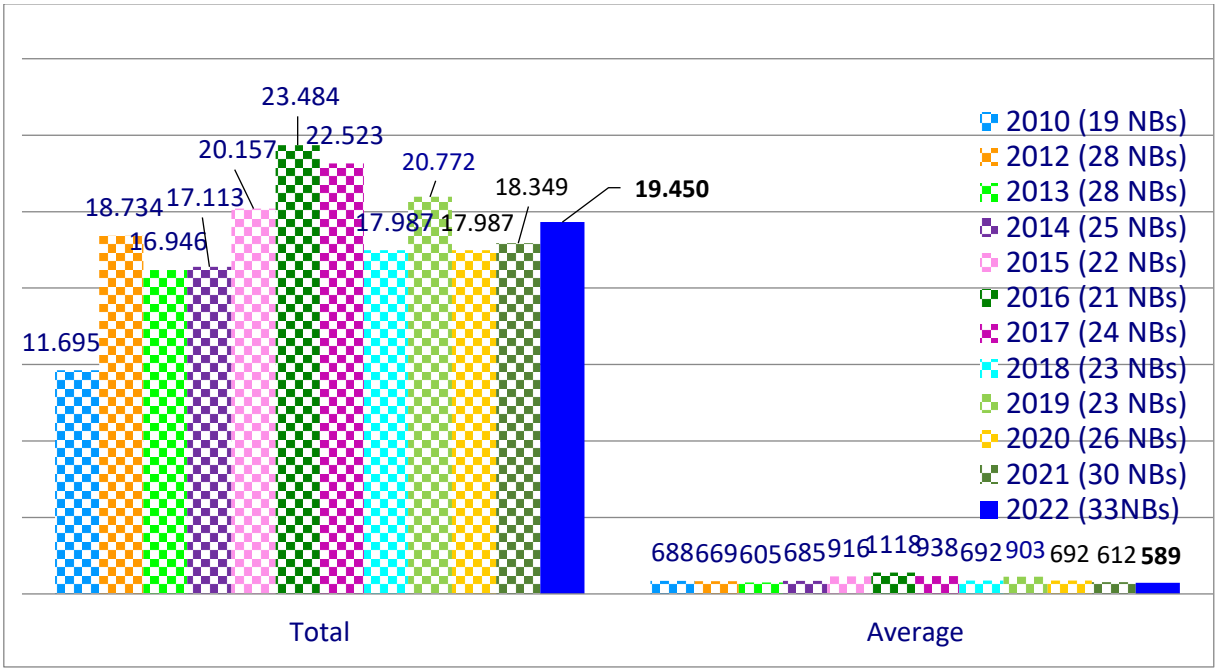
and

- 2% for active implantable (instead of 3%).



- **ISO 13485 certificates**

The total number of ISO 13485 certificates increased by 6% mainly thanks to the increase of members. If we consider the mean, we see a decrease in the average of issued certificates (612 decreasing to 589).



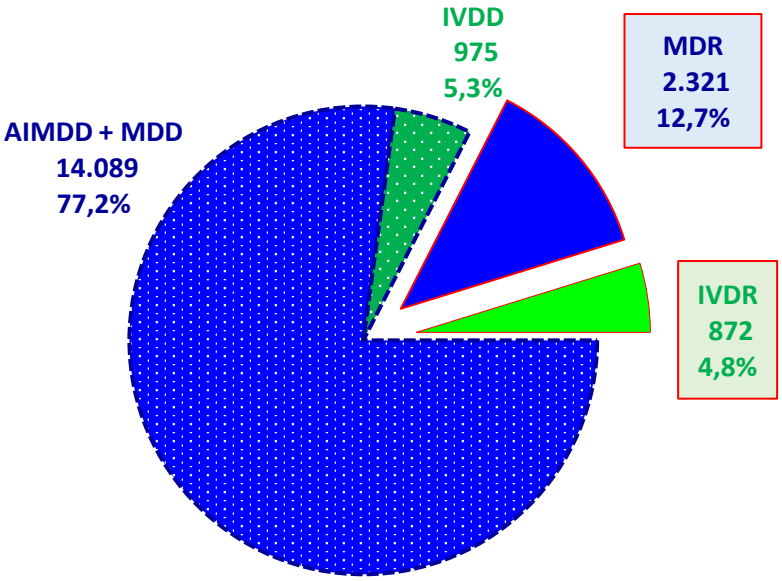
- **Number of Manufacturers**

In compiling the number of Certification holders based on QMS (Quality Management System) certificates, we have a good estimation of Manufacturers.

This compilation is taking into consideration the QMS (Quality Management System) certificates:

- under the Directives, the certificates considered are
  - for AIMDD – Annex 2 & 5,
  - for MDD - Annex II, V & VI and
  - for IVDD - Annex 4,
- under the Regulations, the certificates considered are
  - for MDR equal to Annex IX - Ch I & III + Annex XI - part A and
  - for IVDR - Annex IX - Ch I & III + Annex XI.

This year against the Directives, the total number makes 15 064 medical devices manufacturers. That makes an increase of 2,7% in comparison with last year. This is probably a false indication since Regulations certificates cover partial device portfolios and the manufacturers have simultaneous Directive certificates.

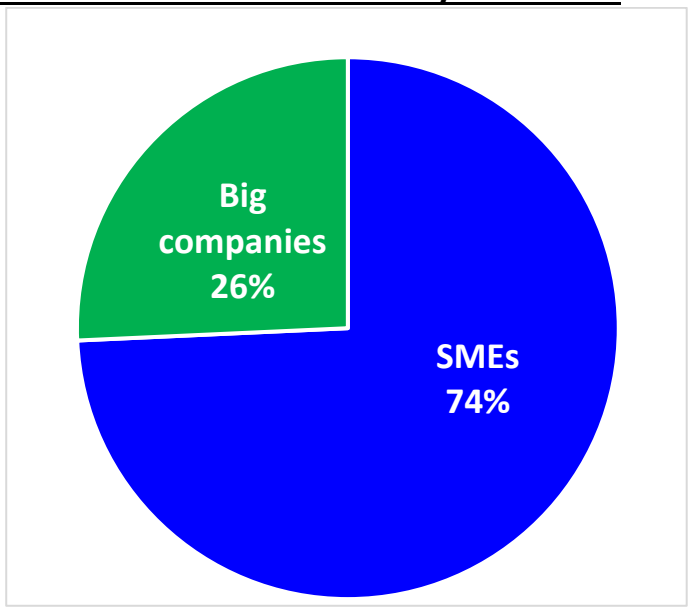


- **<u>Access to Notified Bodies by SMEs are taken into accounts by Members.</u>**

Indeed, 27 members on 29 responses indicate that SMEs represent minimum 50% of their activities

and

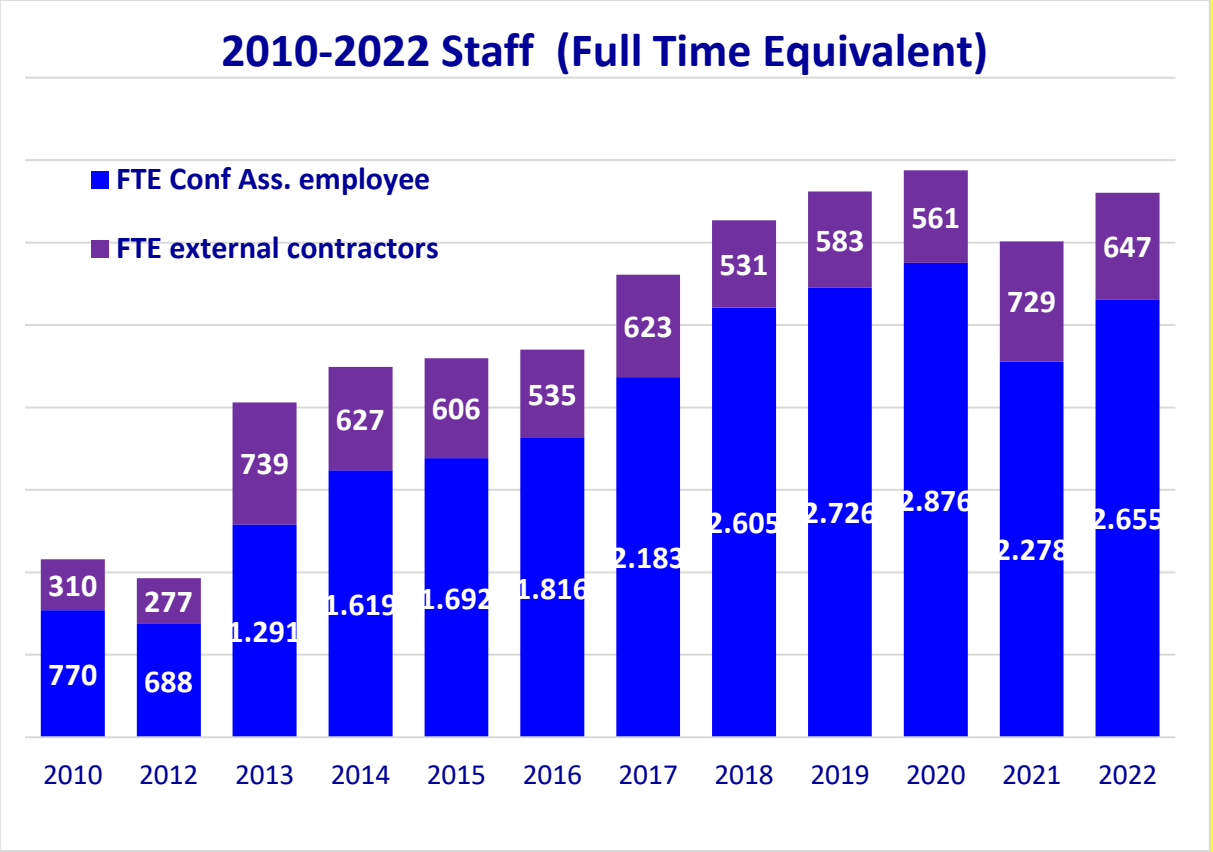
as a mean of all responses, SMEs are representing 74% of their activities.



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

Until 2020, the data included all Notified Bodies employees for both doing conformity assessments and being administrative supports.

From 2021, the focus was put on technical resources being entitled to do conformity assessments. The below data show that Notified Bodies have hired in 2022 more technical resources to do conformity assessments in comparison to 2021. Concerning subcontractors, the number has decreased probably link to the difficulty to meet the Regulations requirements in terms of independency.



In any case, to meet the need the notified bodies still wish to hire additional personnel. Notified bodies are facing stiff competition with manufacturers and consulting companies to hire people with the required competences in medical devices on the market.

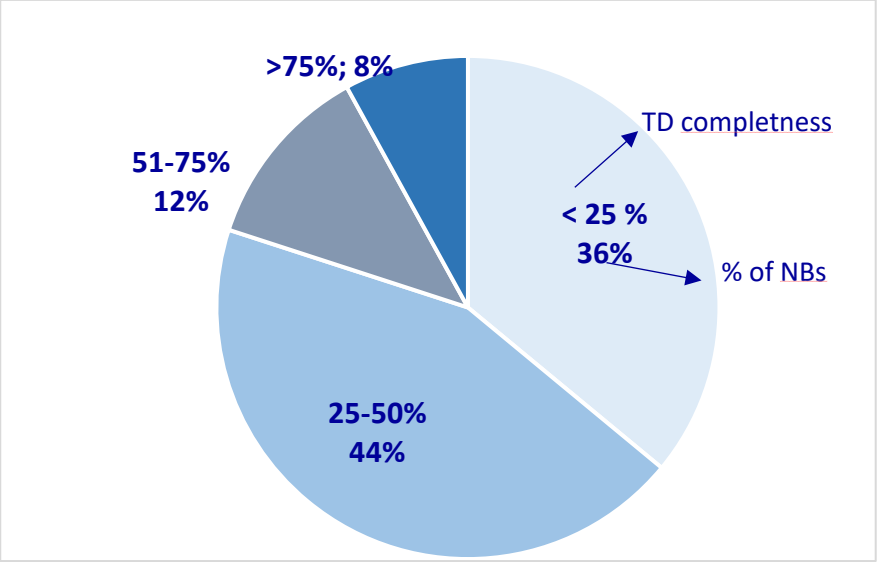
- **Completeness check**

The question regarding the "completeness check" in line with the requirements of the new regulations has been introduced last year. Indeed, under this new framework, Notified Bodies are required to ensure that the complete technical documentation has been received (sometimes referred to as a completeness check) before undertaking a review of its content.

81% of the Notified Bodies members answered that they were **doing the completeness check.**
It is not yet applied by 19% of the NBs that indicated that they will perform it as soon as they will be designated against a regulation.

⚠ **On the basis of the NBs doing the check (81%).**

⇨ 80 % of those NBs indicate that the technical documentations submitted are missing half of the needed information and thus they request additional information to be able to start the assessment. Surprisingly, that percentage is increasing by 4% in comparison of the last year response although we had expected a decrease thanks to the learning curve and the consensus Technical Documentation Best Practice Guidance documents published by Team-NB.

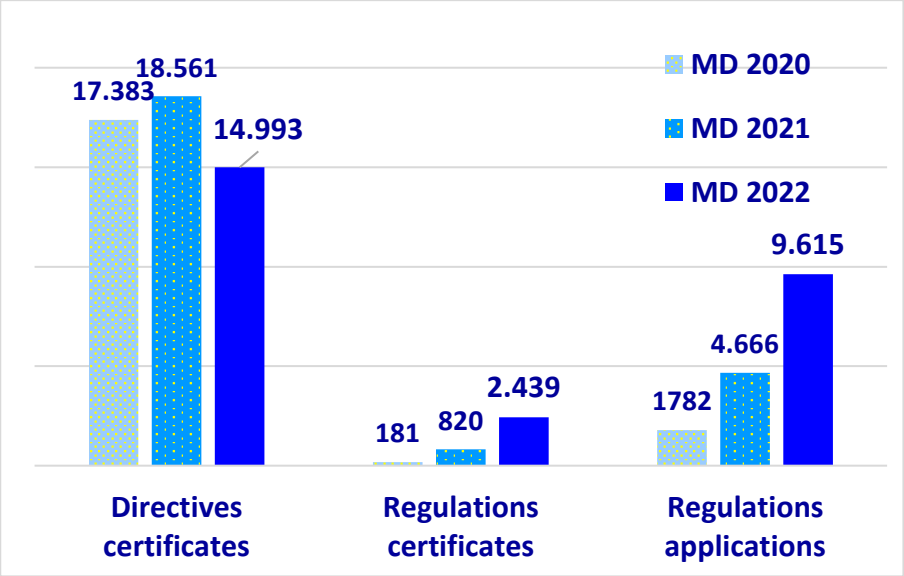


- **Transition process from directives to regulations**

  - Transition process from AIMDD and MDD to MDR

    Thanks to the Regulation EU 2023/607 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, legacy devices may be placed on the market or put into service until December 2027 or 2028 (following certain conditions).

    As we can see below the transition process continued to be too slow in 2022 to be completed prior to the original MDR transition dates.



    In 2022, we reached 14 % of issued Regulation certificates compared to the total of Directive certificates.
    The good news is that the received applications reached 63% of the remaining Directives certificates.

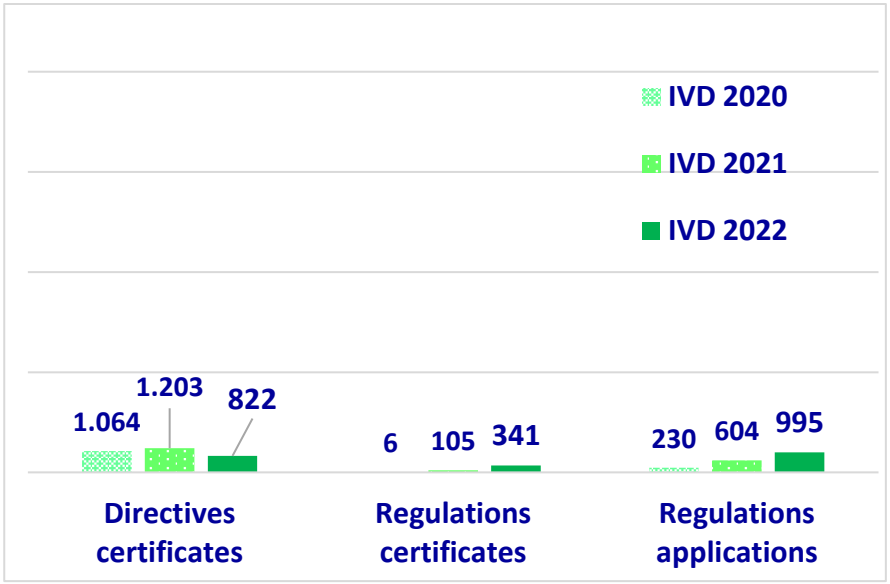
Be aware that this positivity needs to be considered, as many applications are for smaller scopes than those on the Directives certificates. We are told that it is mainly because MDR Technical Documentations for all devices are not ready.

Moreover, it is to be noticed that the new legislation will require more certificates issued to the MDR Regulation than were issued to the Directives. For example, a certificate will be issued for each class IIb implantable device. In addition, the way manufacturers are structuring their families, taking Basic UDI-DI into consideration, may also increase the number of certificates.

- Transition process from IVDD to IVDR

Taking into consideration the MedTech Europe survey of 2021, it has been estimated that the number of certifications against the Regulation will be 10 fold the number of Directive certificates. Thus, we can anticipate that the number could reach around 10 000 Regulation certificates.

As we can see below, we could consider that we reach one tenth of the total number of certificates against the Regulation.



Considering class D, MedTech Europe survey, tells us there are 1 188 certificates with one half being submitted. Knowing that the deadline is May 2025 and that the process is 12 to 18 months, manufacturers need to submit their applications by end of this year to have a chance of completion prior to the end of the transition.

As a whole, NBs still need to receive 8 400 applications

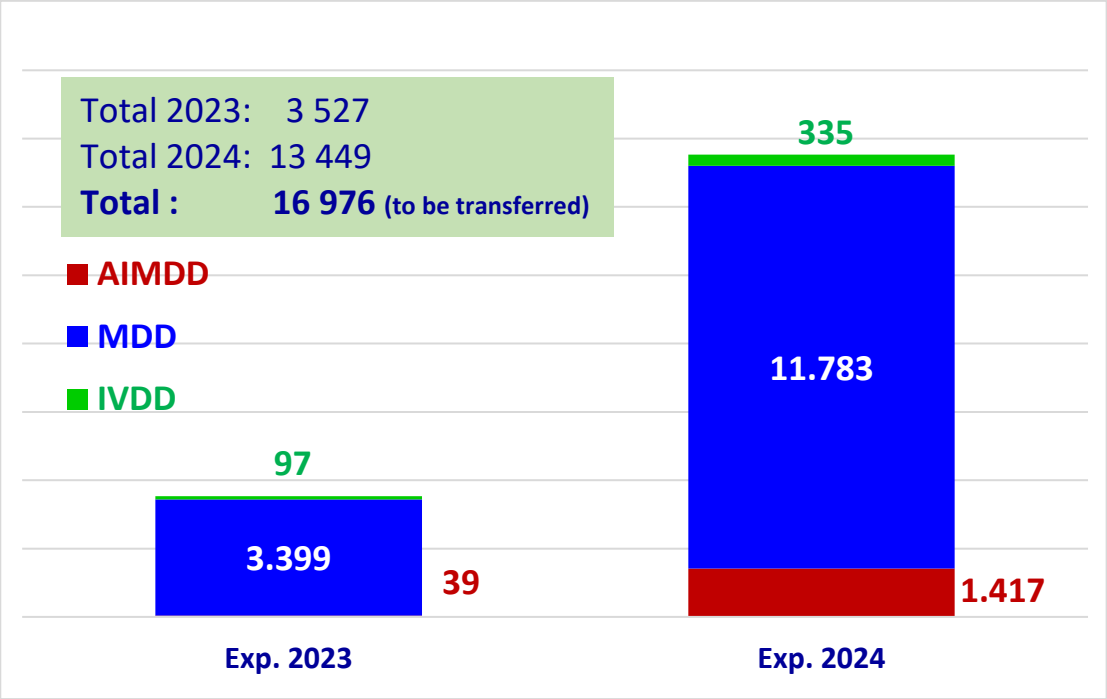
- ✓ by end of 2024 for class C that will need to be certified by May 2026 and
- ✓ by end of 2025 for class B that will need to be certified by May 2027.

Thus, Notified Bodies are encouraging all manufacturers to make applications now as times flies and only 1 ¾ years remain for class C and 2 ¾ years remain for class B. It should be clear that Notified Bodies will not have the resources to take on board all the applications if they are submitted late.

- **Expiration of directives certificates**

Trends in expiring Directives certificates

The below graph is comparing the data from the 2 last annual surveys.



In previous years, following the Directives, it was estimated to 6 300 certificates per year could be issued.

Thanks to the today data, we have 1 619 MDR certificates that have been issued in 2022 knowing that there were 63% of the members designated against MDR at the end of 2021 (19 NBs).

If we extrapolate to the 38 NBs designated today, we could estimate the capacity to issue MDR certificates to be 3 200 MDR certificates per year.

This may be refined in light of the number of new organisations which will be designated and the learning curve which will make it possible to reduce the duration of the certification process on one side, and on the other side of the fact that the largest Notified Bodies have been designated since 2019.

Thanks to the Amendment EU 2023/607, we see that the complete numbers are achievable if the manufacturers do not delay their applications to allow a smooth transition. Today our main concern is the Regulation applications only represent a fraction of the Directive certified devices.

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

- **About Team-NB**

Team-NB is the European Association for Medical Devices of Notified Bodies, Team-NB 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.

Team-NB set up **Mirror MDCG-working groups** to allow the members the opportunity to support development of European guidance and enable comments on draft documents 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. Today there are 21 tasks forces working on topics such as article 117, classification interpretation, cybersecurity,…

Moreover, the **Team-NB academy** organised several trainings related to the new MDR/IVDR with the aim to help notified bodies deal with new requirements in their assessments. Another purpose is to achieve a better harmonisation among notified bodies thanks to the exchanges that will be favoured during the presentations and the cases studies sessions. In 2022, 3 new topics have been added to the 7 existing ones.
Moreover, a new kind of **session for harmonisation** has been set up at the senior experts' level to share their experience on burning clinical evaluation topics. The objective is that attendees cascade the info into their organisation to reach all reviewers.

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