The European Association Medical Devices - Notified Bodies

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PRESS RELEASE

Team-NB sector survey 2023

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.

This year the questionnaire has been enriched to provide data to shed light on the effects of Regulation 2023/607 for the extension of the transitional period for certain systems. In addition, other questions aim to shed light on specific transitions for certain articles (16, 17, 22), for artificial intelligence aspects or for Annex XVI of Regulations 2017/745and 2017/746, where applicable. In addition, 1 question focused on certificates issued under MDSAP.

The 2022 survey compiled data from 35 notified bodies, the total number of Team-NB members at the end of 2023. This is an increase of 2 members in comparison with 2022. It should be noticed that the total number of Team-NB member includes "candidate member" which are still in the designation process and were not designated against the directives and thus have not yet issued any certificate.

Below some explanatory graphs of our **2023 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 2023 distribution is

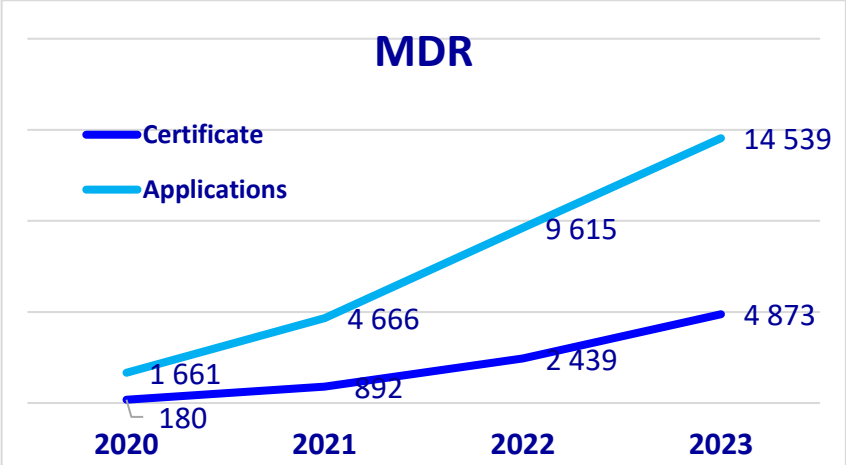
"big"	"medium"	"small"
11 %	29%	60%

The trend of growth in the number of small notified bodies is confirmed, with once again growth of around 10% compared to the previous year.

- **Evolution of the number of Regulations certificates**

MDR applications and certificates (QMS + Product)

The growth is presented below for MDR with information to be considered on the number of designated members of Team-NB compared to the total number of designated notified bodies:



2020: 16 members / 18 designated NBs

2021: 21 members / 25 designated NBs

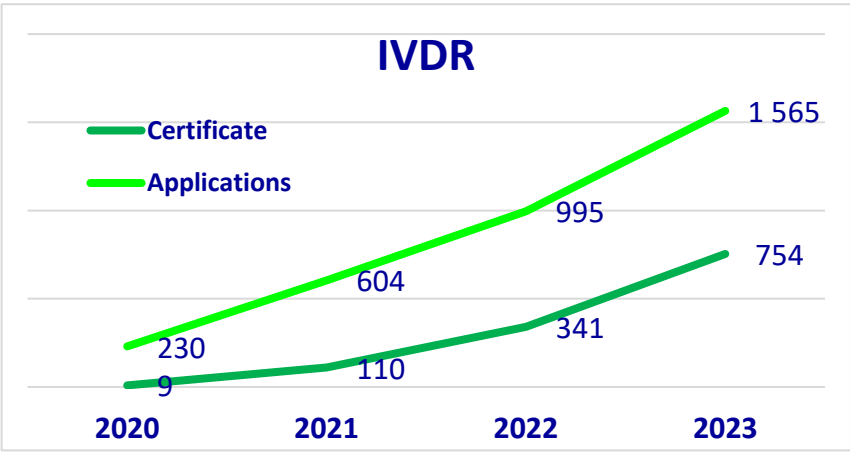
2022: 25 members / 36 designated NBs

2023: 32 members / 42 designated NBs

In comparison with the results of the "Study supporting the monitoring of availability of medical devices on the EU market" extrapolated to December 2023, Team-NB certificates represent 77% of the total issued and the applications received are representing 91%.

IVDR applications and certificates

The growth is presented below for IVDR with information to be considered on the number of designated members of Team-NB compared to the total number of designated notified bodies:



2020: 4 members / 4 designated NBs

2021: 6 members / 6 designated NBs

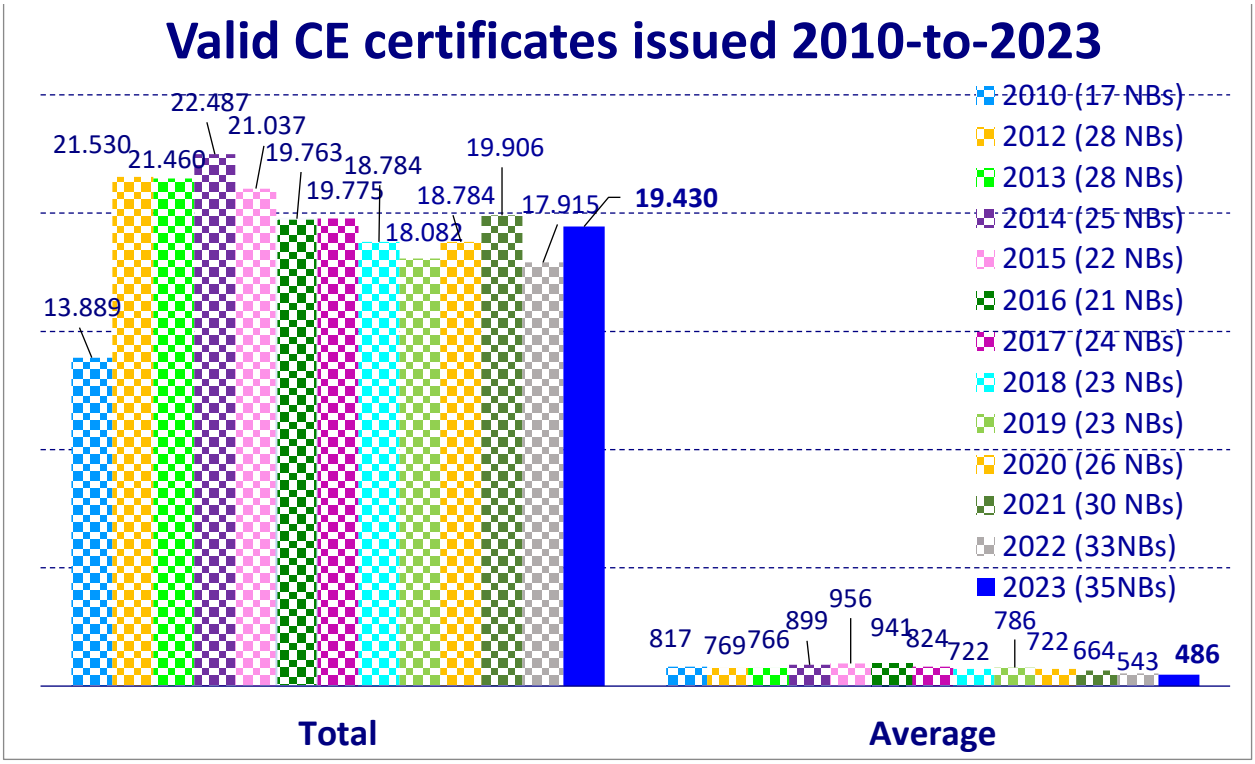
2022: 6 members / 7 designated NBs
2023: 10 members / 12 designated NBs

In comparison with the results of the "Study supporting the monitoring of availability of medical devices on the EU market" extrapolated to December 2023, Team-NB certificates represent 94% of the total issued and the applications received are representing 96%.

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

After last year's result where we noted a significant decrease, in 2023 we are back to previous figures.

We could consider that the Manufacturers could have recertified their products for which they cancelled the certification or that were withdrawn by Notified Bodies.



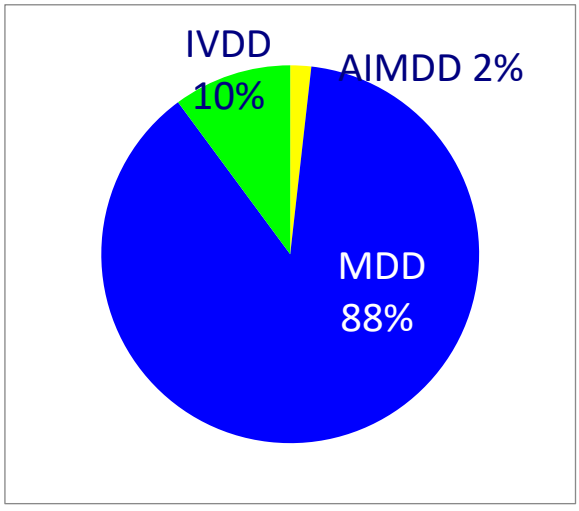
- **Certificates split among the 3 directives**

The ***Distribution of valid certificates in 2023*** has not significantly changed from last year:

- the majority of valid certificates in 2022 are still under MDD (88% to be compared with 91% last year),
- the "*In Vitro*" diagnostics certificates increased (10% to be compared with 7% last year)

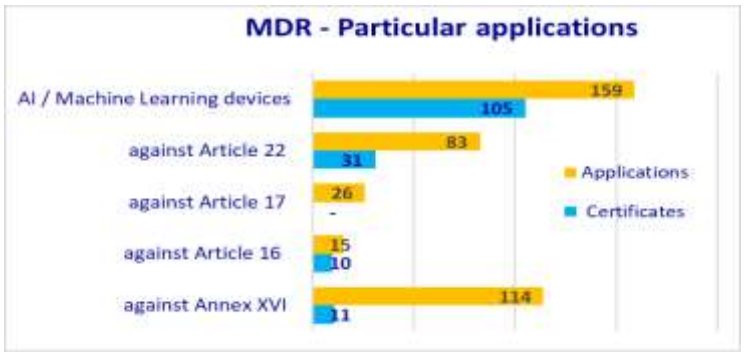
and

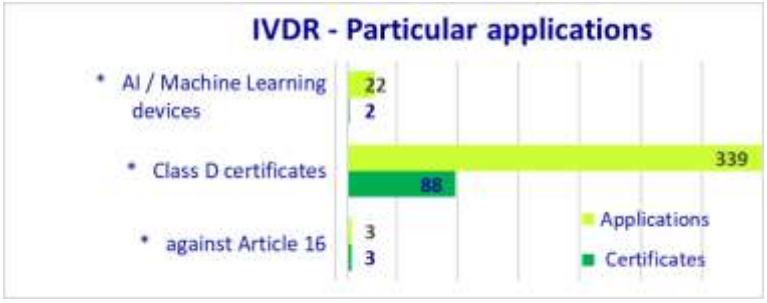
- 2% for active implantable which stayed comparable at 2%).



- **Particular transitions to MDR and IVDR**

For information, below are the responses to the request concerning particular transitions to both regulations in terms of issued certificates and received applications.

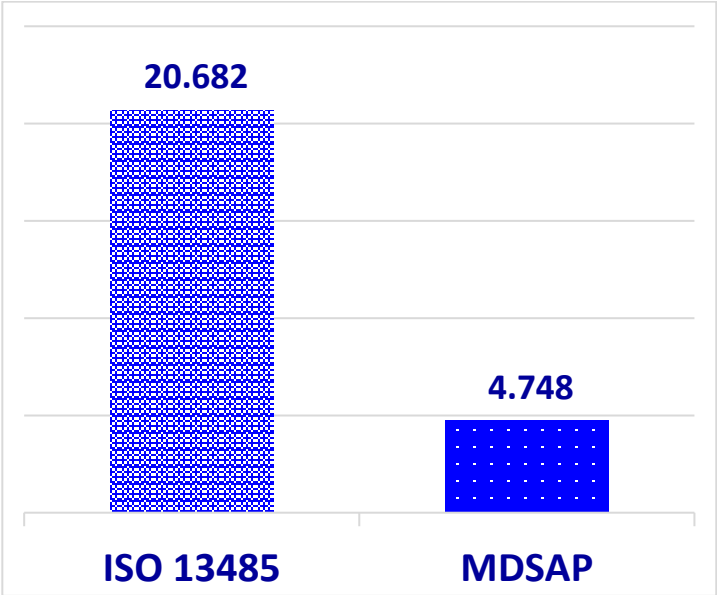




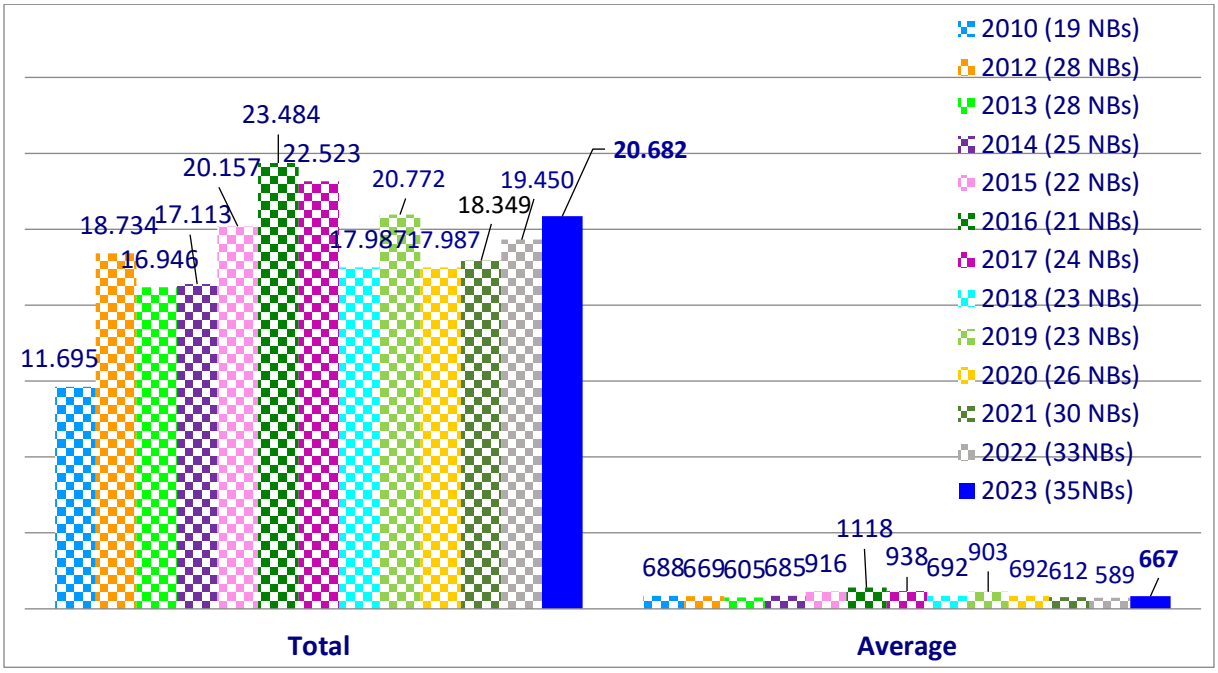
- **Others certifications**

Beside the certifications against directives and/or regulations for medical devices, the notified bodies are also providing other certifications in the international frameworks to ensure recognition over the world.

In 2023, the members issued certificates against ISO 13485 and also against the MDSAP format.

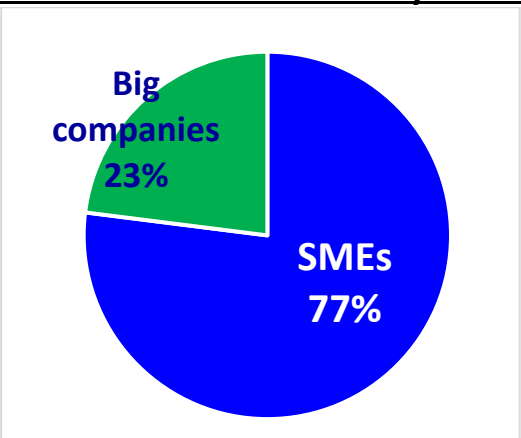


The total number of **ISO 13485 valid certificates** increased for the 4th time in a row – this year by an additional 6%. This increase is even more important when we have a look to the means.



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

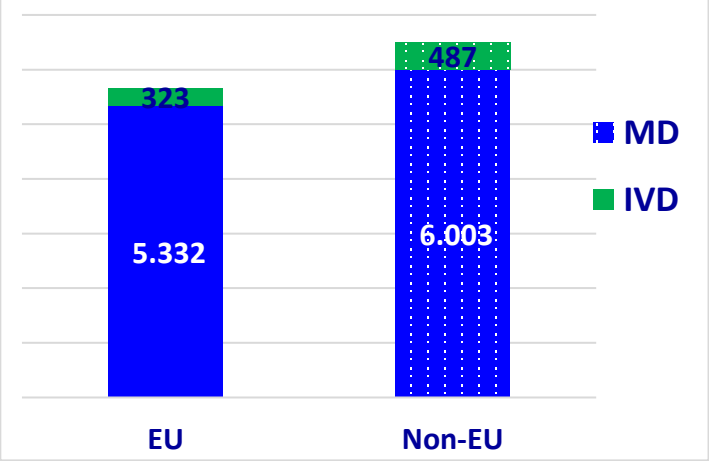
As a mean of all responses, SMEs are representing 77% of the activities of the Notified Bodies members.



- **<u>Number of Manufacturers</u>**

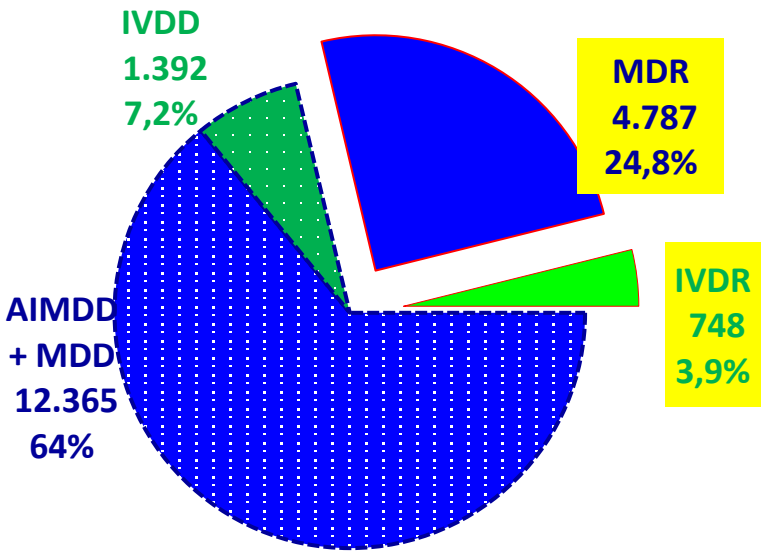
Following the answers of the members, they have a total of

- 11.335 MD manufacturers
- 810 IVD manufacturers



- **Number of Certificates**

The compilation of certificates issued against the 2 directives and the 2 regulations is giving the below repartition at the end of 2023.

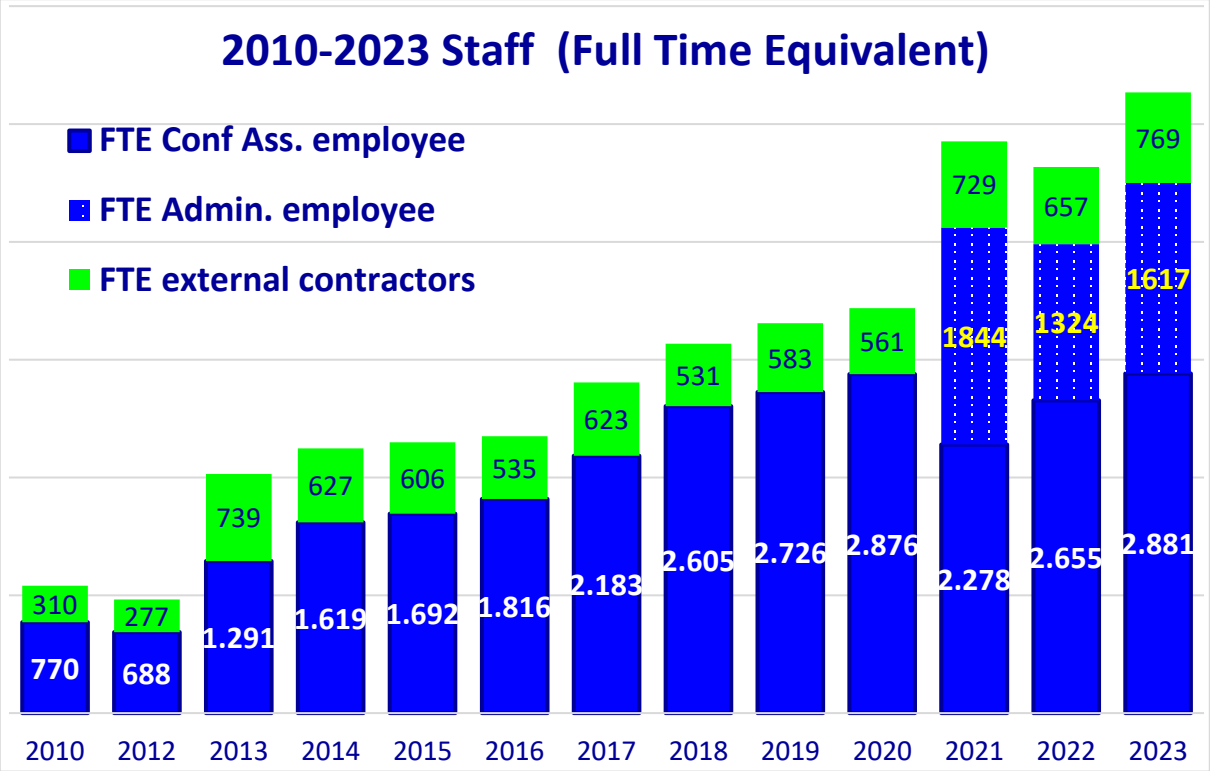


We note that

- certificates according to the Directives represent 71% while
- certificates according to the Regulations represent 29% of the total distribution between medical devices and in vitro diagnostics.

- **Continuing increase in the number of full time employees**

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 2023 more technical resources to do conformity assessments in comparison to 2022 as well as more subcontractors with an increase of 10,2%. Also, the number of hired administrative employees who support the process have increased by 22%.



That said today, the notified bodies are facing a difficult situation. Some of the technical resources have a lack of work following the request of some manufacturers to put their application on hold or to delay responses.

- **<u>Completeness check</u>**

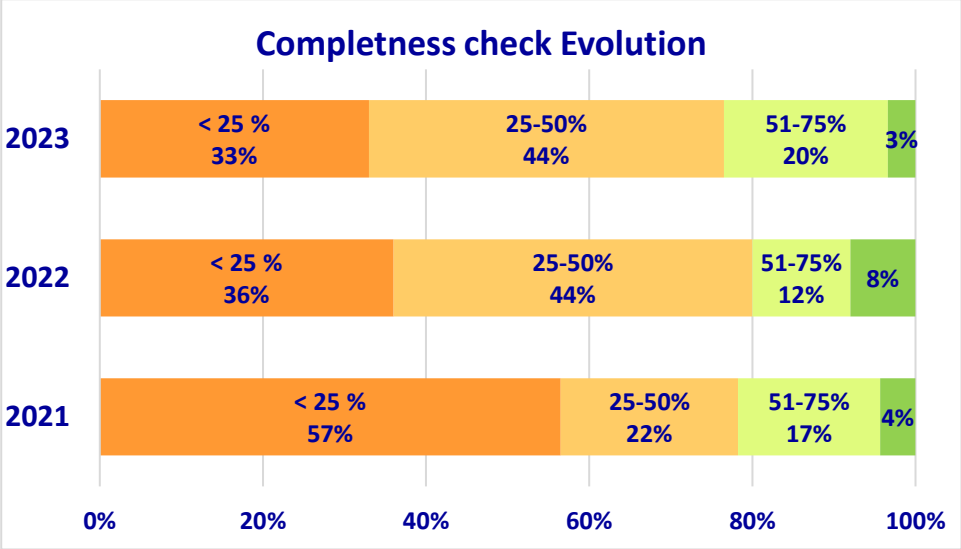
The question regarding the "completeness check" in line with the requirements of the new regulations has been introduced last year. Indeed, under this new framework, Notified Bodies are required to ensure that the complete technical documentation has been received (sometimes referred to as a completeness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

In considering the 3 last years, we can see the percentage of **the Notified Bodies** members doing the completeness check raised to **87%.**

2021	79%
2022	81%
2023	87%

The ones NBs not doing the check 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 (79% - 81% - 87**%), we can see the evolution of the completeness of the received technical documentation is positive.



⇨ The percentage of submitted files that are missing half of the needed information is improving.

That said there are still 75% of submitted files that are missing half of the needed information and thus they request additional information to be able to start the assessment.

Just to noticed that the results of the "Study supporting the monitoring of availability of medical devices on the EU market" published following their February 2024 is indicating as well that NBs answered that 23 % of submissions had a completeness rate above 50%.

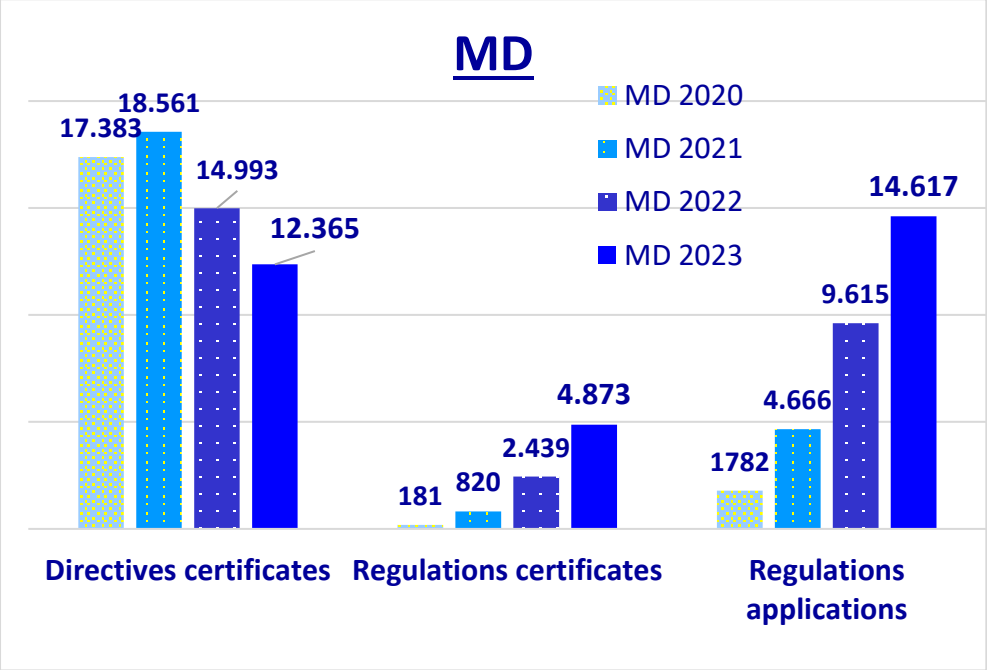
To helps the Manufacturers to meet the regulations requirements, Team-NB published Technical Documentation Best Practice Guidance documents for both MDR and IVDR. In addition, Team-NB organized trainings sessions for MD and IVD technical documentation since June 2023 with respectively :

- 3 sessions for IVD with a total 200 participants from 111 organisations knowing that a 4th session is going to take place on July 3rd.
- 5 sessions for IVD with a total 412 participants from 232 organisations knowing that a 6th session is going to take place on June 24th.

- **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).



In 2023, the number of issued Regulation certificates double compared to the ones issued in 2022. The number of received applications considerably increased as well. It is superior to the remaining Directives certificates.

Be aware that this positivity needs to be considered, as both many regulations certificates and 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.

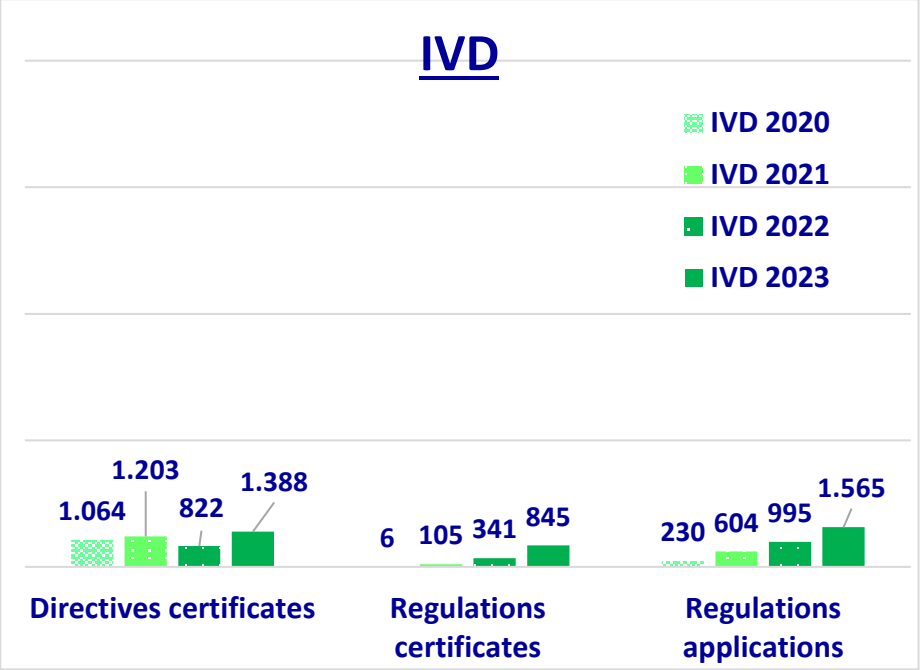
Moreover, it is to be noticed that the new legislation will require more certificates issued to the MDR Regulation than were issued to the Directives. For example, a certificate will be issued for each class IIb implantable device. In addition, the way manufacturers are structuring their families, taking 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 15% of the total number of certificates against the Regulation.

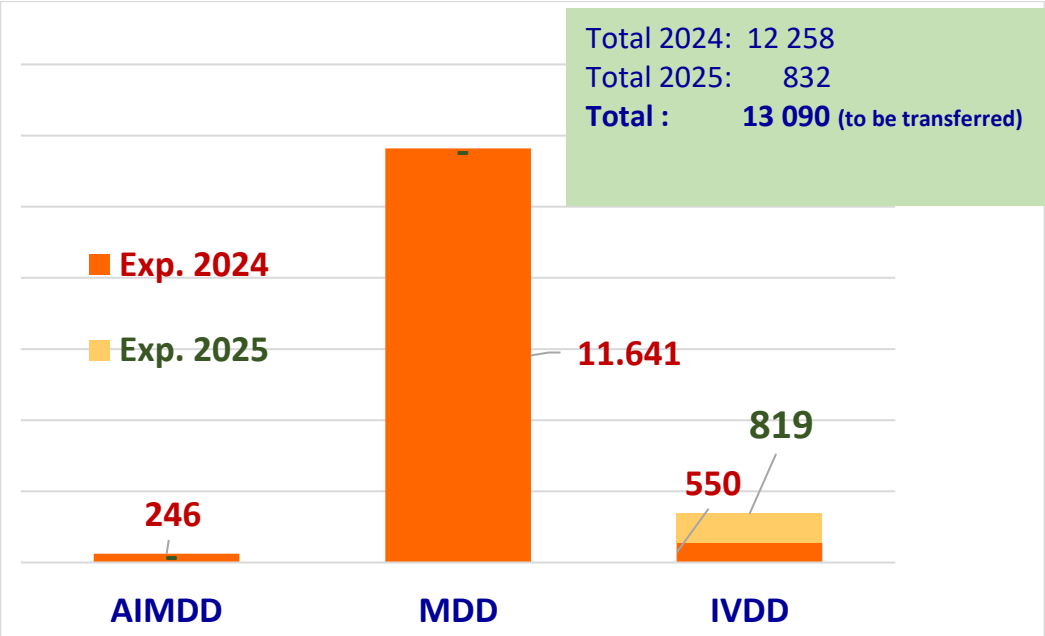
Although proposal 2024/043 will extend the IVDR transitional timelines, Notified Bodies continue to encourage all manufacturers to apply for IVDR certification as soon as possible. The IVDR application is particularly critical for the IVD devices that have an IVDD certificate expiring in May 2024 as the IVDR application must be submitted before the IVDD certificate expires.



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**

As we can see below, there are still efforts to be made to get the remaining Directives certificates transfer towards the regulation process on time.



The full survey is available on our web site as a graphical presentation.
http://www.team-nb.org/documents-2024/

- **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 European 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(at)team-nb.org.