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## PRESS RELEASE

### Team-NB sector survey 2021

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 2021 survey compiled data from 30 notified bodies, the total number of Team-NB members at the end of 2021. This is an increase of 4 members in comparison with 2020, a 15% increase in membership. Membership growth has exceeded 10% for 2 years in a row.

Below some explanatory graphs of our **2021 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”
20%	33%	46%

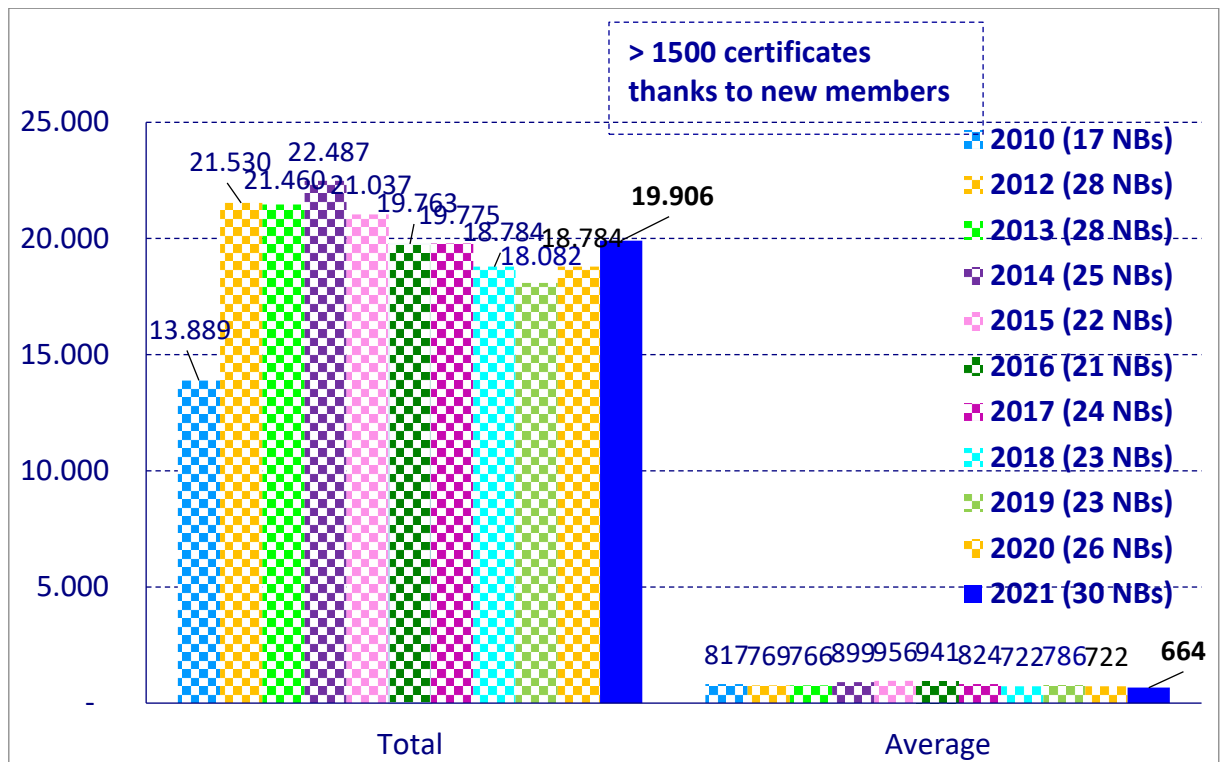
Noteworthy trends are an increase of the medium size notified bodies with 73% of growth and a decrease of 20% of small notified bodies, as compared to 2020.

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

The upward trend in the number of valid certificates continued last year.

In 2020, it was considered that the growth in the number of certificates was due to the postponement of the date of application of the MDR due to the pandemic, which pushed Manufacturers to request a re-certification against the directives. Without this postponement, some manufacturers would have been trapped in a situation without valid certificates.

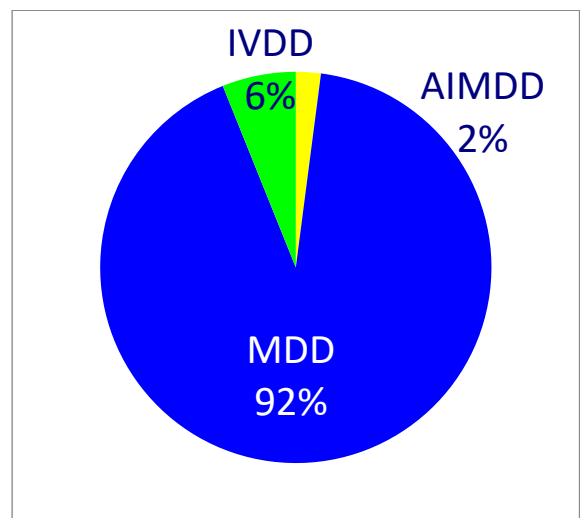
The additional increase this year could be partly due to the 5 first months of 2021 with renewal of Directives certificates and in addition we have also seen new certificates issued against the regulations.



• **Certificates split among the 3 directives**

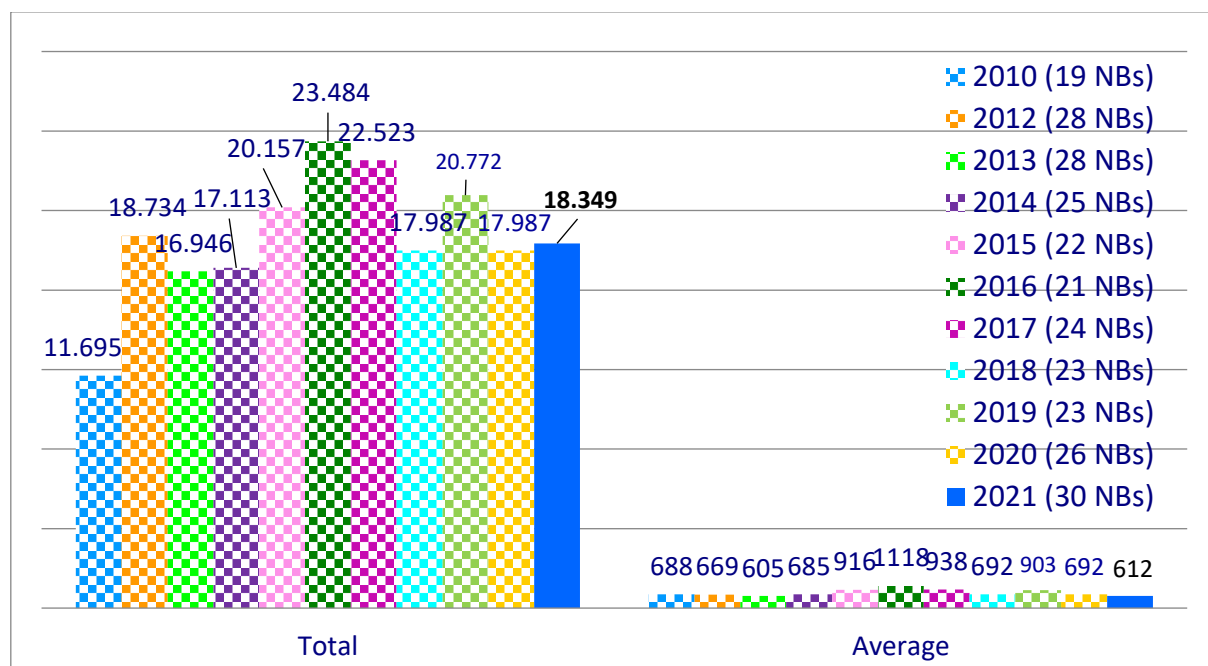
The *Distribution of issued certificates in 2021* has not significantly changed from last year:

- the majority of certificates issued in 2021 are still under MDD (92% to be compared with 91% last year). Note: issuing of MDD certificates was only possible until 26 May 2021, so less than 5 months,
  - the “In Vitro” diagnostics certificates stayed comparable (6%)
- and
- 2% for active implantable (instead of 3%).



- **ISO 13485 certificates**

The number of ISO 13485 certificates is stable. Even though with increased number of members we see a decrease in the average of issued certificates (692 decreasing to 612).



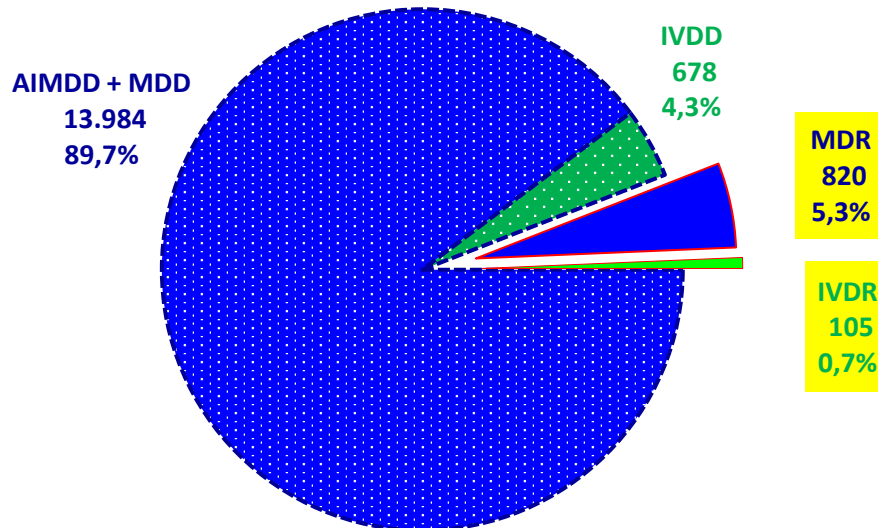
- **Number of Manufacturers**

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

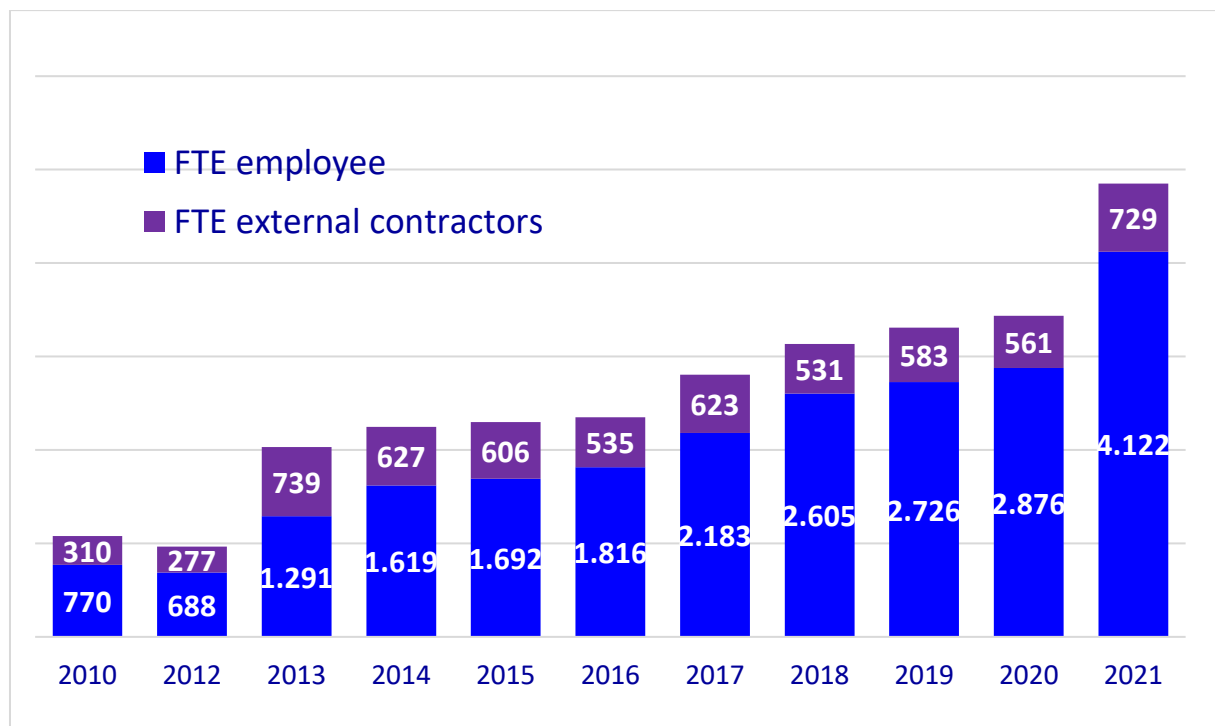
- under the Directives, the certificates considered are
  - for AIMDD – Annex 2 & 5,
  - for MDD - Annex II, V & VI and
  - for IVDD - Annex 4,
- under the Regulations, the certificates considered are
  - for MDR equal to Annex IX - Ch I & III + Annex IX - Ch II + Annex XI - part A and
  - for IVDR -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

Last year against the Directives, the total number makes 14 259 medical devices manufacturers. This year, it has increased to 14 662. This is probably mainly due to the fact that regulations certificates are partial and that manufacturers have simultaneously Directive certificates.



Total certification holders estimated to 14 662 / 30 NBs based on QMS (Quality Management System) certificates

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



For the 9th year in a row, notified bodies' workforce, expressed as the number of FTEs (Full-Time-Equivalents) has increased. The average number of employees of the members has increased by 43% as compared to 2020.

It is to be noted that a change in question on FTEs has been made in 2021, staff is divided in 3 categories:

- FTE of employee active in conformity assessment activities
- FTE of employee active in administrative and supporting activities
- FTE externalised contractors within conformity assessment activities

Until this year, we only had 2 categories, the increase shows that probably in former years some notified bodies underestimated the resources active in the whole organisation necessary to comply with all the requirements.

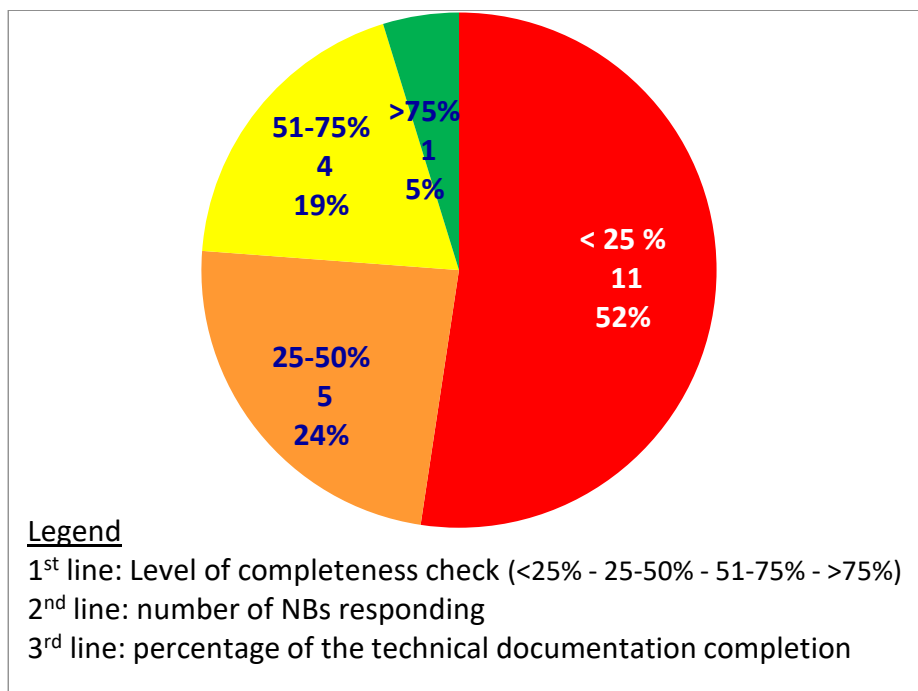
In any case, to meet the need the notified bodies still wish to hire additional personnel. It is hard to find people with the required competence on the market, as notified bodies are facing stiff competition with manufacturers and consulting companies to hire people with previous work experience in medical devices.

To face the needs, the number of subcontractors has increased as well.

- **Completeness check**

As part of the alignment of the surveys between the Commission and Team-NB, a new question was proposed in line with the requirements of the new regulations. 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 5 NBs (19%) that indicated that they will perform it as soon as they will be designated against a regulation.

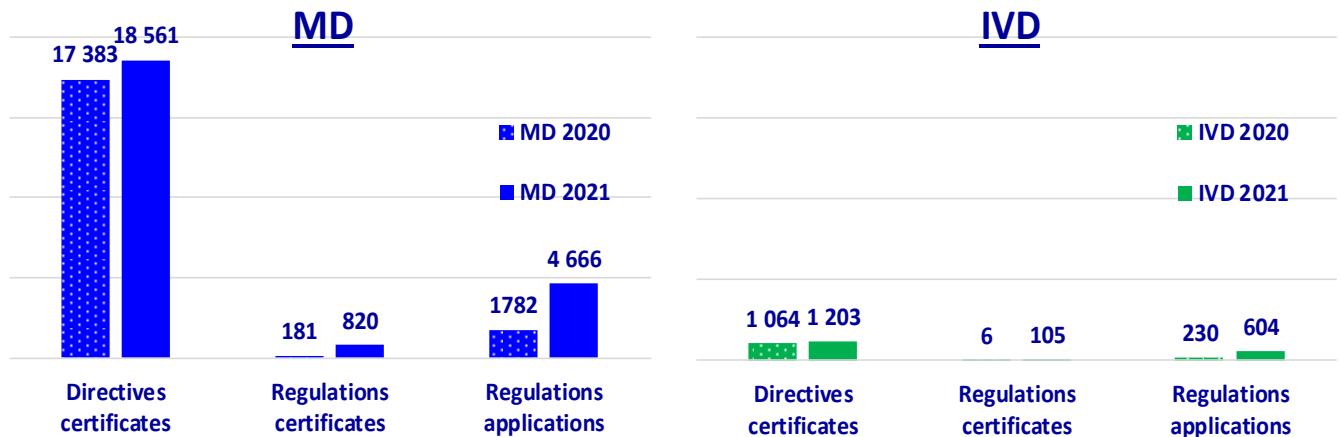


⇒ 75 % of notified bodies indicate that at least half of the TD submitted are deemed incomplete, and request additional information to start the assessment.

- **Transition process from directives to regulations**

The transition process is rather slow considering the deadline approaching in 2024.

If manufacturers holding directive certificates wish to continue to place products on the market, numerous QMS (Quality Management System) and Technical Documentation reviews need to be completed. Even applications are low considering that there are only two years remaining.



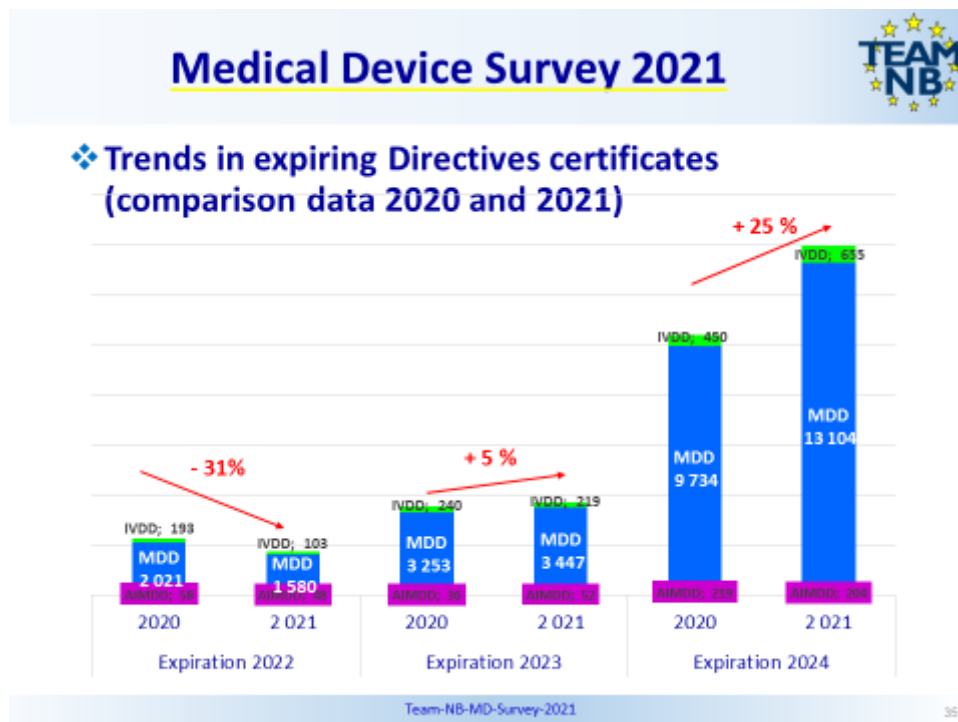
- Directives certificates increasing (thanks to new members)
- Regulation certificates increasing (> 4 times)
- Regulation applications increasing (2,5 times)
- ⇒ Still numerous certificates to be transfer against MDR (> 95%) and applications to be received (75%)
- Directive certificates : small increase
- Regulation certificates increasing (17 times)
- Regulation applications increasing (> 2,5 times)
- ⇒ Transfer against IVDR (>90%) + new certificates against IVD Regulation tremendous

Notified Bodies are encouraging all manufacturers to make applications now so that they are not disappointed when their Directive certificates expire.

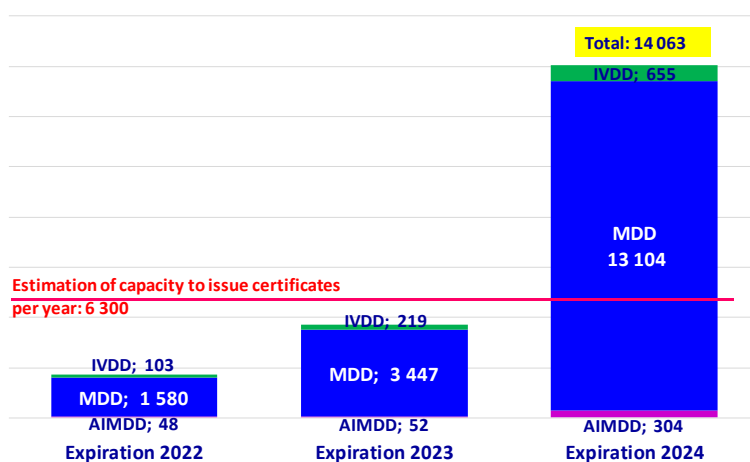
- **Expiration of directives certificates**

**Trends in expiring Directives certificates**

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



Thanks to the opportunities offered to solve the issues caused by the pandemic, we are witnessing a shift towards 2024 of the expiration of certificates.



The number of certificates that could be issued has been estimated to **6 300 certificates per year** (on the basis of same number of designated NBs against the regulations - in comparison to Directives - and same duration for the audits against the regulations - in comparison to Directives).

There is a risk to the continuous availability of some device with expiring certificates in 2024. To avoid this risk, solutions have to be found as it will not be feasible to issue 14 063 certificates in a year.

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](mailto:schlemmer@team-nb.org)