|  |  |  |  |
| --- | --- | --- | --- |
| R-TEAM-NB-Logo-2-0  The European Association Medical Devices - Notified Bodies | |  |  | | --- | --- | | TEAM-NB A.I.S.B.L.  Boulevrd Frère Orban 35A  B – 4000 Liège BELGIUM  Tel.: + 32 (0)4 254 55 88 | E-mail: [secretary@team-nb.org](mailto:secretary@team-nb.org)  Web: <http://www.team-nb.org>  VAT BE0864.640.677  IBAN BE09 3401 5174 8757 | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Editor : | Francoise SCHLEMMER |  | Date : | June 16, 2025. |
| **PRESS RELEASE**  **Team-NB sector survey 2024** | | | | |

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 maintained the questions aimed 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, the question focused on certificates issued under MDSAP was also maintained.

By the end of 2024, the number of notified bodies that were members of the association reached 43. This represents a substantial increase of 23% with 8 more members compared to 2023.

It should be noticed that the total number of Team-NB members includes "candidate members" which are still in the designation process. The 2024 survey compiled data from 41 Notified Bodies. These members are designated under two regulations or three directives.

Below some explanatory graphs of our **2024 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 against both Regulations and Directives as follow:

|  |  |  |
| --- | --- | --- |
| **“big”** | **“medium”** | **“small”** |
| above 1000 certificates | between 300 and 1000 certificates | less than 350 certificates |

The 2024 distribution is

|  |  |  |
| --- | --- | --- |
| **“big”** | **“medium”** | **“small”** |
| 17 % | 32% | 51% |

The compilation of both certificates could consider some duplicates certificates as we are in a transition phase.

* **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:

Legend: 2020: 16 members / 18 designated NBs

2021: 21 members / 25 designated NBs

2022: 25 members / 36 designated NBs

2023: 32 members / 42 designated NBs

2024: 41 members / 50 designated NBs

The results were compared with those of the “Study supporting the monitoring of the availability of medical devices on the EU market” presented for February 2025. Team-NB data concerns certificates issued in December 2024. Team-NB represents 79% of the total issued and applications received represent 73%.

**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:

Legend: 2020: 4 members / 4 designated NBs

2021: 6 members / 6 designated NBs

2022: 6 members / 7 designated NBs

2023: 10 members / 12 designated NBs

2024: 10 members / 12 designated NBs

The results were compared with those of the “Study supporting the monitoring of the availability of medical devices on the EU market” presented for February 2025. Team-NB data concerns certificates issued in December 2024. Team-NB represents 100% of the total issued and applications received represent 94%.

It is worth noting that at the beginning of 2025, 5 additional notified bodies were designated against the IVD and this brings the number of designated members to 14.

* **Certificates split among the 2 regulations annexes :**

The 2 below graphs shows the distribution of certificates between different conformity assessment modules under MDR (left) and IVDR (right)

|  |  |
| --- | --- |
|  |  |

* **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.

It should be noted that there has been a significant increase in submissions under Annex XVI; they have more than doubled. As for the number of Annex XVI certificates issued, it has more than quadrupled.

Regarding AI/machine learning devices, the number of submissions is stable and the number of certificates issued has increased by 20%.

It is worth noting a significant increase in Class D applications, an increase of 73%. The number of Class D certificates issued has increased by 170%.

* **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.  Compared to 2023, in 2024 the number of certificates issued by members according to the **ISO 13485 standard is stable**; on the other hand, there is a decrease in the number of certificates according to the MDSAP format. |  |

* **Access to Notified Bodies by SMEs is taken into accounts by Members.**

|  |  |
| --- | --- |
| As a mean of all responses, SMEs are representing 79% of the activities of the Notified Bodies members. |  |

* **Number of Manufacturers**

|  |  |
| --- | --- |
| Following the answers of the members, they have a total of   * 13 101 MD manufacturers * 1 082 IVD manufacturers |  |

* **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 data below shows that notified bodies recruited more technical resources to carry out conformity assessments in 2024 compared to 2023.

The number of internal employees for conformity assessment increased by 26%.

The number of subcontractors also increased by 22%.

These figures confirm that **notified bodies have more than sufficient resources to meet market needs**. They also confirm the difficult situation notified bodies are facing. Some technical resources are short of work following requests from some manufacturers to suspend their applications or delay their responses to ongoing processes.

* **Completeness check**

Under the regulations, 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.

We can see the evolution of the completeness of the received technical documentation is slowly 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 help the Manufacturers to meet the regulations requirements and to improve the quality of applications, Team-NB published Technical Documentation Best Practice Guidance documents for both MDR and IVDR.

Team-NB organized trainings sessions for MD and IVD technical documentation since June 2023 with respectively:

* + 4 sessions for IVD with a total 280 participants from 154 organisations knowing that a 5th session is going to take place on July 3rd.
  + 8 sessions for MD with a total 625 participants from 353 organisations knowing that a 9th session is going to take place on June 17th.

Additionally, to meet participants' requests, Team-NB has developed a session focused on clinical aspects:

* + the first clinical focused MDR training session took place in May, with a total of 91 participants from 53 organizations. Registrations exceeded the limit to allow for fruitful exchanges, and we have already planned a second session to take place on August 27.

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, 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 further improve harmonisation in and between notified bodies.

In case of any further clarification needed, please contact : schlemmer(at)team-nb.org.