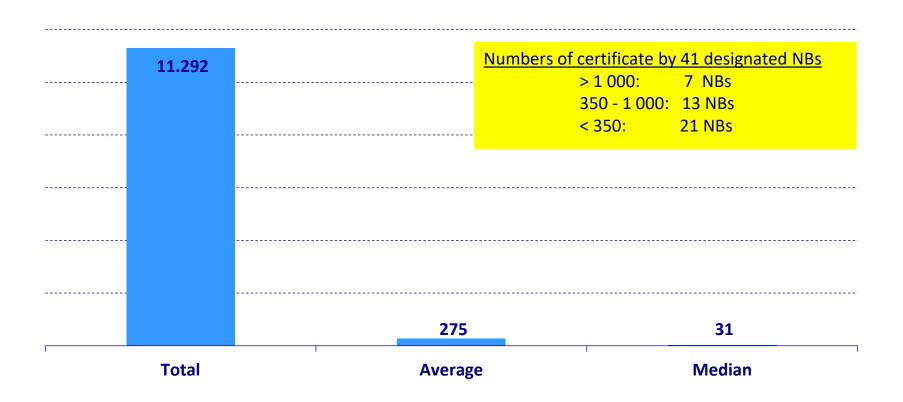


Medical Device Survey 2024 Data from all 41 designated members



Regulations certificates issued end of 2024





MDR applications and certificates (QMS + Product)

For information,

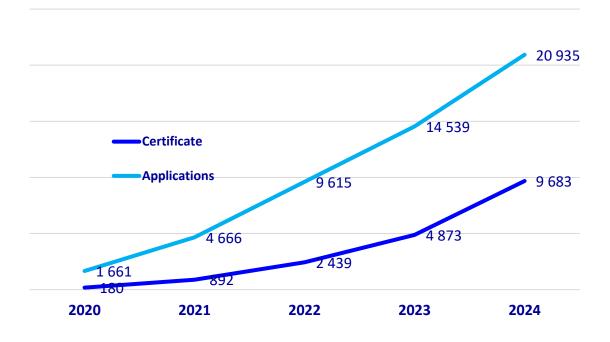
number of designated members of Team-NB compared to the total number of designated notified bodies:

2020: 16 members / 18 designated NBs 2021: 21 members / 25 designated NBs 2022: 25 members / 36 designated NBs 2023: 32 members / 42 designated NBs 2024: 39 members / 50 designated NBs

MDR

In comparison with the data 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

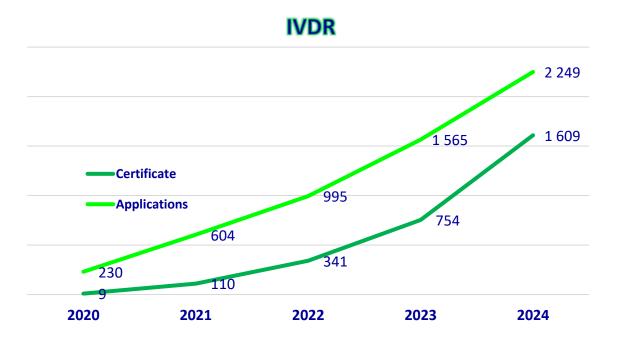
For information,

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 2024: 10 members / 13 designated NBs

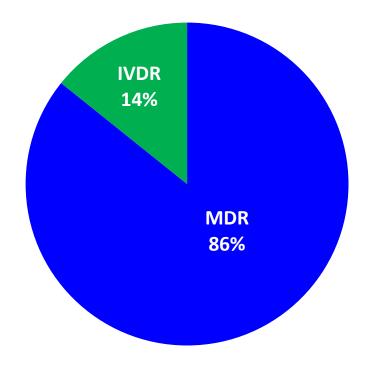
In comparison with the data of the "Study supporting the monitoring of the availability of medical devices on the EU market" presented for February 2025. Team-NB data concerns certificates issued in December 2024.

Team-NB represents 100% of the total issued and applications received represent 94%.



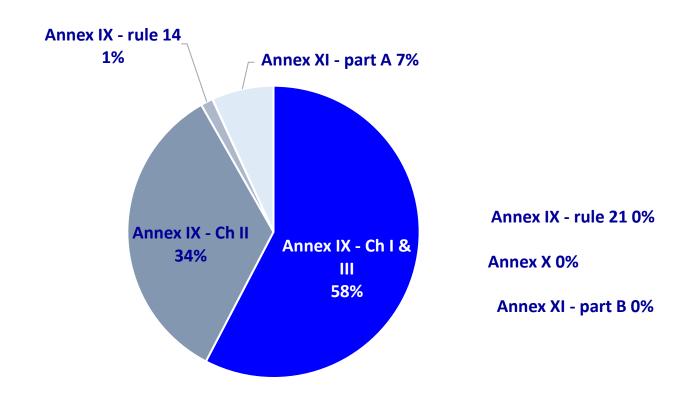


Distribution of certificates between different Regulations



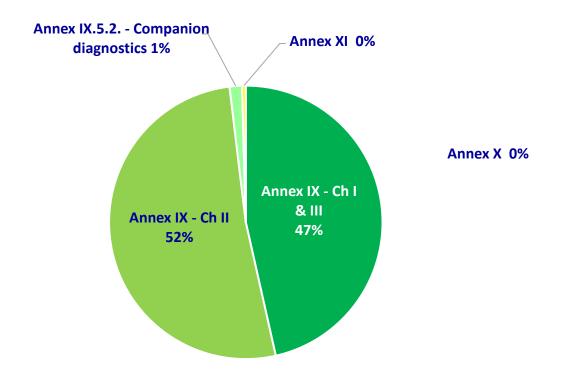


Distribution of certificates between different conformity assessment modules under MDR





Distribution between different conformity assessment modules under IVDR





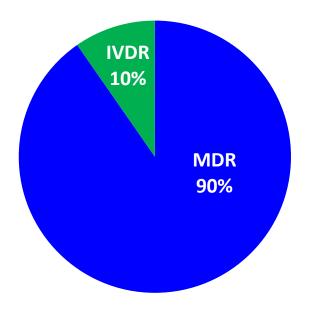
Comparison of issued certificates among regulations



→ For the second consecutive time between 2022 and 2023 and between 2023 and 2024, doubling of the issuance of regulatory certificates.

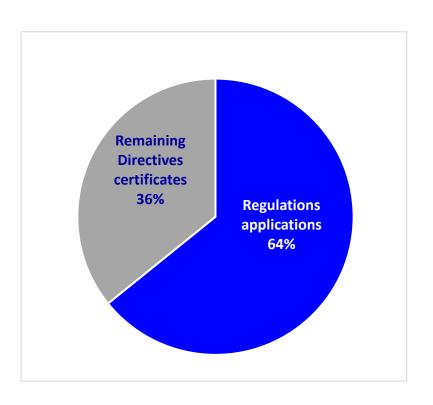


Distribution of applications between different Regulations





Regulations applications versus Directives remaining certificates



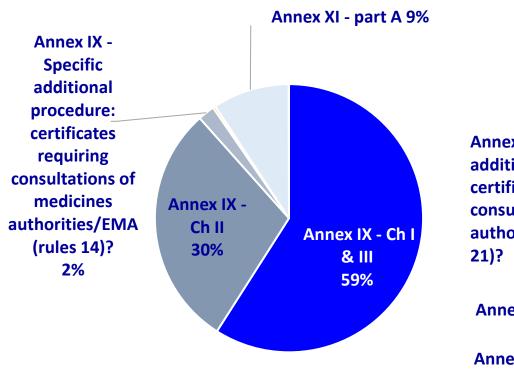
To be noticed

Does not take scopes into consideration

(although Regulations applications scope received often much smaller than Directives scopes)



Distribution of applications between different conformity assessment modules under MDR



Annex IX - Specific additional procedure: certificates requiring consultations of medicines authorities/EMA (rules 21)? 0%

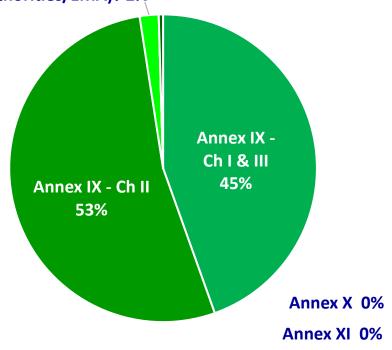
Annex X:0%

Annex XI - part B: 0%



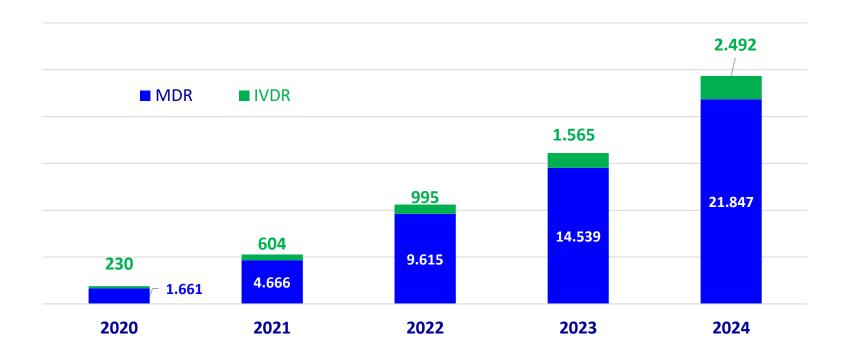
Distribution of applications between different conformity assessment modules under IVDR

Annex IX.5.2. - Companion diagnostics (consultations of medicines authorities/EMA)? 2%



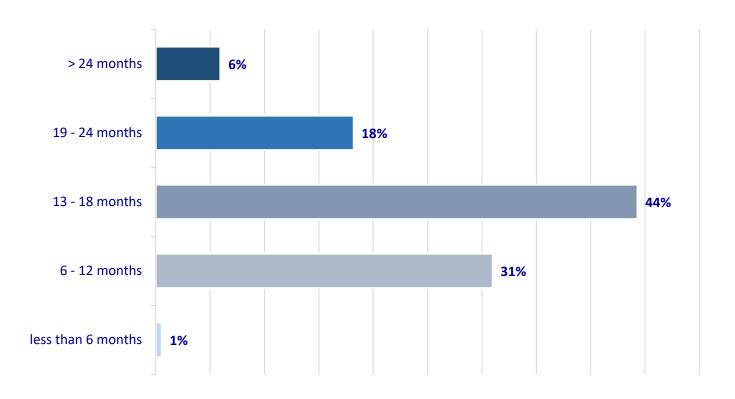


Evolution of received applications against Regulations



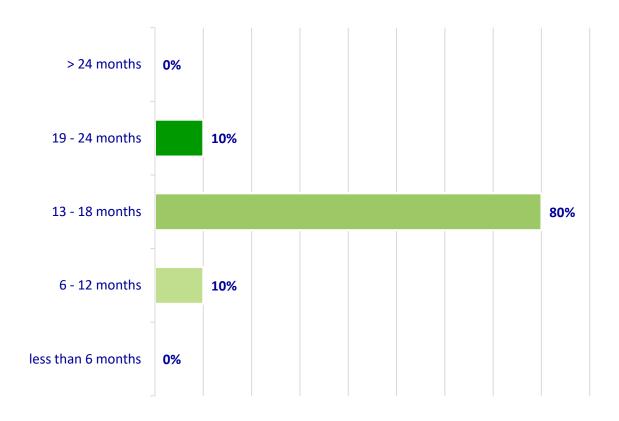


Average time to reach issuance of a NEW (not renewal) MDR certificate





Average time to reach issuance of a NEW (not renewal) IVDR certificate

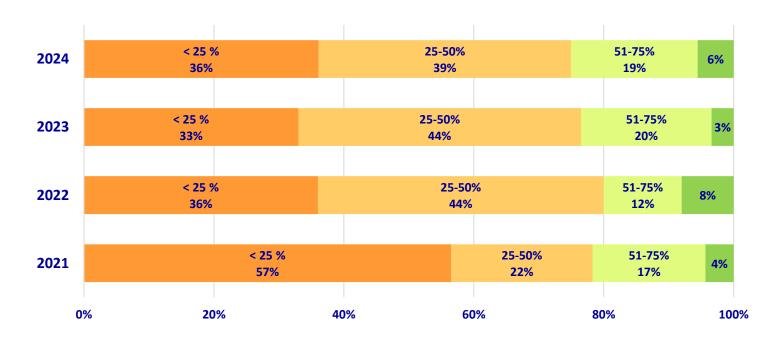




MDR Completeness check - evolution

Activity to ensure that complete technical documentation has been received before undertaking the review of its content

below graph with comparison of completeness over the 4 last years

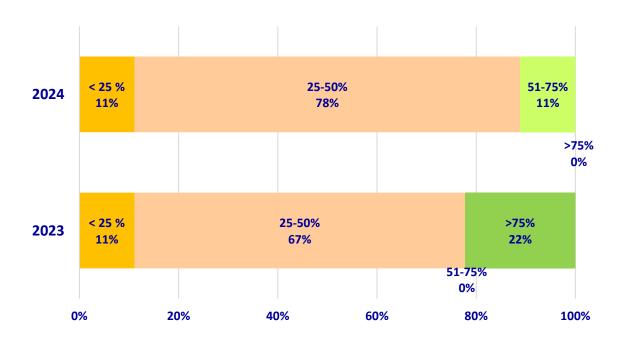




IVDR Completeness check - evolution

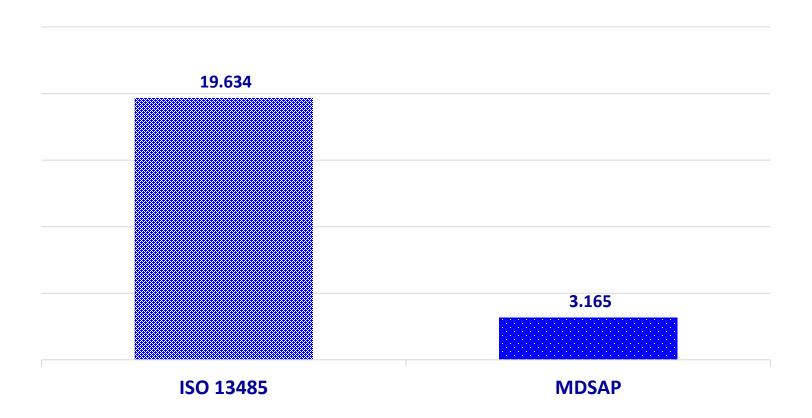
Activity to ensure that complete technical documentation has been received before undertaking the review of its content

below graph with comparison of completeness over the 2 last years



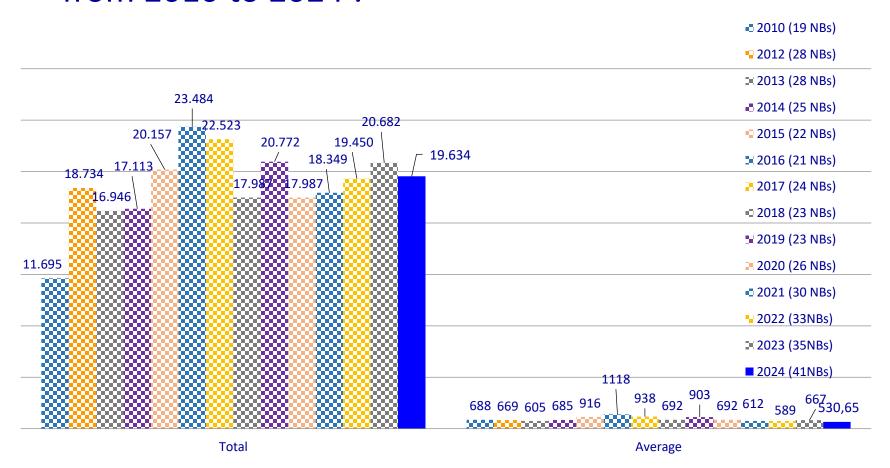


Other certifications: ISO 13485 / MDSAP



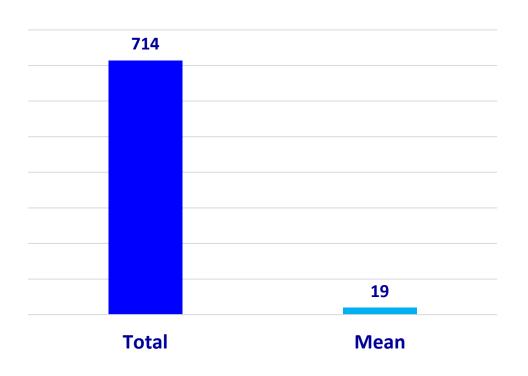


❖ Valid certificates against ISO 13485 from 2010 to 2024 :





Number of certificates withdrawn in 2024



Reasons for withdrawing:

Cancelled due to end of Directives

Cessation of activity

Change of NB

Clients request

Contractual obligations not fulfilled

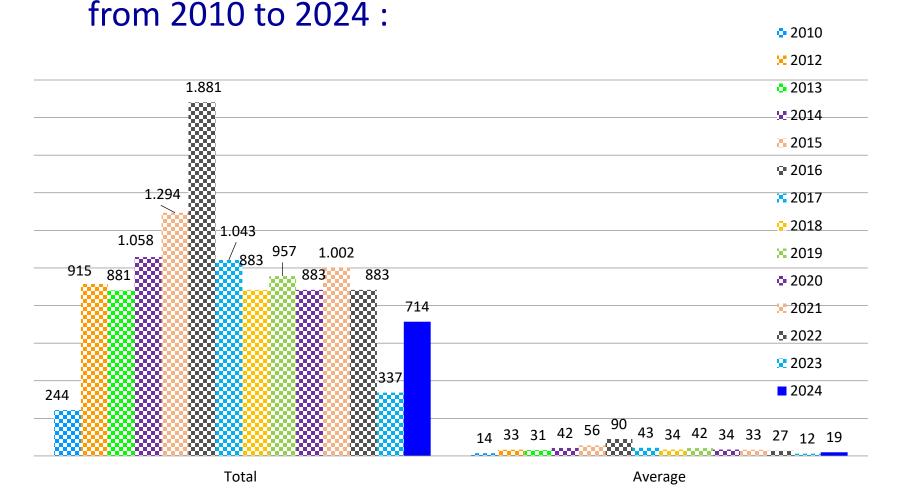
Financial issues

No longer manufacturing product

Non conformities not closed

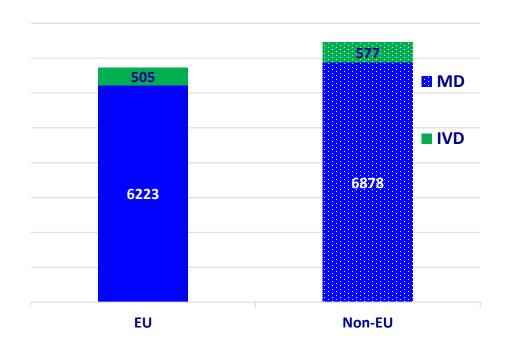


Number of certificates withdrawn





Clients



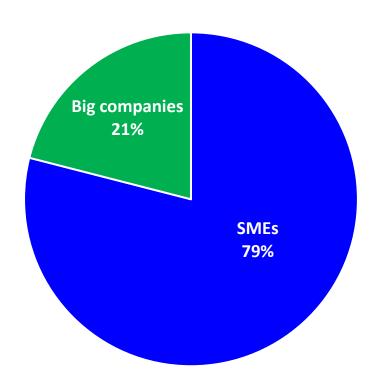
For clarification, the number of clients is smaller than the number of certificates holders as 1 client can have more than 1 QMS (quality management certificate) (for example: more than 1 plant).

Moreover, during this transition period, some clients could have both a QMS <u>Directive</u> certificate and a QMS <u>Regulation</u> certificate.



Clients of the NBs:

percentage of SMEs versus Big companies

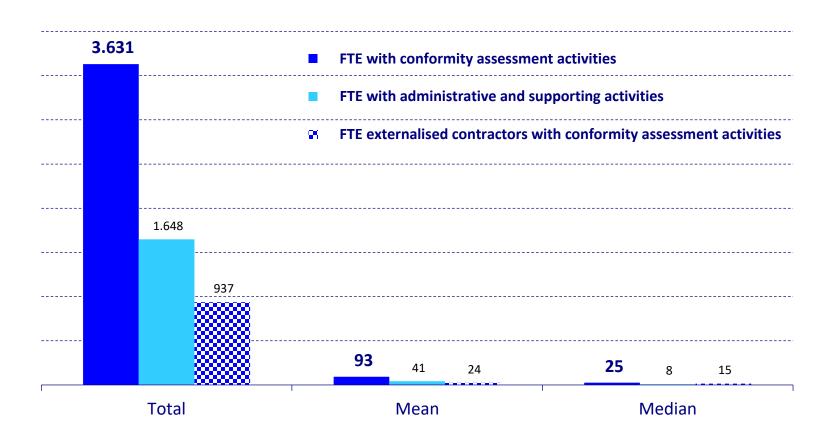


Important to notice that 35 members indicating that

SMEs represent minimum 50% of their activities



Staff in 2024 (full time equivalent in MD sector)





Staff dedicated to conformity assessments
(full time equivalent in MD sector) - From 2010 to 2024



In 1 year, increase of

 25,2% of the conformity assessment employees and contractors

Members







































































Note: some members of the same group are represented by only 1 logo