Team-NB Members

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

TEAM NB

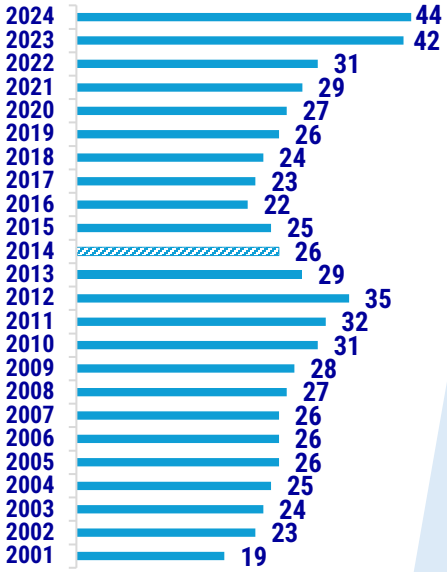
Since 2001

Our aims:

- Represent Notified Bodies
- Communication with :
  - European Commission
  - European Medicines Agency
  - Competent Authorities
  - Industry
  - Patients associations
  - Other stakeholders
- Promote technical and ethical standards
- Participate in improving the legal framework
- Support innovation
- Contribute to harmonization

44 Members

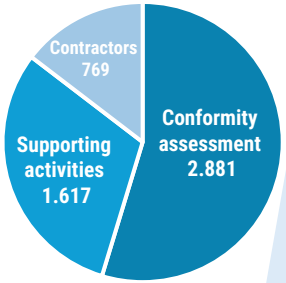
Evolution since 2001



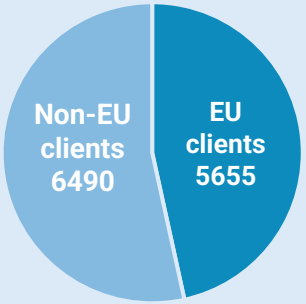
Since 2014, Code of Conduct mandatory (V.5 – Sept. 2024)

5.267 (2023)

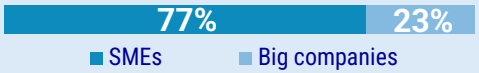
Team-NB Members Staff



12.145 Manufacturers Clients



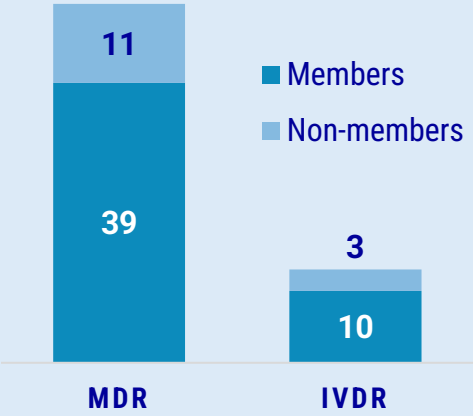
77% of SMEs as clients



41 Designated Members

3 in the designation process

20 different countries



11 Mirror MDCG - WGs

2 EMA - WGs

1 HTA Stakeholders Network

27 Task forces

- Class D specific requirements
- Medical Gas Systems
- Artificial Intelligence
- IVDR Harmonisation
- Code of Conduct
- Orphan Devices
- Cybersecurity
- PSUR / CEAR
- Lifetime
- …

30 Position papers

- BPG for Submission of TD (MD/IVD)
- Conformity Assessment Class D
- Confirmation letter of application against Reg. 2023/607 & 2024/1860
- Transfer Agreement for Surveillance of Legacy Devices
- Lifetime for medical devices
- …

Trainings

- MDR PMS
- Basic UDI-DI
- Hybrid Audits
- Software and AI
- MDR Annex XVI
- MDR Clinical Data
- Risk Management
- Substance Based Devices
- IVDR Technical Documentaion
- MDR Technical Documentation

around **200 NBs staff** trained yearly

Experts sessions

MDR Clinical
IVDR Performance

Trainings for Manufacturers

- IVDR Technical Documentation
- MDR Technical Documentation

more than **800 participants** trained

Annual sector survey
with 100% responses since **2008**