The **E**uropean **A**ssociation of **M**edical devices
Notified **B**odies

Web Site - Presentation

2025

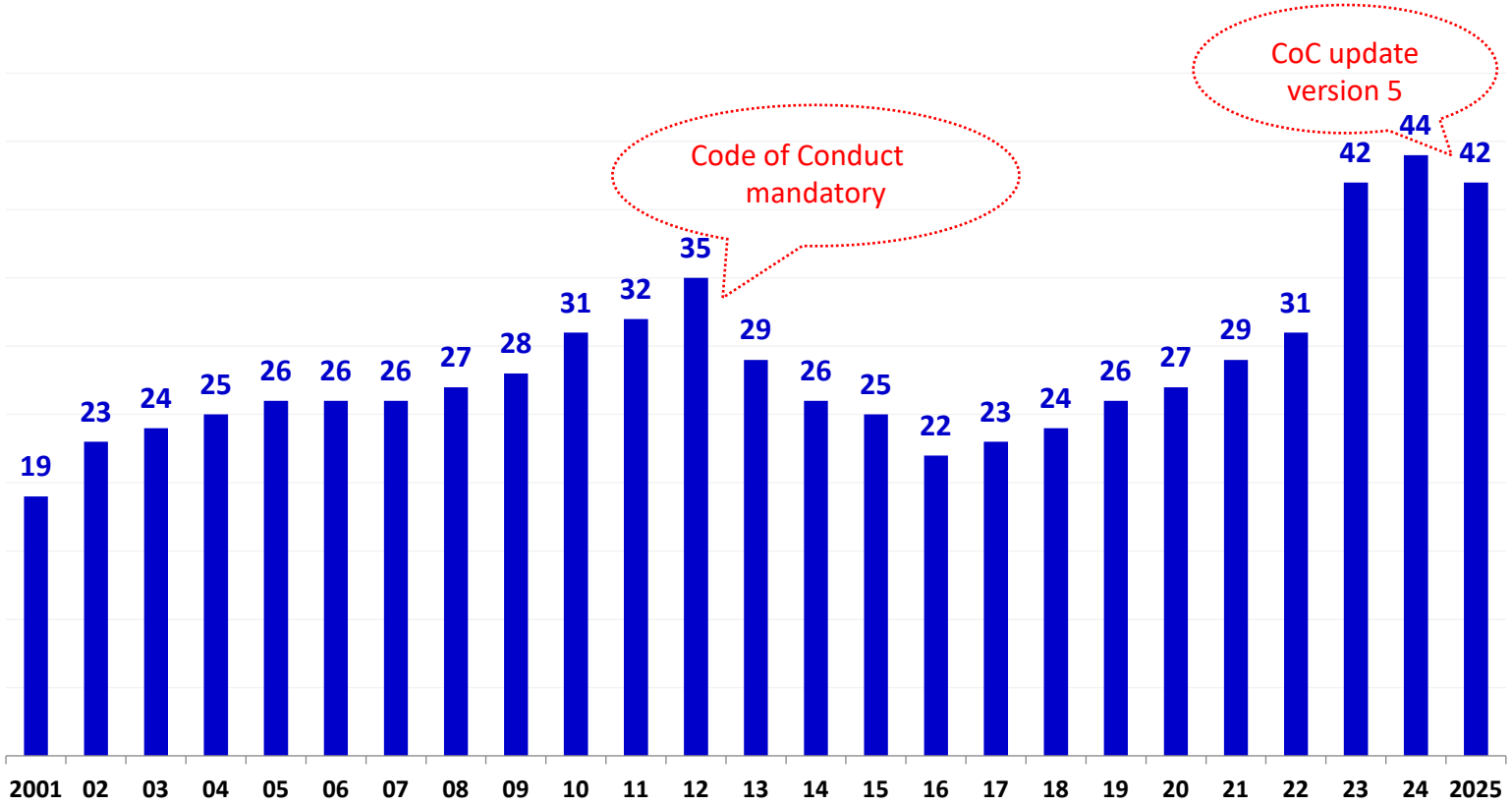
Team-NB

Aims:

- Represent Notified Bodies
- Communication with
  - European Commission
  - European Medicines Agency
  - Competent Authorities
  - Industry
  - Others stakeholders
- Promote technical and ethical standards
- Participate in improving the legal framework
- Contribute to harmonization (e.g. training ‘for notified bodies by notified bodies’)

Members

Members over the years from foundation in 2001

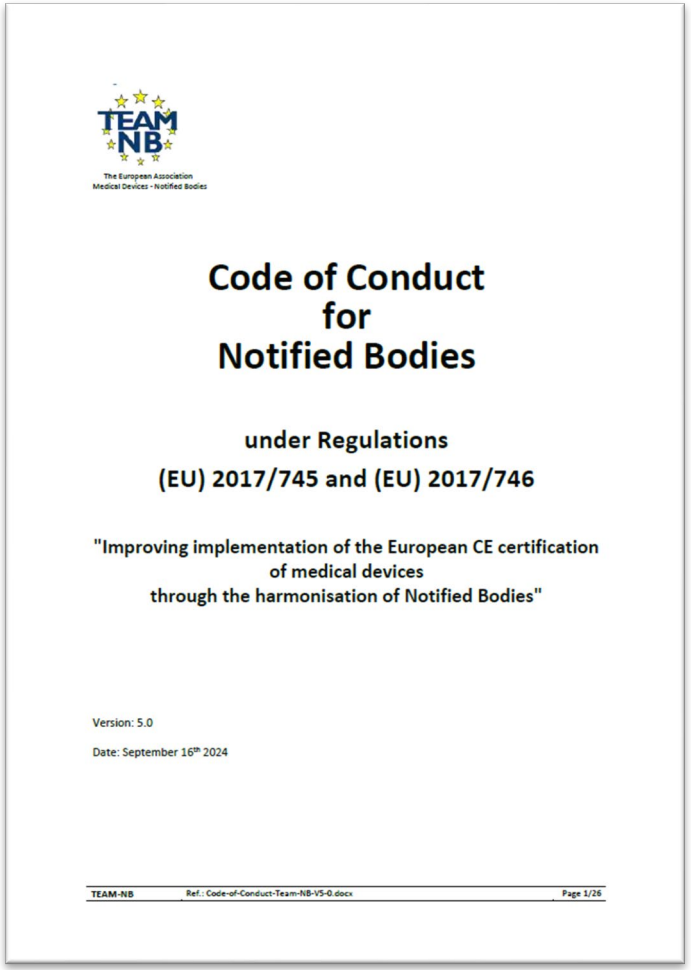


42 members representing 19 different countries

including new category of NBs: 2 in the designation process

Code of Conduct - Version 5

- **Version 5.0 approved on September 2024 and signed by all Members**
  - Removal of references to Directives and general update of references and terminology
  - Compliant with MDCG Guidance and TeamNB & NBCG-Med Papers
  - Estimation of time needed for Technical Documentation review included
  - Clarified requirements for unannounced audit
  - Detailed explanation of re-certification requirements
  - Estimation of time needed for CAPA
  - Included examples for Structured Dialogue
  - Enforcement changed to complaint / appeal process
- **Mandatory to sign for TEAM-NB members**
- **Available on website : www.team-nb.org**



TEAM NB

The European Association Medical Devices - Notified Bodies

Code of Conduct for Notified Bodies

under Regulations (EU) 2017/745 and (EU) 2017/746

"Improving implementation of the European CE certification of medical devices through the harmonisation of Notified Bodies"

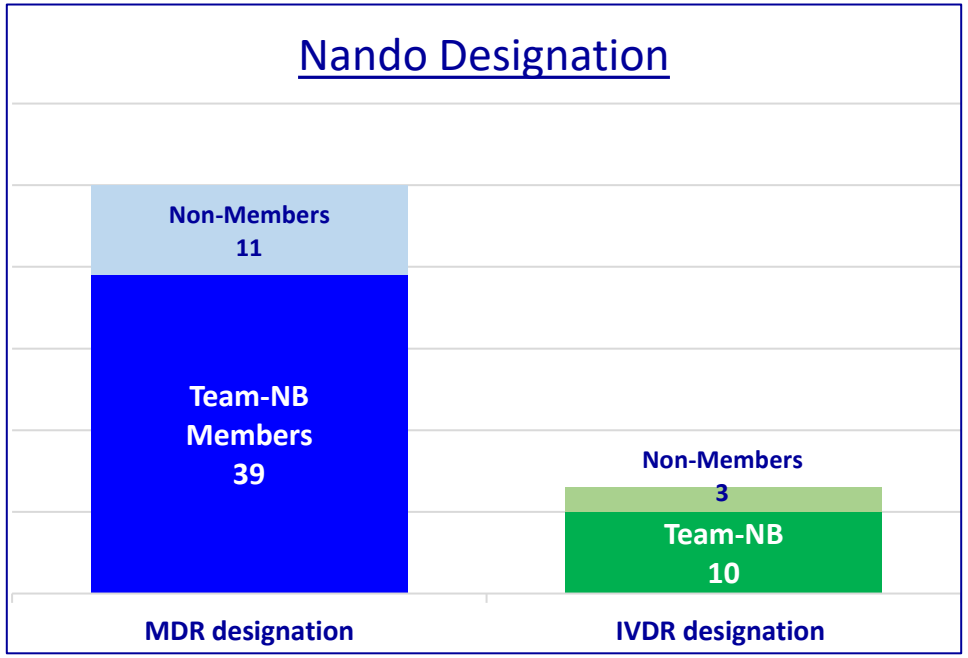
Version: 5.0

Date: September 16th 2024

TEAM-NB Ref.: Code-of-Conduct-Team-NB-V5-0.docx Page 1/26

Interpretation of the new regulations

- **Team-NB established working groups from 2016**
  - ⇨ **Aims**
    - Help members to be designated
    - Allow harmonization



Implementation of new regulations

MDCG mirror WGs

⇨ Aims

- to allow notified bodies members to speak of 1 voice
- to prepare and participate in the MDCG meetings
- to write reports
  - distributed to all members
  - to share information
- to comment on MDCG proposals
- to write Position Papers (published on Team-NB web site)

Implementation of new regulations

Task Forces

Aims

- to address specific topics of NBs interest
  - Class D specific requirements
  - Medical Gas Systems
  - Artificial Intelligence
  - IVDR Harmonisation
  - Code of Conduct
  - Orphan Devices
  - Cybersecurity
  - PSUR / CEAR
  - Lifetime
  - …
- to write Position Papers (published on Team-NB web site)
- to harmonise
  - views
  - practises

Implementation of new regulations

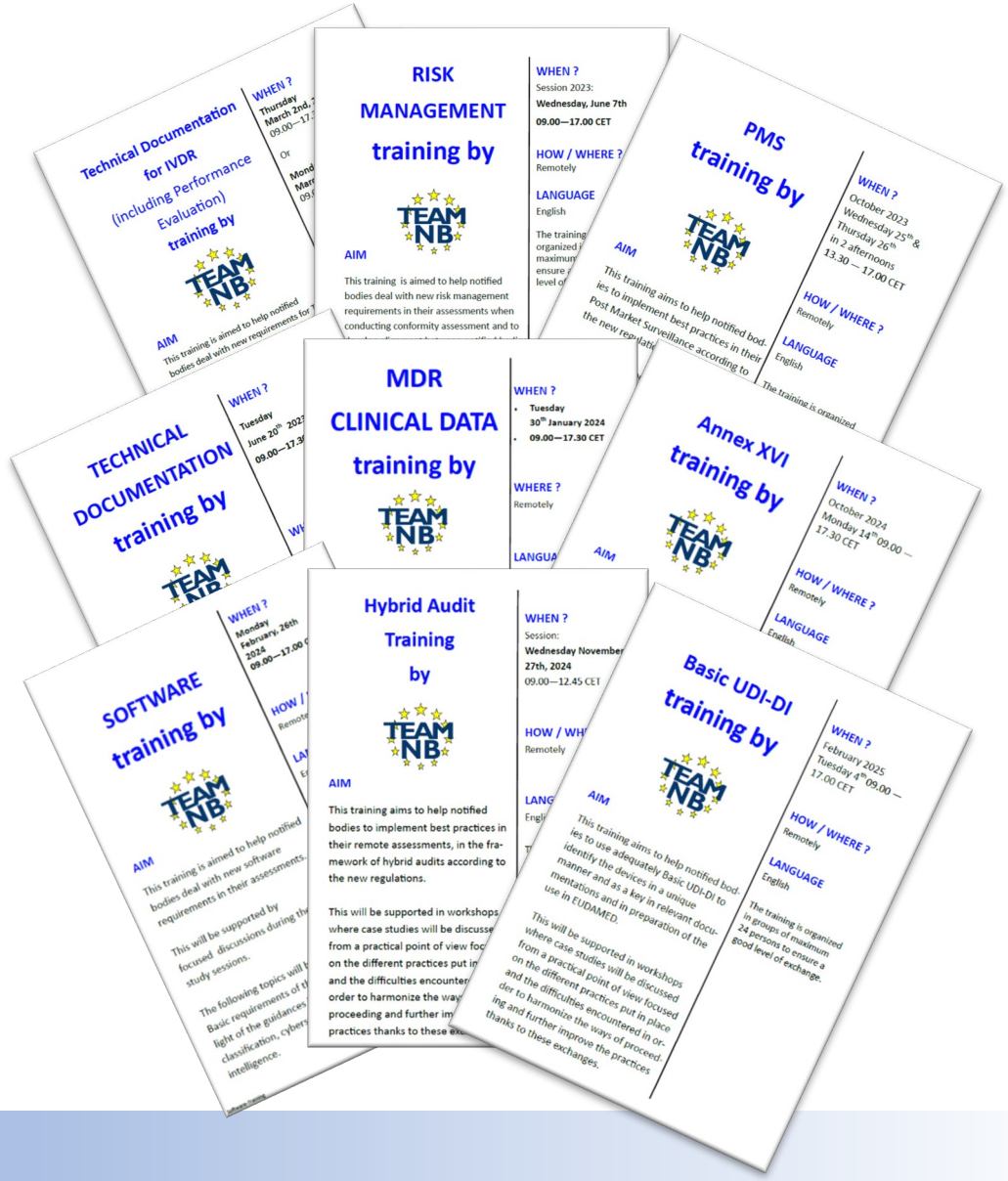
Trainings

⇨ Aims

- to help NBs to deal with new MDR / IVDR requirements in their assessment.
- to achieve a better harmonisation among NBs thanks to the exchanges

Trainings Topics

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

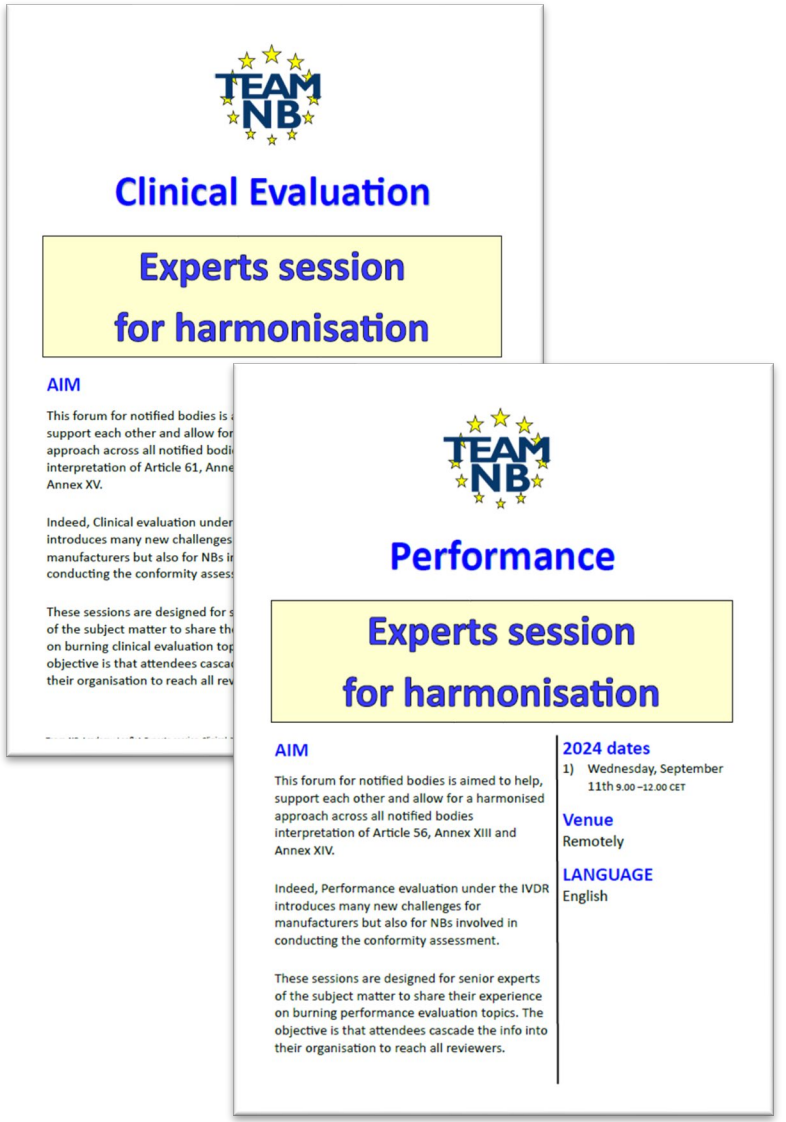


Implementation of new regulations

❖ Experts sessions

⇨ Aims

- to support NBs
- To allow for a harmonised approach across all notified bodies interpretation
- for senior experts to share their experience on burning topics
- with attendees to cascade the info into their organisation to reach all reviewers



Implementation of new regulations

❖ Trainings for Manufacturers

⇨ Aims

- to review the MDR requirements related to technical documentation and share notified bodies insights
- to review the Team-NB technical documentation best practice document for MDR

IVDR Technical Documentation Training for Manufacturers

WHEN ?
Wednesday,
July 3rd
9:00-17:00 CET

WHERE ?
Remotely

LANGUAGE
English

PARTICIPANTS
limited to
40 organisatio
to 2 connecti
member
Priority for
SMEs registra
places reserv
until June 3rd

In case we reach th
additional session
grammed in the co

AIM

The MDCG Position Paper Transition to the MDR and IVDR (MDCG 2022-14) encourages notified bodies to strengthen the communication with manufacturers by means of webinars, workshops, targeted feedback and informative sessions.

The aim of this training is to review the IVDR requirements related to Technical Documentation and share notified bodies insights; it is also planned to review the Team NB Technical Documentation Best Practice document for IVDR (published on March 1st 2023).

The topics are presented by IVD experts of IVDR designated notified bodies.

The content was elaborated by IVD experts of 7 notified bodies, namely BSI, Dekra B.V., Dekra GmbH, GMED, NSAI, TÜV Rheinland LGA and TÜV SÜD.

MDR Technical Documentation Training for Manufacturers

WHEN ?
Wednesday
2025, February 12th
9:00-17:00 CET

WHERE ?
Remotely

LANGUAGE
English

PARTICIPANTS
limited to 50 organisations with up to 2 connections of staff member
Priority for
SMEs registration (25 places reserved) until January 6th

In case we reach the limit, an additional session will be programmed in the coming months.

AIM

The MDCG Position Paper Transition to the MDR and IVDR (MDCG 2022-14) encourages notified bodies to strengthen the communication with manufacturers by means of webinars, workshops, targeted feedback and informative sessions.

The aim of this training is to review the MDR requirements related to Technical Documentation and share notified bodies insights; it is also planned to review the Team-NB Technical Documentation Best Practice document for MDR (version 2—published on April 24th, 2023).

The topics are presented by MDR experts of designated notified bodies.

The content was elaborated by MDR experts of 9 notified bodies, namely **BSI, CeCertiso, Dekra, DNV, ECM, GMED, TÜV Rheinland, TÜV SÜD.**

eaflet-Technical-Documentation-Training for Manufacturers-2023

Contacts

❖ Administrative Commitee:

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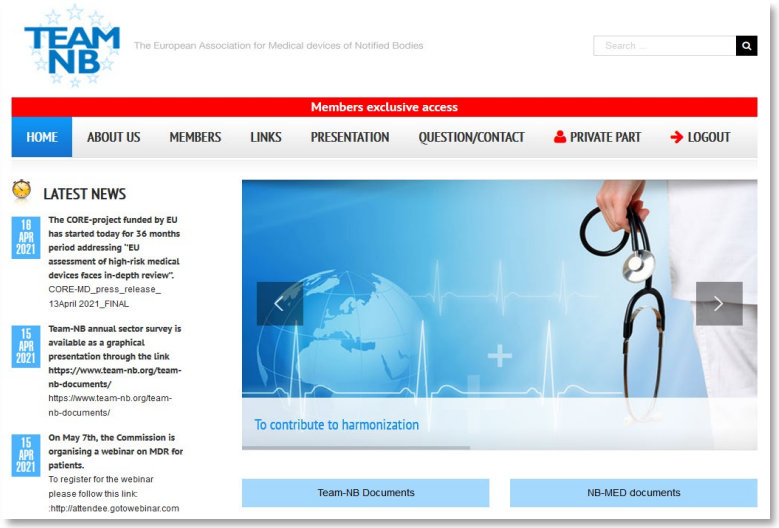

Members

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