The European Association of Medical devices Notified Bodies

Moving forward – How will the work of Core MD support Notified Bodies?

March 25th,2024

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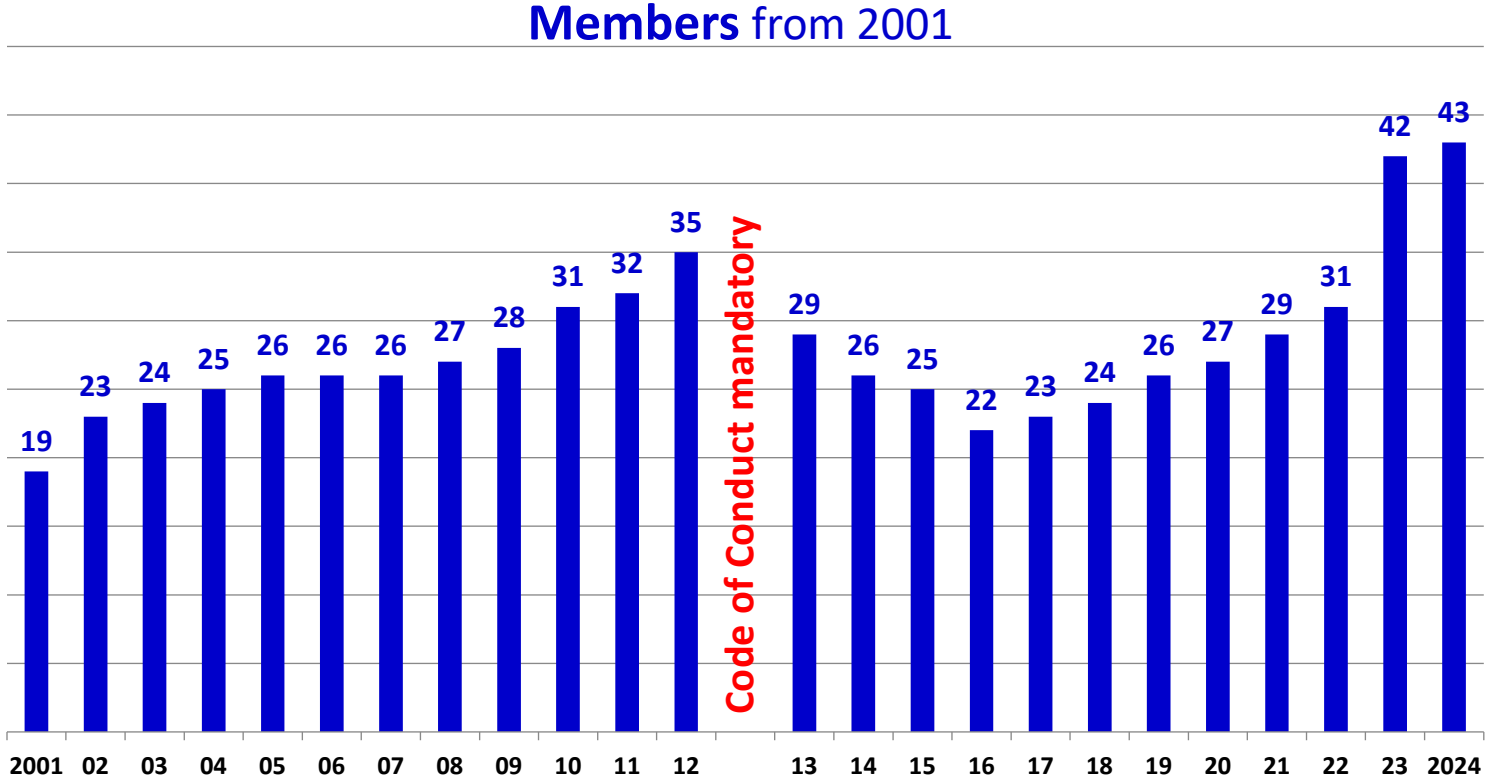
Team-NB

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

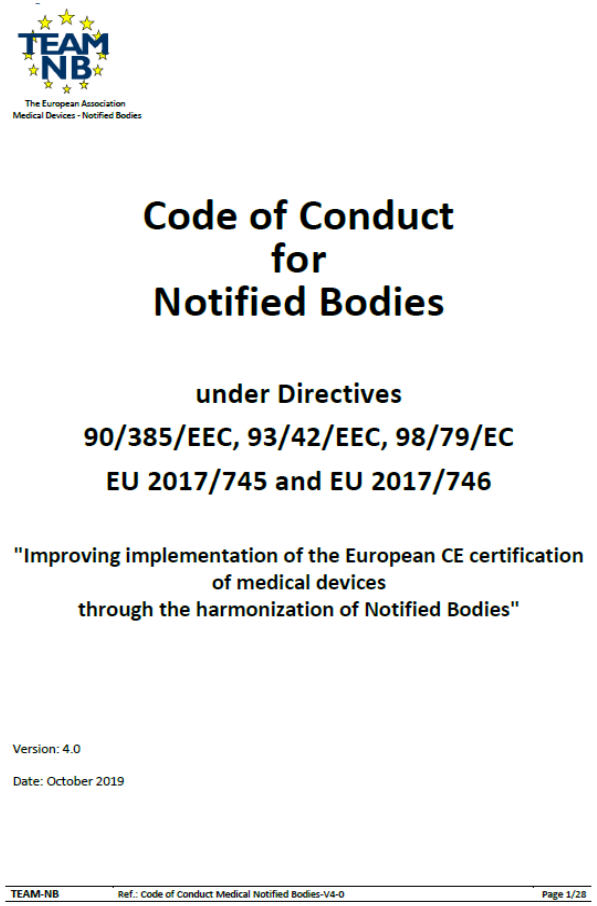


43 members representing 20 different countries

including new category of NBs: **5** in the designation process

Code of Conduct - Version 4

- Mandatory to sign for TEAM-NB members
- Alignment with MDR / IVDR requirements
- Available on website www.team-nb.org
- Version 4.0 approved on October 2019 ⇨ version 5.0 in progress



TEAM NB
The European Association Medical Devices - Notified Bodies

Code of Conduct for Notified Bodies

under Directives
90/385/EEC, 93/42/EEC, 98/79/EC
EU 2017/745 and EU 2017/746

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

Version: 4.0

Date: October 2019

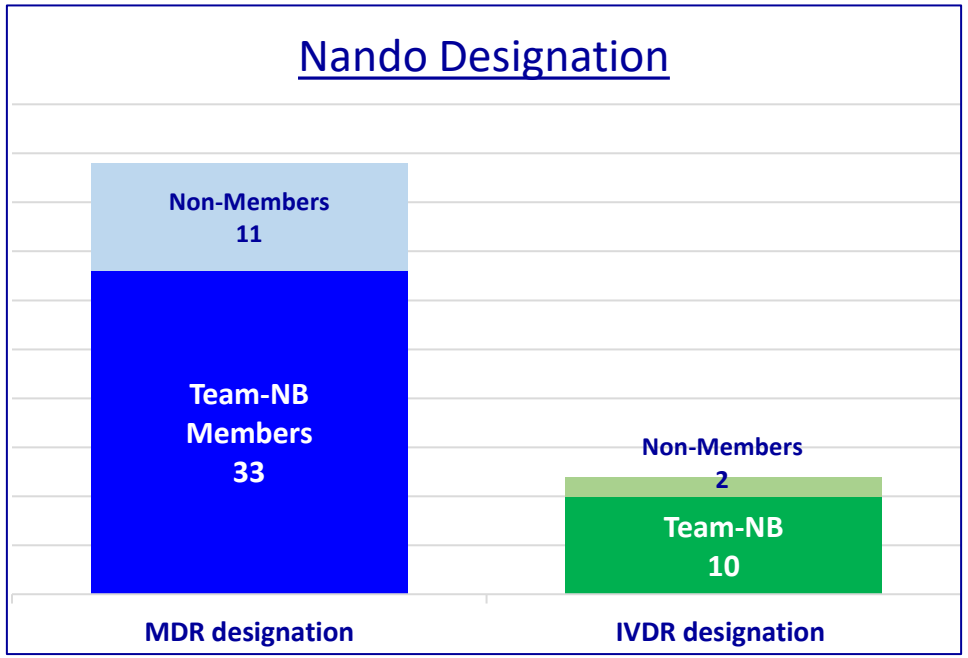
TEAM-NB Ref.: Code of Conduct Medical Notified Bodies-V4-0 Page 1/28

Interpretation of the new regulations

Team-NB established working groups from 2016

⇨ **Aims**

- Help members to be designated
- Allow harmonization



Team-NB actions: Implementation of regulations

MDCG mirror WGs

- MDCG meetings : preparation, participation and write reports distributed to all members -> to allow notified bodies members to speak of 1 voice
- to comment on MDCG proposals

Task Forces

- to address specific topics of NBs interest
  - AI & Mobile-App
  - B&C Rules-NBs-interpretation (rules 8, 11, 14, 21, …)
  - Lifetime
  - Dental Implants (update of an existing PP)
  - Consensus document for MDR applications

⇨ Aims

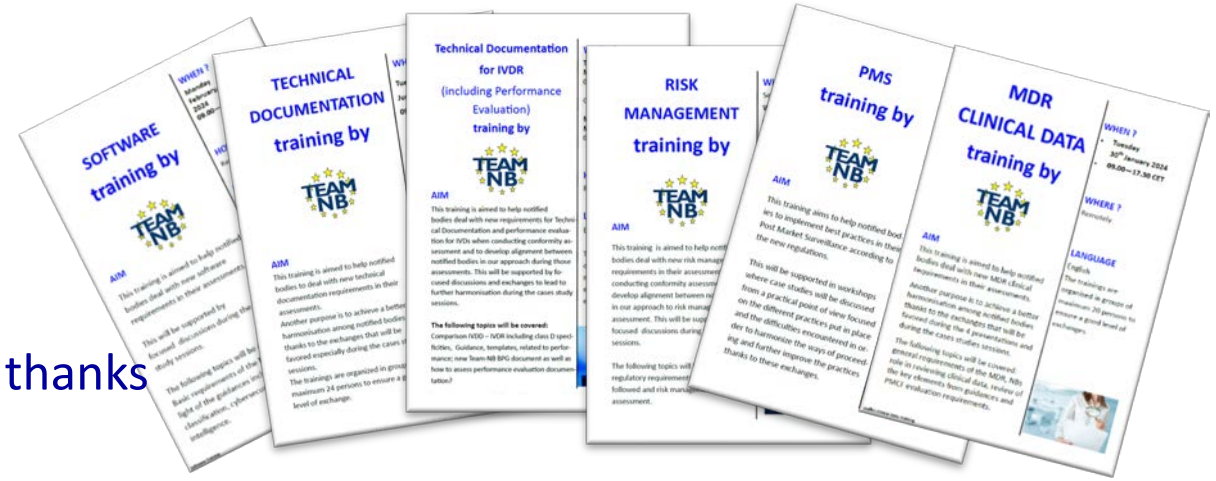
- to harmonise views and practises
- to write Position Papers (published on Team-NB web site)

Team-NB actions: Implementation of 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



Experts sessions

⇨ Aims

- to achieve a harmonised approach across all notified bodies interpretation
- To allow senior experts to share their experience and to cascade the info into their organisation to reach all reviewers

Team-NB actions: Training for Manufacturers

Trainings

⇨ Aims

- to review the MDR & IVDR requirements related to Technical Documentation
- to share notified bodies insights
- to present the Team-NB Technical Documentation Best Practice guide for
  - IVDR (published March 1st, 2023)
  - MDR (version 2—published on April 24th, 2023).
- IVD & MD experts by designated notified bodies (BSI, CeCertiso, Dekra B.V., Dekra GmbH, DNV, ECM, GMED, NSAI, SGS, TÜV Rheinland, TÜV SÜD) elaborated the content, will present and respond to questions

CORE-MD work

Team-NB involvement

- WP 1: Understanding methods used to generate clinical evidence for high-risk medical devices
- WP 2: Strengthening evidence for high-risk medical devices: New methods for generating clinical evidence
- WP 3: Extracting maximal value from medical device registries and real-world evidence
- WP 4: Networking and community building: Engaging with stakeholders

CORE-MD work

Team-NB experts involved

- Sabina Hoekstra-van den Bosch (TÜV SÜD)
- Richard Holborow (BSI)
- Marianna Mastroroberto (Kiwacermet)
- Erman Melikyan (intertek)
- Alexey Shiryaev (DNV)
- Hannah Stapel (Medcert)
- Christoph Ziskoven (TÜV Rheinland)
- Françoise Schlemmer (Team-NB)

CORE-MD work

Move forward – Team-NB point of view

- Team-NB welcomed as participant in the consortium
- Better understanding between clinicians and NB experts
  - Notified bodies learnt that interaction with the medical/scientific community and clinical professional associations is a real asset
  - CORE-MD learnt that notified bodies staff is highly educated and trained rigorously and continuously according to legal requirements

CORE-MD work

- **Move forward, examples:**
  - **Project linked academics, healthcare professionals with NBs**
    - **improved the relationship**
    - **allowed sharing of knowledge**
  - **Project highlighted many of the issues addressed under MDR**
    - **such as the introduction of SSCPs,**
    - **publication of clinical investigations on EUDAMED (when available).**
  - **Certificates under conditions : opportunity to support innovation and orphan devices.**

CORE-MD work

- **Move forward, examples:**
  - **Project leads to many recommendations**
    - **They are helpful and would improve the system**
    - **Be careful, need to select the ones to adopt (as it is needed to consider the lack of capacity and resource in the competent authorities, EU Commission and notified bodies needed to help introduce some of these measures).**
  - **Project produces many guidance documents**
    - **now the EU commission need to think how to use this guidance to produce tools that will drive innovation, patient safety and transparency in the system.**

CORE-MD work

- **Move forward, examples:**
  - **Point on trainings**
    - **Study on existing trainings**
    - **Review of the depth of the trainings**
    - **Establishment of needs to fulfil market needs**
  - **Education in term of clinical / regulatory aspects**
    - **Study on existing programs**
    - **Proposals to fulfil market needs**

CORE-MD work

- **Move forward, future:**
  - **Better understanding of the EU regulatory system needs by academics, healthcare professionals and NBs**
  - **Help to identify regulatory needs to focus on safety and effectiveness for improving public health provision**
  - **Mutual high expectations for continued cooperation in EU-funded projects**

CORE-MD
Coordinating Research and Evidence for Medical Devices

Members

TEAM NB

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bsi.
ce certiso
Ce Cert.
CQY CERTIQUALITY
NCPS
DEKRA
DNV
dqs
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