The European Association Medical devices Notified Bodies

Implementation of the MDR post May 2021,

Sharps injuries and new standard on safety mechanisms in medical devices

Françoise Schlemmer – Team-NB director

Team-NB

Aims:

- **Represent Notified Bodies**
- **Communication with**
  - European Commission
  - Competent Authorities
  - Industry
  - Other stakeholder
- **Promote technical and ethical standards**
- **Participate in improving the legal framework**
- **Contribute to harmonization (e.g. training 'for notified bodies by notified bodies')**

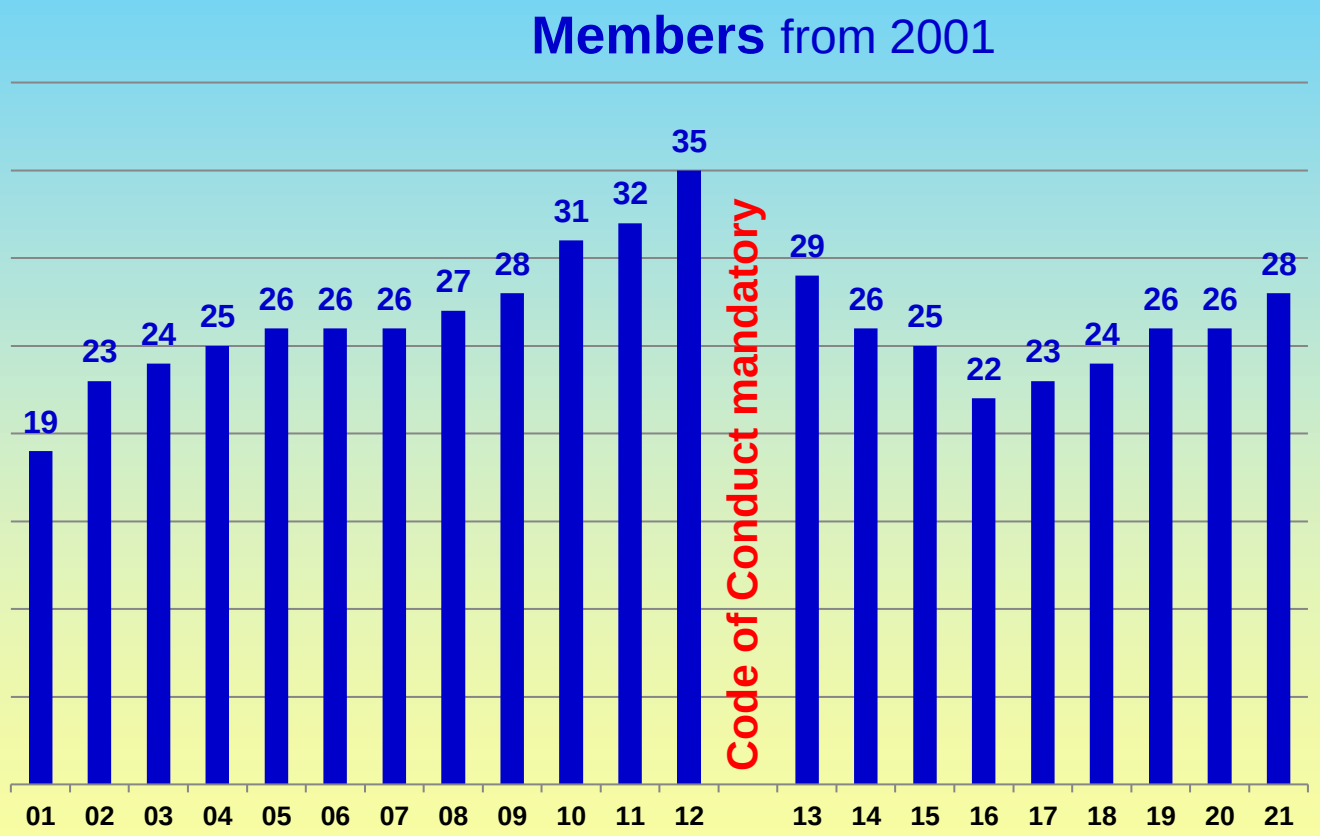
Notified Bodies role in EU regulatory system for medical devices

Tasks:

- Involved in the conformity assessment of medical devices (risk class IIa and higher)
- Involved in assessment of technical documentation (including clinical data)
- Surveillance and review
- Issue a certificate : gives a manufacturer the right to attach CE-marking to the device

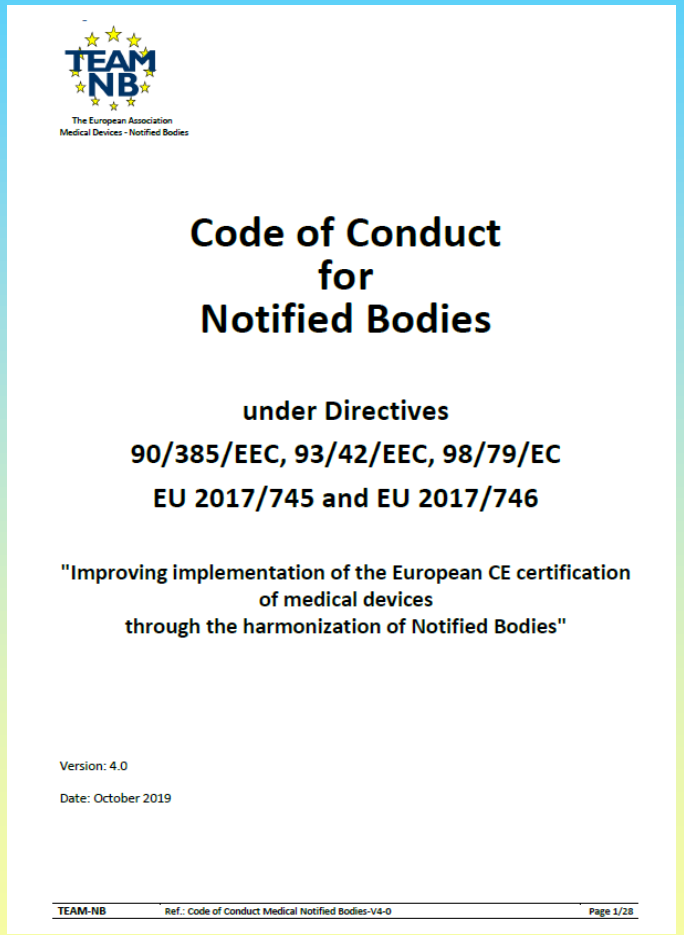
Team-NB

Members over the years



Code of Conduct Version 4

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



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**

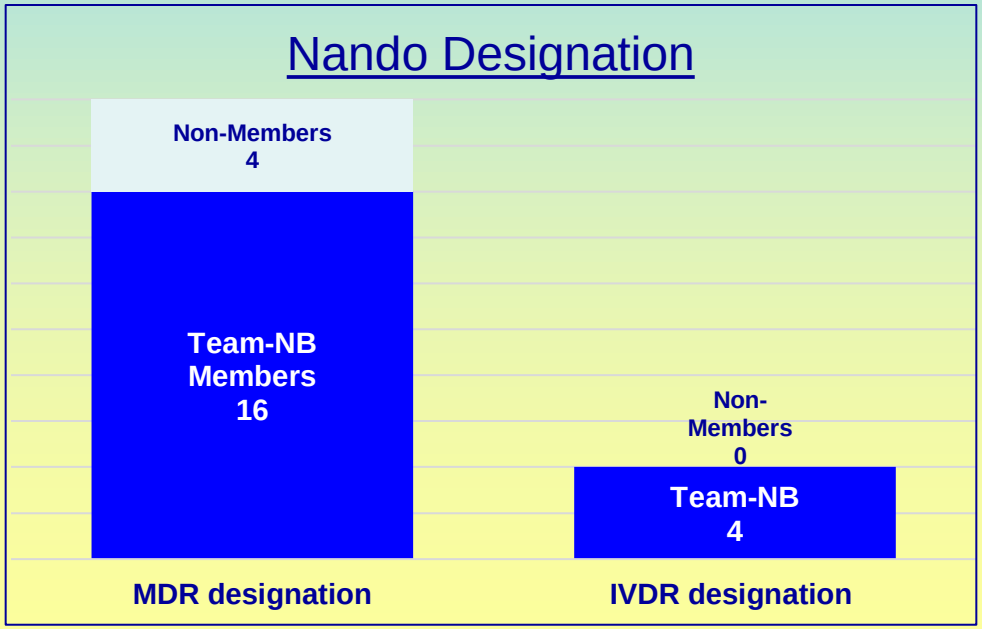
**"Improving implementation of the European CE certification
of medical devices
through the harmonization of Notified Bodies"**

Version: 4.0

Date: October 2019

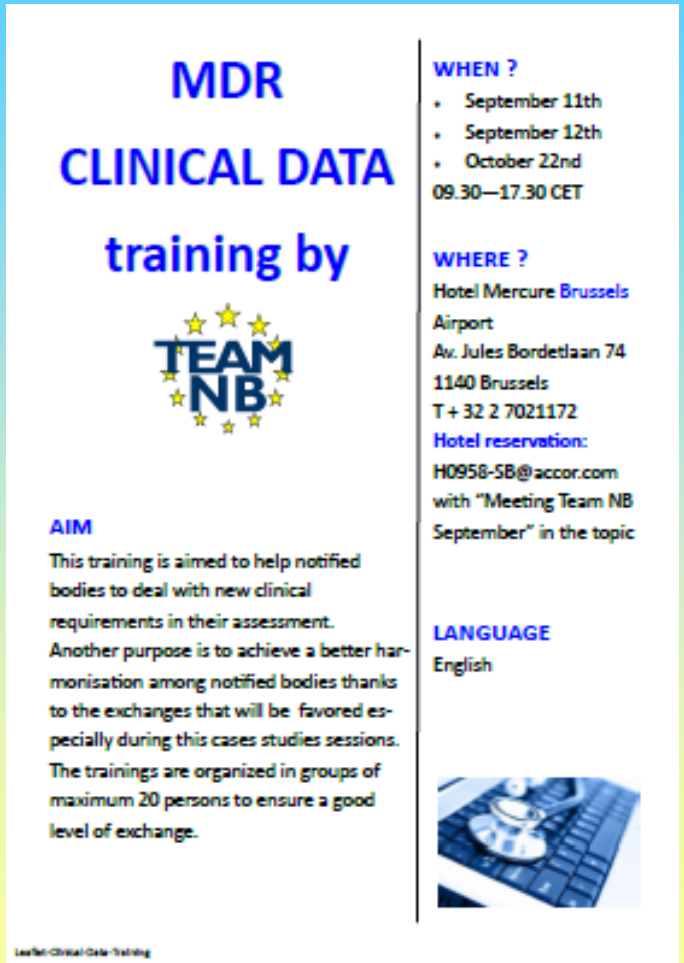
Interpretation of the new regulations

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



Implementation of the new regulations

- **Trainings** – from 2019
  - ⇨ **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
    - Topics: Clinical Data, Technical Documentation, Risk Management, Software, Remote Audit, IVD Performance, PMS


MDR

CLINICAL DATA

training by

TEAM NB

AIM

This training is aimed to help notified bodies to deal with new clinical requirements in their assessment. Another purpose is to achieve a better harmonisation among notified bodies thanks to the exchanges that will be favored especially during this cases studies sessions. The trainings are organized in groups of maximum 20 persons to ensure a good level of exchange.

WHEN ?

- September 11th
- September 12th
- October 22nd

09.30—17.30 CET

WHERE ?

Hotel Mercure Brussels Airport
Av. Jules Bordetlaan 74
1140 Brussels
T + 32 2 7021172
Hotel reservation:
H0958-SB@accor.com
with "Meeting Team NB September" in the topic

LANGUAGE

English

Regulation tools

- **Commission tools:** under the MDCG supervision
  - **Common specifications**
    - New instrument to be adopted by implementing acts which manufacturers will need to apply
  - **Delegated and implementing acts**
    - instrument to precise regulation articles
  - **MDCG Guidance documents**
    - not legally binding (not all available in May 2021)
  - **Harmonised standards**
- **EUDAMED :** European databank on MD **-> May 2022**
    - Module 1 available for actor registration
    - Mandatory nomenclature available in English
    - Module 2, playground done

New regulations: key elements

- **Significantly reinforced**
  - supervision of notified bodies
  - stricter pre-market control
  - conformity assessment procedures
  - clinical investigations & clinical evaluation : more data
  - vigilance and market surveillance: precised process
  - New categories of products included in the scope (Aeshetics devices, nanomaterials, …)

- **New regulations aims**

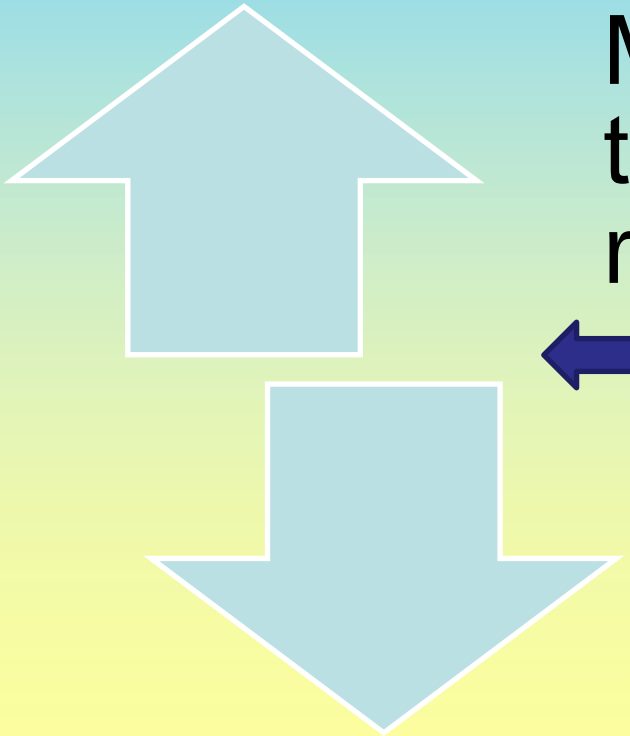
  ⇨ **Safety – Innovation – Transparency - Harmonisation**

New requirement of regulations

- **New features:**
  - EUDAMED & UDI
  - Person responsible for regulatory compliance
  - Control of distributors by manufacturers and vice versa
  - 6 new general requirements for performance and safety (13 to 23)
  - Structure and content of the specified technical file
  - Post-Market Surveillance Report

New requirements of regulations on safety mechanisms in medical devices

- **Annex I, Point 11.1: …**The design shall: a) reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries,
- **Annex I, Point 22.2:** Devices for use by lay persons shall be designed and manufactured in such a way as to: … — reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries, …



Meeting ‘state of the art’ requirements

What devices are here?

Not meeting ‘state of the art’ requirements

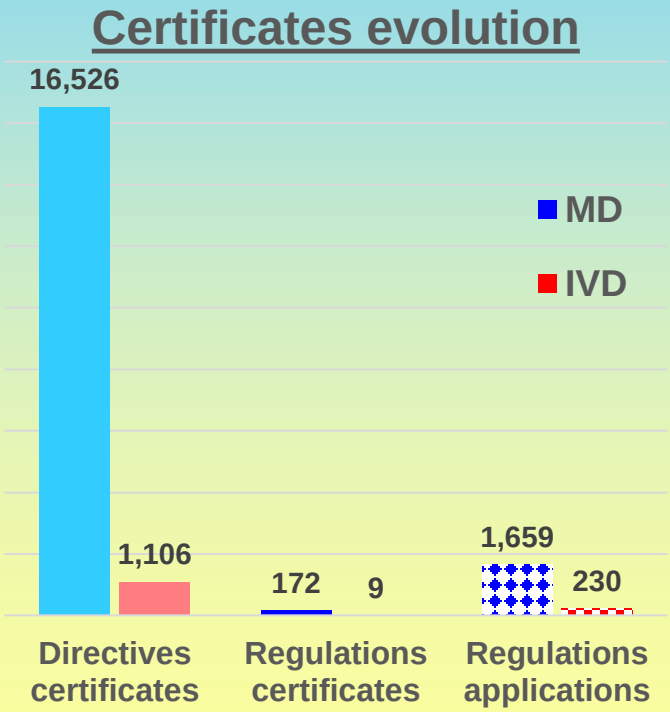
Impact of COVID-19 on transition to MDR:

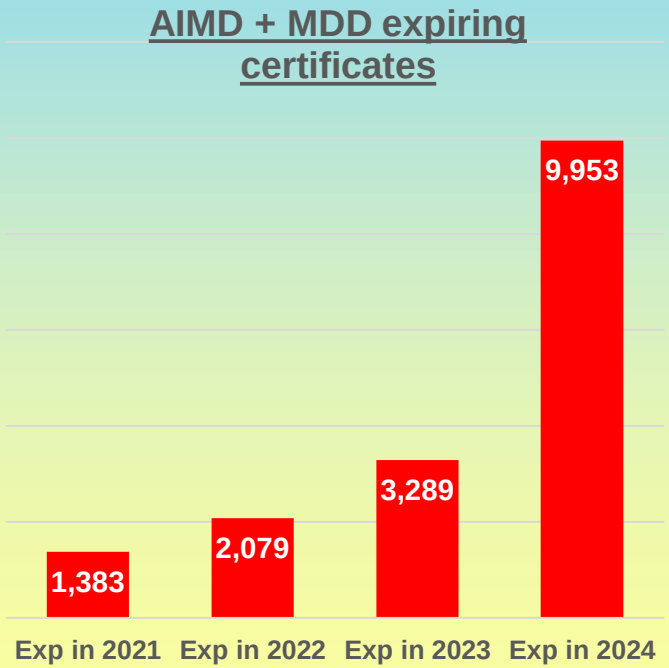
- **MDR DoA postponed** with 1 year:
  from 26 May 2020 to 26 May 2021
- Auditors cannot reach audit locations
- **MDD audits** are **allowed remotely**
  (see MDCG Guidance 2020-4)
- **MDR** (Annex VII) requires 'on site audits'
- "Commission Notice on **remote MDR** initial audits"
  published Jan 2021
  - COM exempts Member States from their obligation to 'punish' NBs if they do not go onsite, and stipulates very strict conditions
  - Implementation differs across Member States; limited number of MDR initial audits can be finalized

Impact of COVID-19 on transition to MDR:

Sequels:

- Transfers from AIMDD /MDD to MDR cannot be finalized
- Massive renewal of AIMDD/MDD certificates…





Contacts

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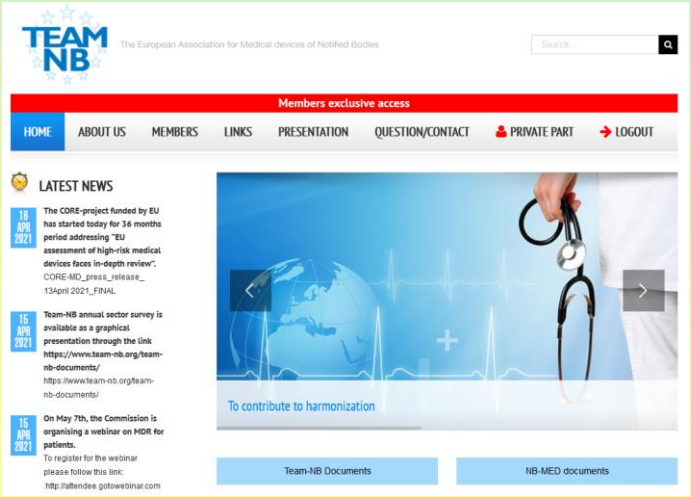
- **Françoise Schlemmer** (schlemmer@team-nb.org) -Director and Secretariat

www.team-nb.org



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