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

Successfull transition

to the new EU marking regulation

EUDAMED: state of play

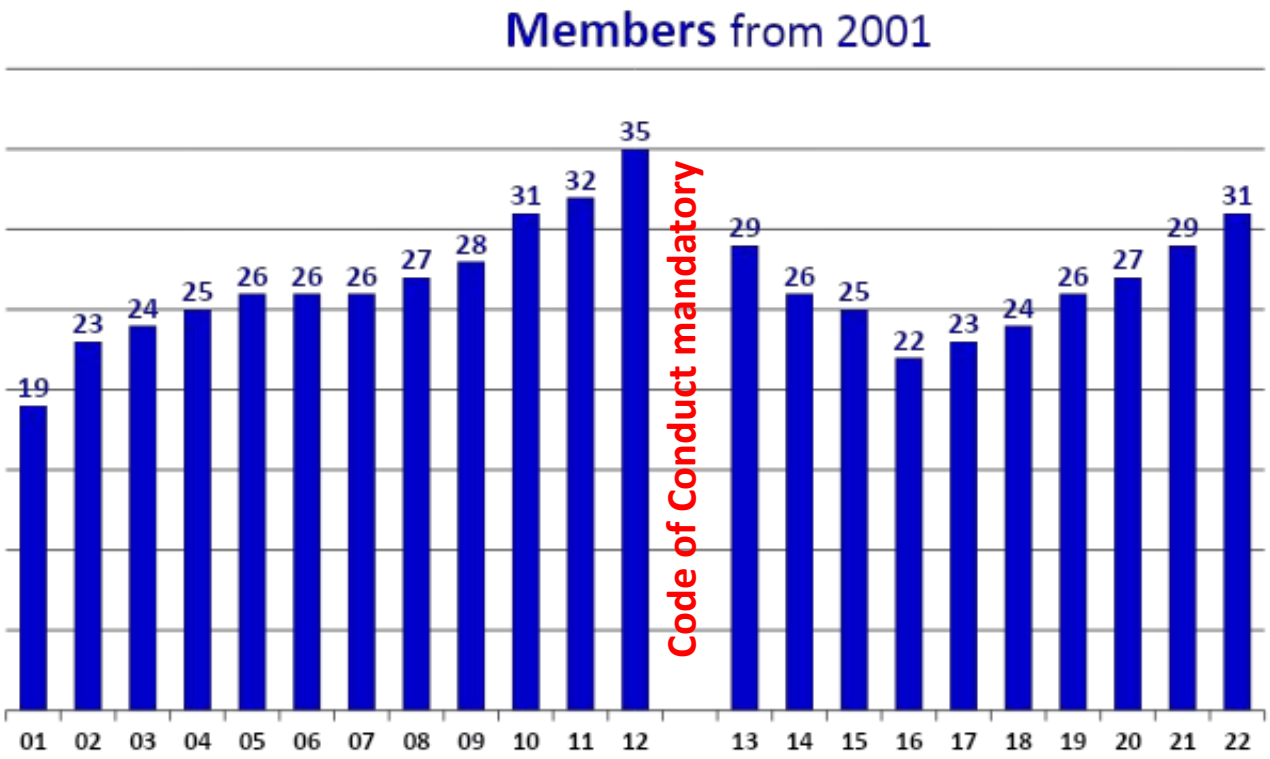
Françoise Schlemmer - TEAM-NB Director

Team-NB

- **Aims:**
  - **Represent Notified Bodies**
  - **Communication with**
    - **European Commission**
    - **Competent Authorities**
    - **Industry**
  - **Promote technical and ethical standards**
    - Other stakeholder
  - **Participate in improving the legal framework**

Team-NB

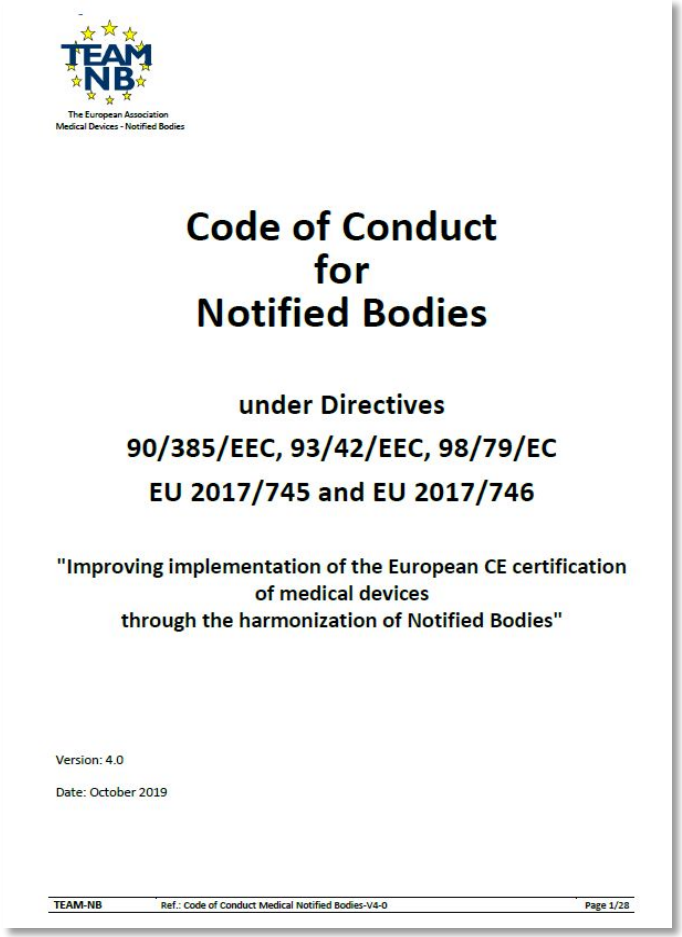
Members over the years



31 members representing 18 different countries

Team-NB 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"

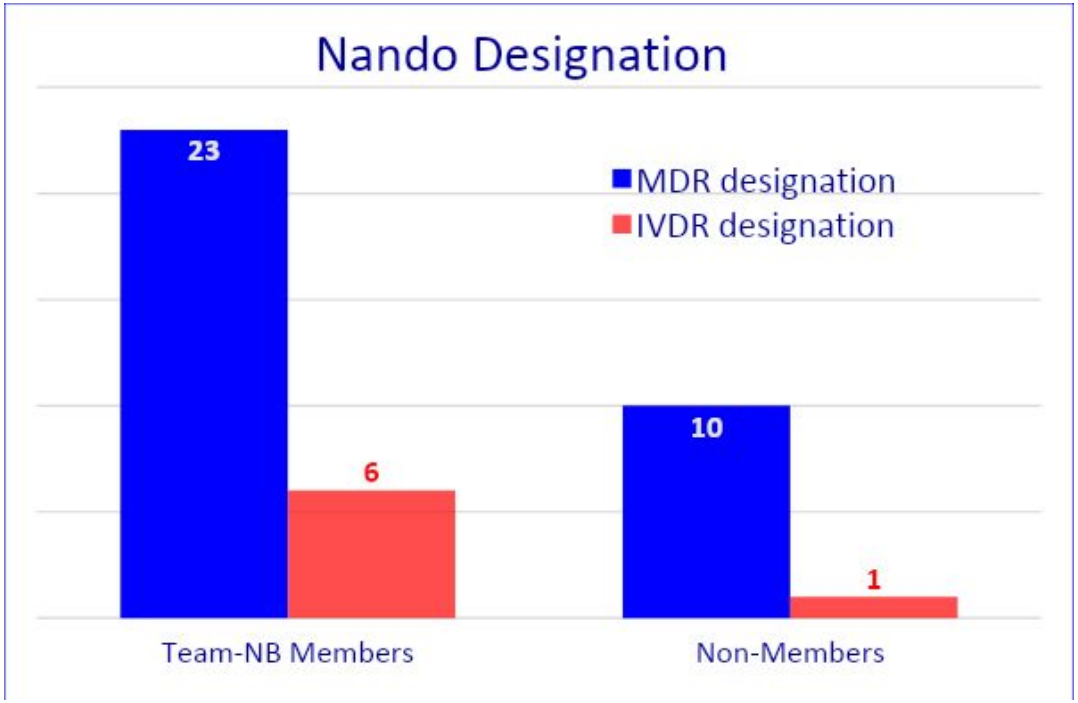
Version: 4.0

Date: October 2019

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



New regulations : implementation

- **Team-NB : Mirror MDCG working groups from 2018**
  - Aim: harmonise NBs views and define NB position
- **Task Forces**
  - Aim: to address specific topics of NBs interest

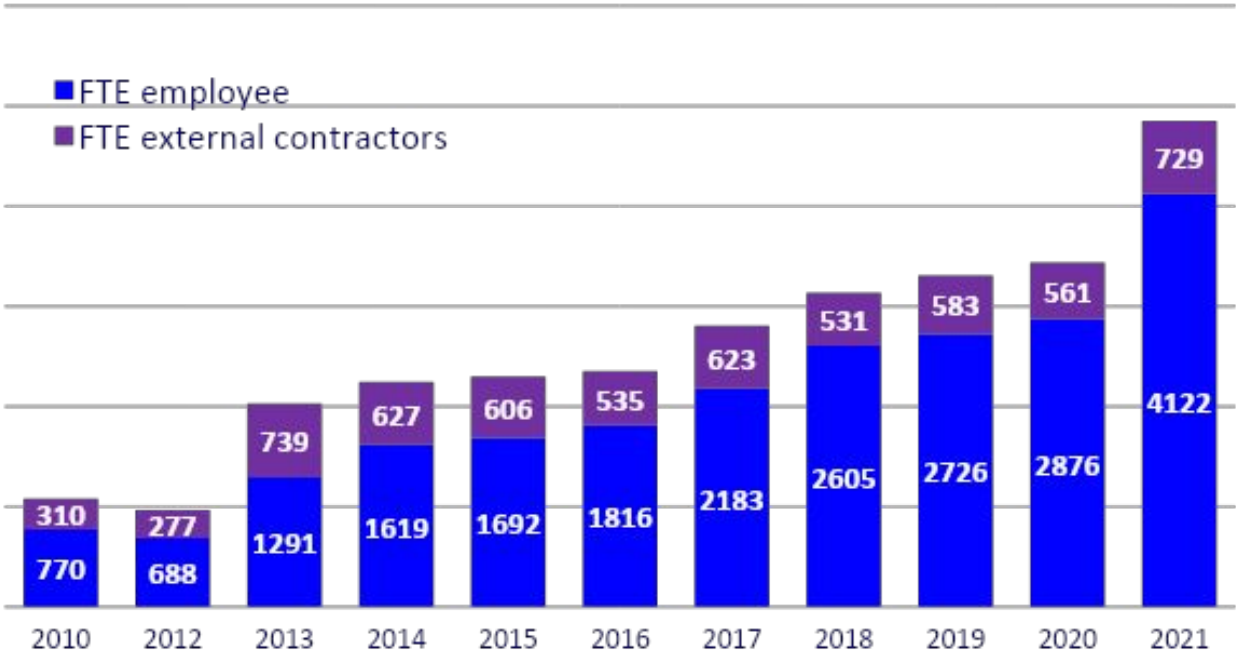
⇨ **to write Position Papers (published on Team-NB web site)**

- **Trainings**
  - Aim: to help NBs in their assessment; to achieve a better harmonisation among NBs thanks to the exchanges

Topics: remote audits, clinical data, Technical documentation, Software, PMS, Risk Management, IVD Technical documentation,…

Notified Bodies Annual survey

NBs Capacities



⇨ Notified bodies' workforce **increased by 43%** as compared to 2020.

Notified Bodies Annual survey

- **Slow transition process considering the deadline approaching in 2024.**

Directives certificates	Regulations certificates	Regulations applications
increasing (thanks to new members)	increasing (> 4 times) but only 4,4%)	increasing (2,5 times) but only 4,4%)

⇨ **Still numerous certificates to be transfer against MDR (> 95%)**

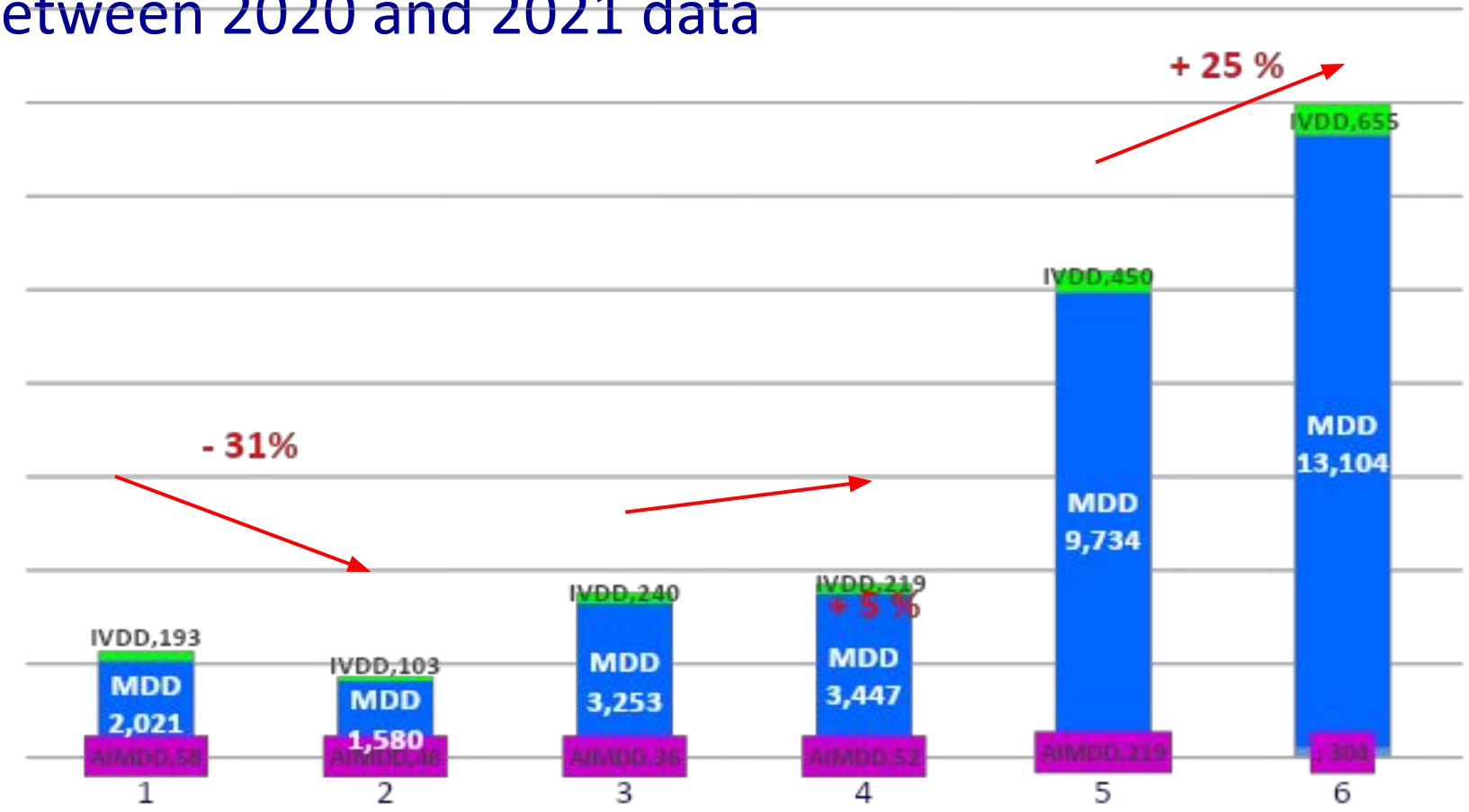
and

applications to be received (75%)

Notified Bodies Annual survey

Trends in expiring Directives certificates

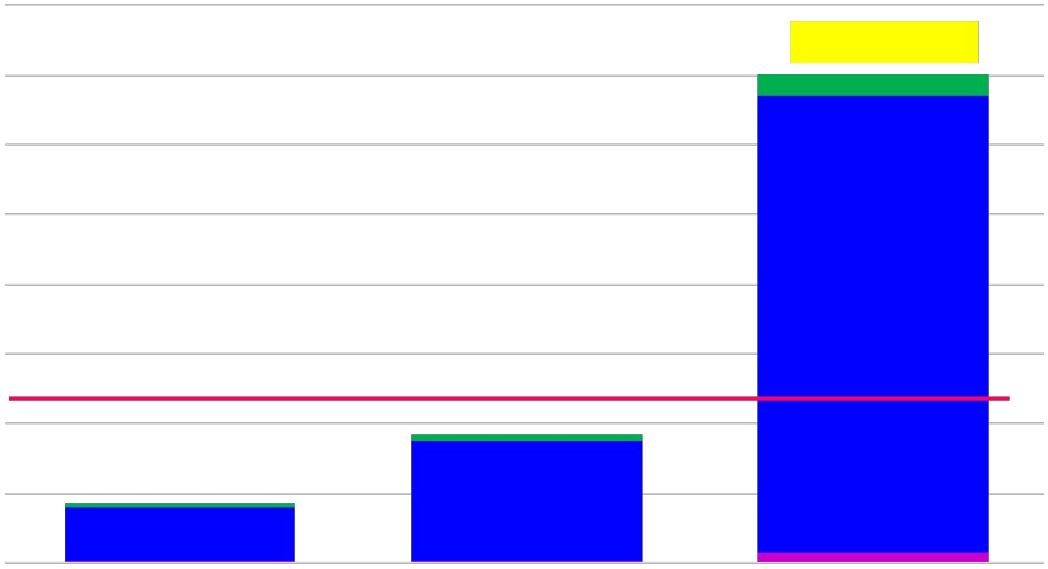
between 2020 and 2021 data



Notified Bodies Annual survey

Pandemic

⇨ Shift towards 2024 of the expiration of certificates



⇨ 2024 above NBs Capacities

EUDAMED : European databank MD

- ***obliged to use a medical device nomenclature : EMDN***
- ***free of charge to manufacturers and other natural or legal persons***
- ***one key aspect is to collate and process information regarding MD***
  - *aspects of conformity assessment*
  - *notified bodies*
  - certificates
  - clinical investigations
  - vigilance and market surveillance

Article 33 : European databank

- **The Commission, after consulting the MDCG, shall develop and manage the European databank on medical devices (Eudamed)**

- **Eudamed shall include the following the electronic system :**
  - on registration of devices
  - on UDI
  - on registration of economic operators
  - on notified bodies and on certificates
  - on information on applications for conformity assessment and on certificates and on summaries of safety and clinical performance
  - on clinical investigations
  - on vigilance and post-market surveillance
  - on market surveillance.

Article 33 : European databank

- **Data shall be entered into Eudamed by**
  - the Member States,
  - notified bodies,
  - economic operators and
  - Sponsors
- **The Commission shall provide for support to users of Eudamed**
- **All the information collated and processed by Eudamed shall be accessible to Member States and Commission.**
- **The information shall be accessible to notified bodies, economic operators, sponsors and the public to the extent specified**
- **public parts of Eudamed are in a user-friendly and easily-searchable format**
- **…**

Annex VI : EUDAMED and UDI

- **Information to be submitted with the registration of**
  - devices

  and
  - economic operators

  in accordance with articles 29(4) and 31

- **The UDI system**

EUDAMED : guidances

MDCG documents

- endorsed by the Medical Device Coordination Group
  - representatives of all Member States and European Commission
  - not legally binding

Reference	Title	Publication
MDCG 2022-12 EN	Guidance on harmonised administrative practices and alternative technical solutions until Eudamed is fully functional (for Regulation (EU) 2017/746 on in vitro diagnostic medical devices)	July 2022
MDCG 2021-13 Rev. 1 EN	**Questions and answers** on obligations and related rules for the **registration** in EUDAMED **of actors other than** manufacturers, authorised representatives and importers subject to the obligations of **Article 31 MDR and Article 28 IVDR**	July 2021
MDCG 2021-1 Rev. 1 EN	Guidance on harmonised administrative practices and **alternative** technical **solutions until EUDAMED is fully functional**	May 2021
MDCG 2020-15 EN	MDCG Position Paper on the **use of the EUDAMED actor registration module** and of the Single Registration Number (SRN) in the Member States	August 2020
MDCG 2019-5 EN	**Registration of legacy devices** in EUDAMED	April 2019
MDCG 2019-4 EN	**Timelines for registration of device** data elements in EUDAMED	April 2019

EUDAMED : guidances

MDCG documents

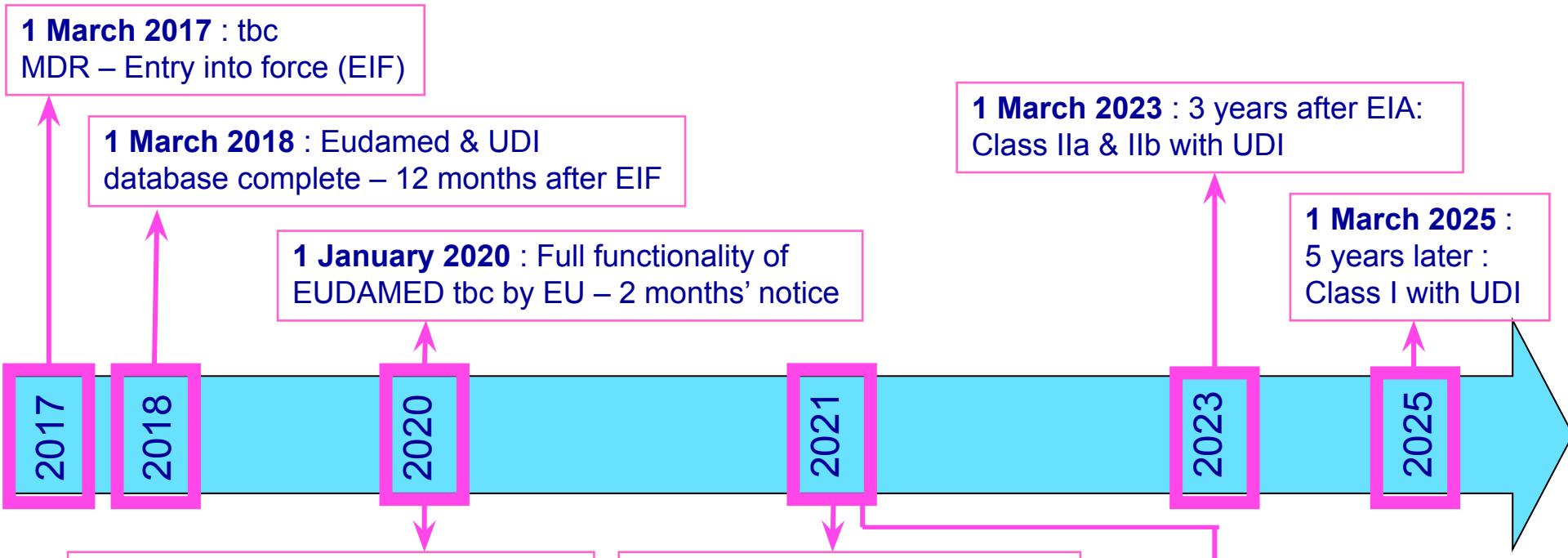
- MDCG 2022-12

  Guidance on harmonised administrative practices and alternative technical solutions until Eudamed is fully functional (for Regulation (EU) 2017/746 on in vitro diagnostic medical devices)

  July 2022

  - NBs to introduce document on a Commission platform documents will need to be re-introduced in EUDAMED)
  - NBs to fulfill EUDAMED and national database
  - NBs asked to request Manufacturers registration in EUDAMED

EUDAMED : initial time-line



1 March 2017 : tbc
MDR – Entry into force (EIF)

1 March 2018 : Eudamed & UDI database complete – 12 months after EIF

1 January 2020 : Full functionality of EUDAMED tbc by EU – 2 months' notice

1 March 2023 : 3 years after EIA:
Class IIa & IIb with UDI

1 March 2025 :
5 years later :
Class I with UDI

1 March 2020 :
- **MDR Mandatory:** 3 years after EIF
- Class III : «Summary of safety and clinical performance» in EUDAMED
- Start reporting vigilance and FSCA-FSN in EUDAMED

1 March 2021:
1 year after EIA (Application):
Implantable & Class III with UDI

30 August 2021: 18 months after EIA:
- assign UDI to device
- MD entered in EUDAMED
- NB/CE certificates entered in EUDAMED

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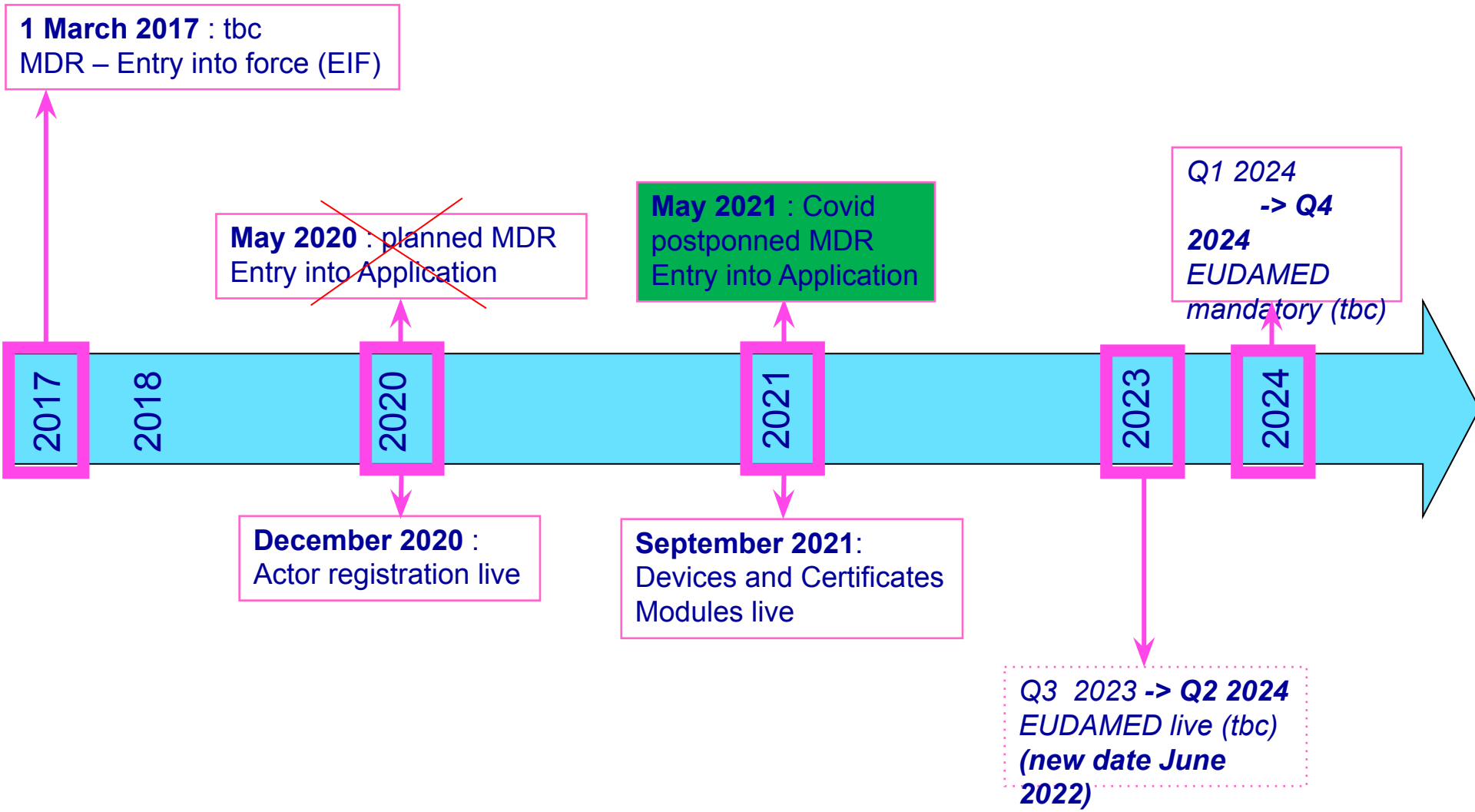
EUDAMED : time-line state of play



Contacts

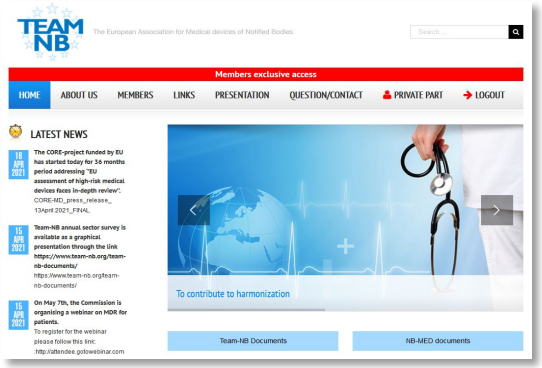
- Administrative Commitee:

President	Vice-President	Vice-President	Treasurer	Secretary
Alexey Shiryaev	Suzanne Halliday	Sabina Hoekstra-van den Bosch	Gero Viola	Béatrice Lys
				
DNV	BSI	TÜV SÜD	TÜV Rheinland	GMED

- Management:

Director
Françoise Schlemmer

- Web site: www.team-nb.org



Members

Certification B.V.
Certification GmbH

Kiwa Cermet
Kiwa Dare