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

EMA Medical Device awareness session

Notified body perspective of implementation of the new regulations

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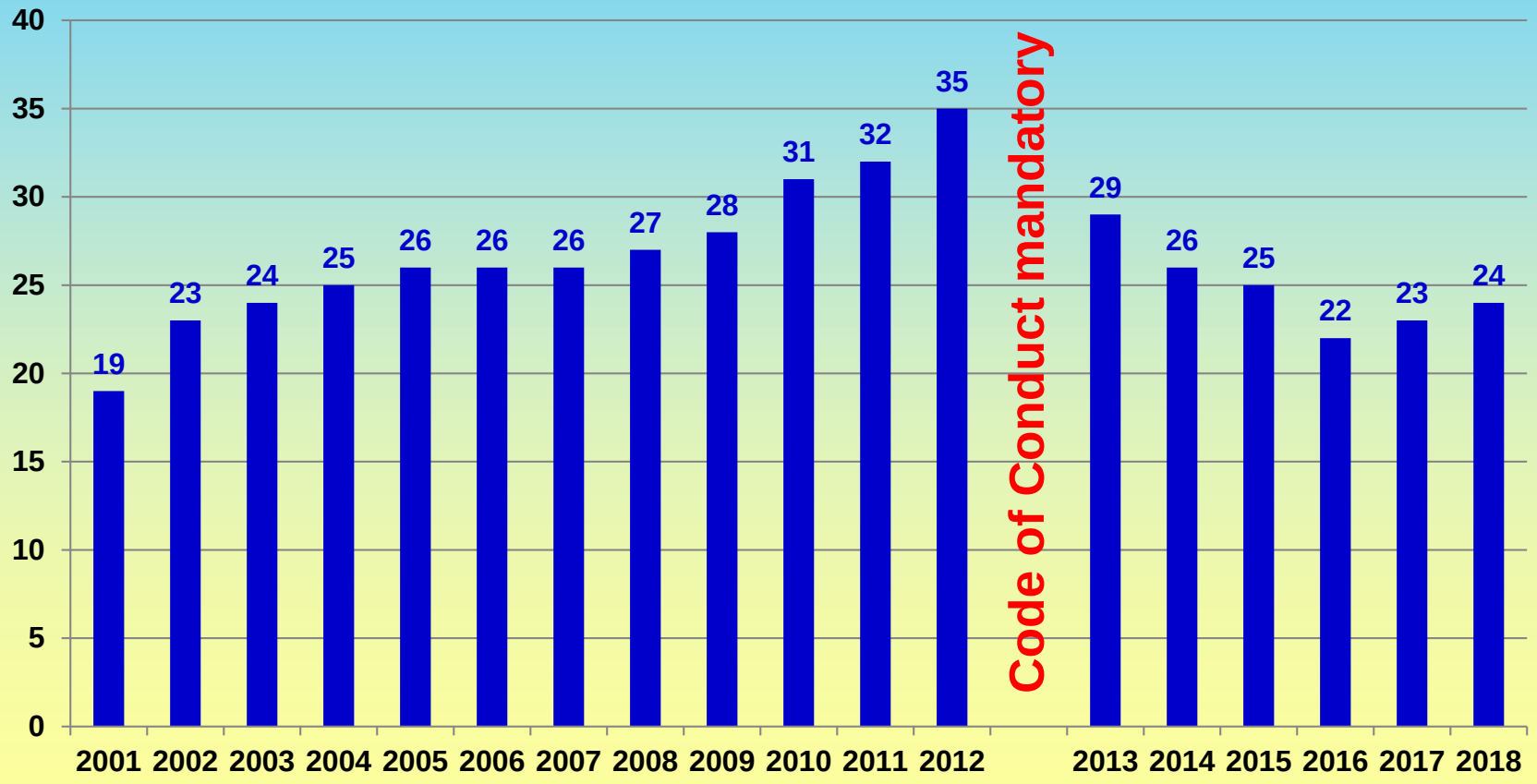
June 22nd 2018 – London

TEAM-NB

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

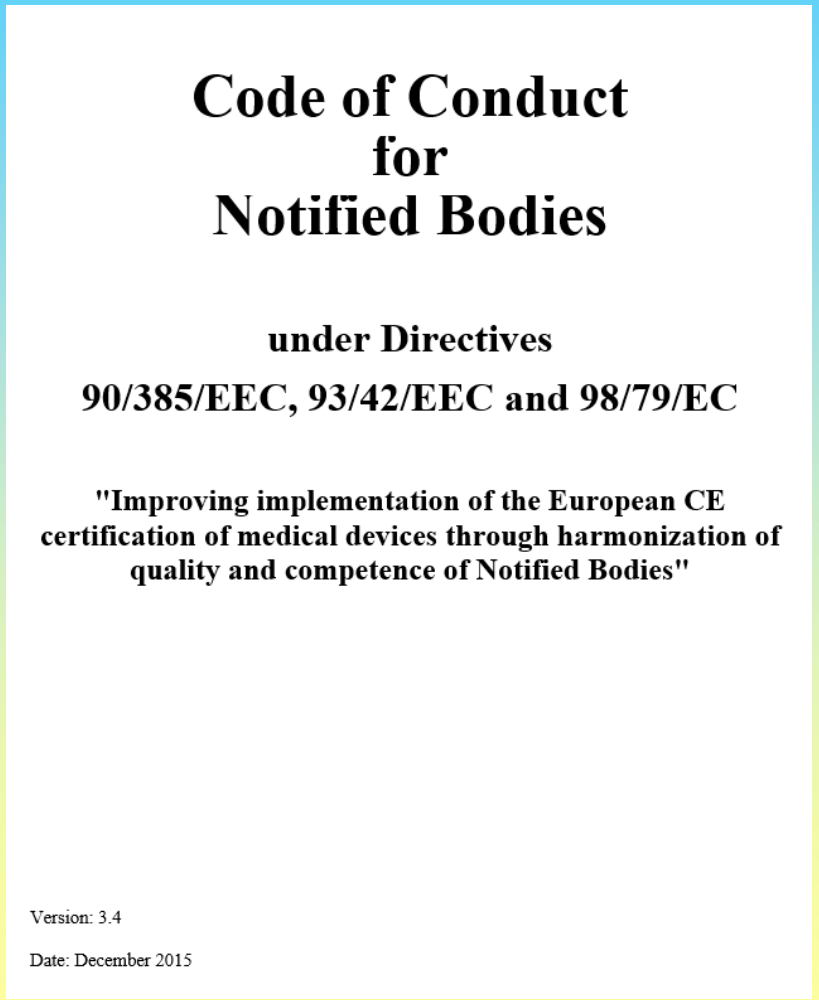
TEAM-NB

Members



Code of Conduct V 3.4

- Mandatory to sign for TEAM-NB members
- Version 3.4 approved
  Available on website :
  www.team-nb.org



Code of Conduct for Notified Bodies

under Directives

90/385/EEC, 93/42/EEC and 98/79/EC

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

Version: 3.4

Date: December 2015

Interpretation of the new regulations

- Team-NB established working groups from April 2016

Classification & Conformity Assessment	NB requirements	Clinical	Vigilance

- **Aim**: formulate an analyse of the new regulations and propose to the members
  - Procedures to be put in place
  - To-do lists
  - …

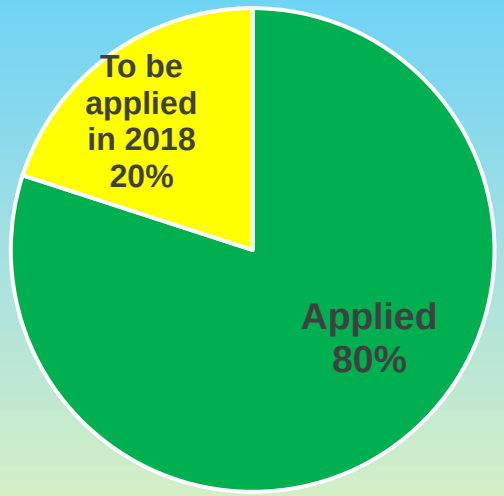
to be done to submit application for designation and/or wait for implementing acts

➔ **Help members to be designated**

➔ **Allow harmonisation**

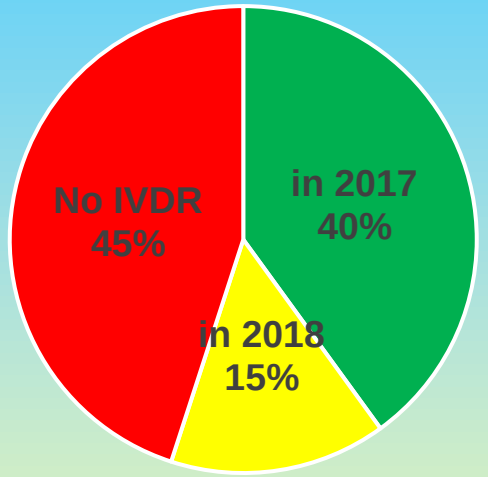
Team-NB: designation process

MDR



- 80% of applications before February 2018
  - 50% for bigger scope of application
  - 50% for same scope of application

IVDR



- 55% of the members are candidates for IVDR
  - 73% applied before February 2018
  - 27% to apply in 2018

Designation of notified bodies

- **Notified body designated according to MDR / IVDR before certification of manufacturers**
- **Steps**
  - List of codes published in an implementing act - November 2017
  - Introduction of an application for designation by NBs
    - On November 26th, 2017 at the earliest
    - 80% of the members did it 2017

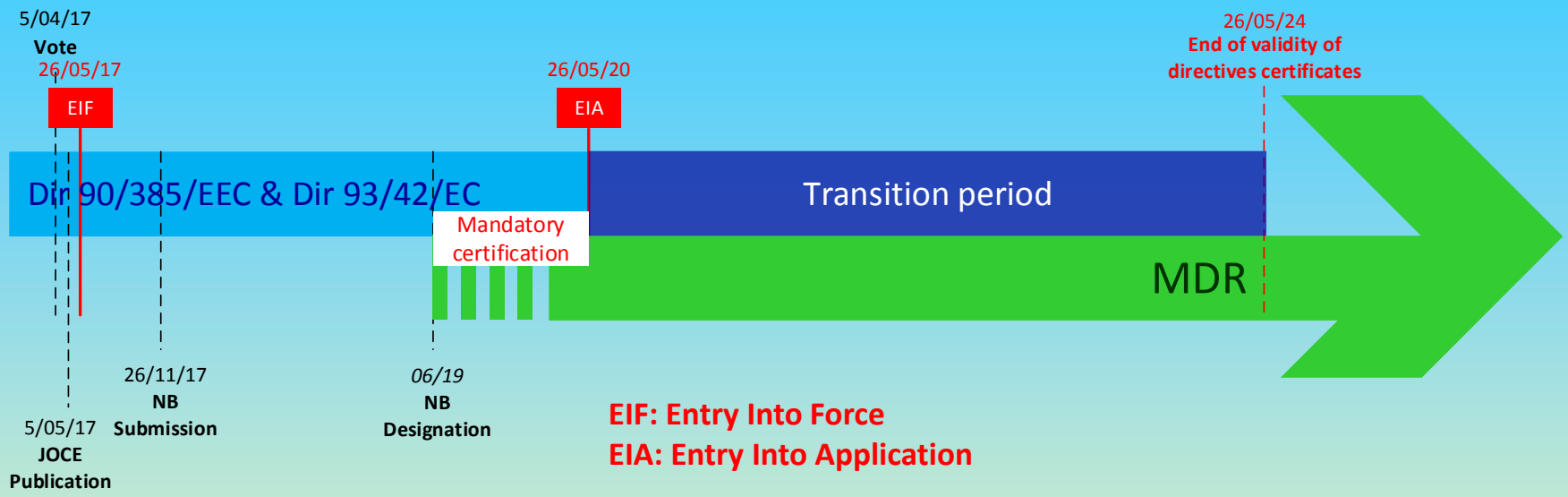
Designation of notified bodies

- **Steps (… to be followed)**
  - Joint audit assessment
    - April 2018: 3 assessments performed
  - …
  - Conformity assessment bodies designated on NANDO

➥ **Transparency of the designation process** (on-going survey)

➥ **All codes to be covered**

Transition period



- **MDR:** From **May 26th 2020 to May 2024**
- **IVDR:** From **May 26th 2022 to May 2024**
- **Contract between Manufacturers and NBs**
  - update to be signed to allow surveillance audits

Transition period

- **CE mark after "Entry into Application"**
  - Compliance with MDD or AIMD
  - No significant change in design and intended purpose
  - Application of the requirements of the Regulations related to
    - Post-market surveillance, Market surveillance, Vigilance, Registration of economic operators and devices,
  - NB remains in charge of surveillance

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**

European databank on MD (EUDAMED)

- **Use of a medical device nomenclature mandatory**
- **Data to be uploaded to collate and process information regarding MD**
  - **SRN** – single registration number
  - **UDI** – unique device identifier **-> traceability**
  - **aspects of conformity assessment**
  - **notified bodies**
  - **certificates**
  - **clinical investigations**
  - **vigilance and market surveillance**

Drug Device Combinations (DDC)

- **Single integral products not reusable – Article 117**
  - **Product is a pharmaceutical**
    - **Notified Body assess the device part - Annex I**
      - **Product not CE marked**
  - **Notified Body and EMA may need to work out a conformity assessment process for the " reverse consultation" on medical device aspects, through published guidance, including designation code (MDS)**

Drug Device Combinations (DDC)

- **Device incorporating a medicinal product – Rule 14** - medicinal product derived from human blood or human plasma, versus human blood derivatives;
  - Device part reviewed by a Notified Body for both
    - ✓ the technical documentation and
    - ✓ the QMS
  - Pharmaceutical part reviewed by EMA or a medicinal products CA

Product CE marked

Drug Device Combinations (DDC)

In both case

- **appropriate interaction in terms of**
  - consultations during pre-market assessment, and
  - vigilance activities.

Devices that are systemically absorbed

- **Device part reviewed by a Notified Body for both**
  - ✓ the technical dossier and
  - ✓ the QMS
- **Compliance of the device reviewed by EMA or a medicinal products CA on relevant aspects in Annex I Directive 2001/83/EC.**
  - **Product CE marked**
  - **Classified in Class III – Rule 21**

Companion diagnostics (*in vitro* MD)

- **Linked with quantitative or qualitative determination of specific markers (biomarker)**
- **Draft IFU and Draft Report on Safety and Performance to be provided by NB to MPCA / EMA**

Classified in class C - Rule 3

Classified in class D – Article 48

- **Article 48 requires short consultation process with either MPCA or EMA before CE marking**

Companion diagnostics (*in vitro* MD)

- **NB shall**
  - have procedures for consultation of EMA or a medicinal products CA
  - assess the technical documentation (Annex IX or X)
  - seek a scientific opinion from 1 CA or EMA
  - assess the Quality management system (Annex IX or XI)

    Need to set up of guidance's with participation of NBs

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