The European Association Medical devices
Notified Bodies

Status of the Notified Bodies and MDR/IVDR implementation

Alexey Shiryaev MD PhD, Global Clinical Affairs Manager,
DNV GL Presafe AS, Team-NB Committee

1

Table of content

- Team-NB
- Designation process
- Notified Bodies capacity
- Outcomes of High level meeting
- Measures to improve the implementation of new regulations

2

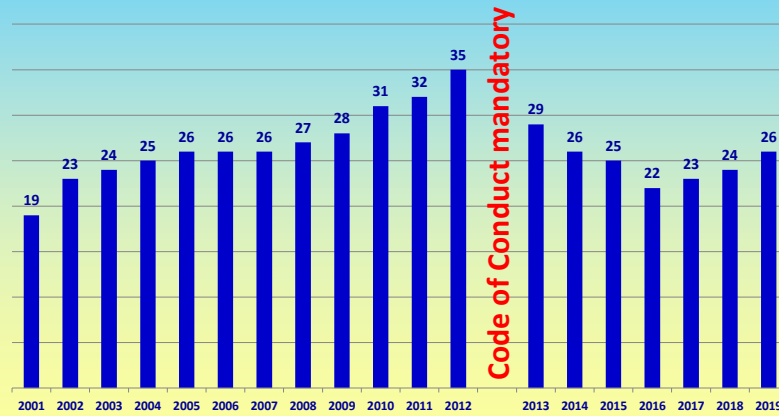
Team-NB

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

3

Team-NB : Members

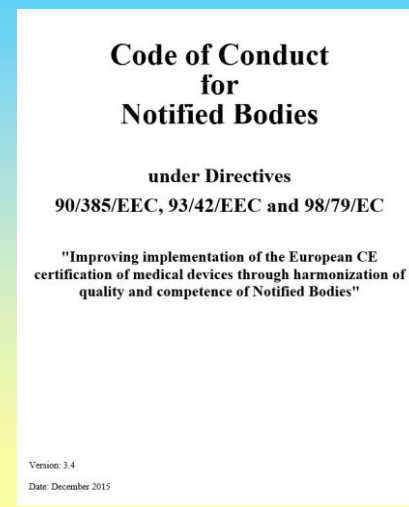
- **Members**



4

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

5

Understanding of the new regulations

- Team-NB established working groups already from April 2016

Classification & Conformity Assessment	NB requirements	Clinical	Vigilance

- Aim: analyse 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

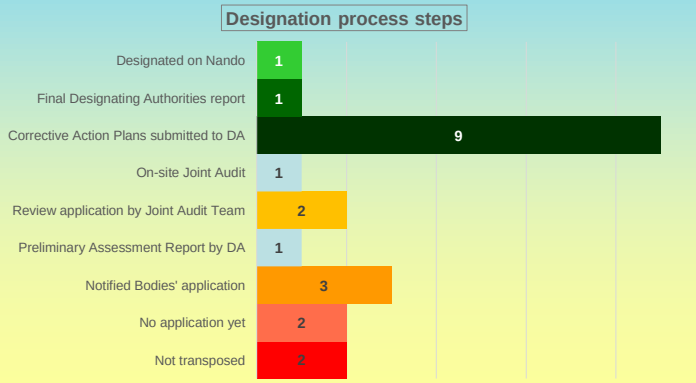
6

Implementation of the new regulations

- **Team-NB established mirror MDCG working groups from November 2018**
- **Aim: harmonise NBs views and speak as much as possible with one voice**
  - arrange internal meetings
  - comment on the documents
  - set up guidances to harmonise NBs practices, …

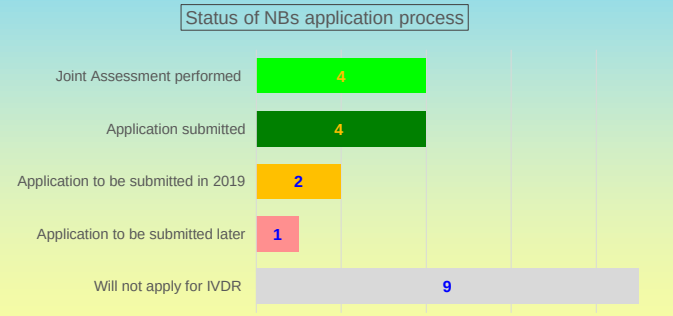
MDR Designation process

- **Data collected in December 2018 with responses of 22 out of 24 members** (knowing that 57 Notified Bodies were designated for MDD and AIMD)



IVDR Designation process

- **Data collected in January 2019 with responses of 20 out of 24 members** (knowing that 10 Notified Bodies members currently designated for IVDD)



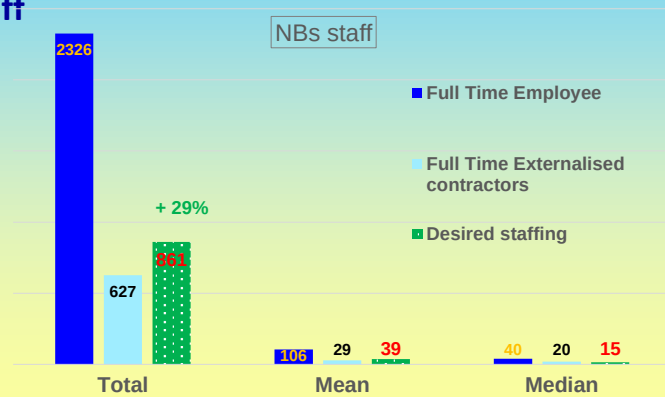
➔ **8 members in the designation process**

➔ **3 members intending to apply**

9

Notified Bodies capacities

- **Data collected in February 2019 with responses from 22 out of 24 members: wish to hire 29 % more staff**



10

Outcomes of High level meeting

- **Compilation of the comments / questions / requests received from members and non-members notified bodies**
  - ➔ **sent on January 8th**
- **Future exchanges to be organised**
- **Feedback to be received**

Measures to improve the implementation new regulations

- **Mechanism to have communications on decisions** (example decisions on divergent opinions)
  - ⇨ Allow secondary working contracts for application & contract reviewers, those that allocate resources and final reviewers
- **Have guidances** (classification, software, significant changes, article 117,…)

Measures to improve the implementation new regulations

- **Allow adequate allocation of staff capacity**
  - Broader sampling of technical files during the initial audit
  - For MDD certified products, allow no PSUR, SSCP reviewing during grace period (as NB role not clearly defined yet)
  - For Product that should be certified by May 2020, allow a technical review with focus on the specific aspects, for ex. reusable aspects for class Ir products
  - For upclassified class I devices allow to place products on the market until May 2024 based on the existing Declaration of Conformity.

Measures to improve the implementation new regulations

- **Accelerate designation process**
  - allow designation for scope with one expert for code during a transitional period
  - allow designation as soon as major deficiencies resolved
  - allow that one diploma give automatic competencies on certain scope (especially for IVD codes)
  - Allow other clinical expert than physicians (ex: pharmacist, …) to assess IVD clinical performance
  - allow gap audit for NBs already audited for one regulation (MDR/IVDR)
  - Create a documentary process for the extension of designation to new codes

Contacts : www.team-nb.org

- **Guy Buijzen** President (guy.buijzen@dekra.com)
- **Hans Heiner Junker** Vice President (hans-heiner.junker@tuev-sued.de)
- **Kevin Butcher** Vice President (kevin.butcher@sgs.com)
- **Corinne Delorme** Secretary (corinne.delorme@lne.fr)
- **Alexey Shiryaev** Treasure (Alexey.Shiryaev@dnvgl.com)
- **Françoise Schlemmer** Director&Secretariat (schlemmer@quasys.com)

Members :