Members

Note : some members of the same group are represented by only 1 logo

Administrative Committee

CONTACTS		
President	Alexey Shiryaev	shiryaev@team-nb.org
Treasurer	Gero Viola	viola@team-nb.org
Secretary	Béatrice Lys	Lys@team-nb.org
Vice President	Suzanne Halliday	Halliday@team-nb.org
Vice President	Sabina Hoekstra-van den Bosch	Hoekstra@team-nb.org
Director	Françoise Schlemmer	schlemmer@team-nb.org

www.team-nb.org

Ref: R-TEAM-NB-Leaflet-21

Team-NB stated for

The European Association for Medical devices of Notified Bodies.

We are an AISBL (international not for profit association) formed in 2001. In 2022 the association has 32 members representing 18 countries.

Our members are **Notified Bodies** (see member list) under any or all of the three medical device new approach directives: 90/385/EEC; 93/42/EEC; 98/79/EC and the two regulations (EU) 2017/745 and (EU) 2017/746.

Our aims are :

- ✓ Demonstrate commitment of Team NB members in improving Public Safety in relation to medical devices
- ✓ Support the implementation of actions in relation to ensuring continued public safety in relation to medical devices
- ✓ Actively contribute to the transition to the new Regulations by, amongst others, supporting the creation and pragmatic updates of guidance
- ✓ Improve stakeholder perception and understanding of the work of responsible Notified Bodies
- ✓ Inform members on trends concerning new regulations, guidelines,… and help in their harmonised implementation.

Team-NB provides information to all the sector stakeholders through its web site **www.team-nb.org** with documents such as position papers or other useful information such as news, press release and events.

Medical Devices CE marking system

Legislative framework: 3 European Medical Devices Directives

90/385/EEC -> Active Implantable Medical Devices

93/42/EEC -> Medical Devices

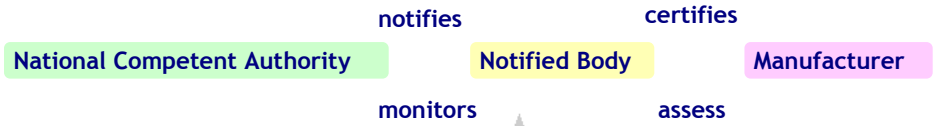
98/79/EC -> *In Vitro* Diagnostics Medical Devices

New legislative framework : 2 European Regulations

from May 2021 : 2017/745 -> Medical Devices

from May 2022 : 2017/746 -> *In Vitro* Diagnostic Medical Devices

A transition period will take place until *May 2024 for MDR* regulation and until *2028* for IVDR *at the moment*.



The National Competent Authority is in charge of both the market surveillance and the designation and monitoring of the Notified Bodies. The monitoring ensures the maintenance of Notified Bodies competences and expertise. The list of Notified Bodies and their scope of notification are available on the Nando web site.

Conformity assessment procedures

These regulatory controls are based on a risk-based approach. The level of regulatory control increases with increasing degree of risk for the public Health.

Notified Bodies assess that Manufacturers have demonstrated through the use of appropriate conformity assessment procedures that the device complies with the relevant Essential Requirements covering safety and performance, …. That includes the obligation to have in place a quality management system which, from the inspection of the device to the end of its market life, allows the manufacturer to control the benefit/risk ratio of the device.

CE marking system

Notified bodies evaluate the conformity of products and the associated quality systems for manufacturers that seek to sell products in Europe.

They issue certificates intended to allow the free movement of goods within the EU as well as to protect safety and health.

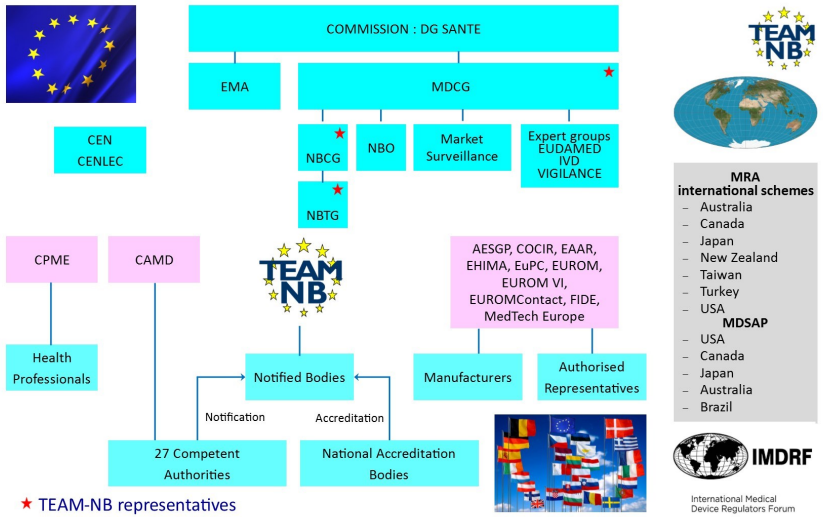
A Notified Body must ensure its independency, impartiality and integrity.

The EU's decentralised procedure to review and approve new medical devices has proven its benefits to European patients and to innovation.

Notified bodies have proved highly effective and efficient at carrying out

product and facility inspections of a worldwide basis.

TEAM-NB context



TEAM-NB Code of Conduct:

for Notified Bodies under Directives 90/385/EEC, 93/42/EEC, 98/79/EC & Regulations EU 2017/745 and EU 2017/746

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

This Code of Conduct, version 4.0 dated October 2019, is mandatory for all Team-NB members.

The document's purpose includes defined organizational criteria and assessment competence which helps the Team-NB members in their preparation in order to be designated against the new regulations and allow a greater harmonization of the practices.

TEAM-NB Training academy

Trainings are held on significant topics aimed to help notified bodies to deal with requirements of the new regulations in their assessments.

Another purpose of these trainings courses is to achieve a better harmonisation among notified bodies thanks to the exchanges that will be favored during the different sessions including the practical part of cases studies.

Experts Harmonisation Sessions are organised, in addition ,to allow senior experts of the subject matter to share their experience on « hot » topics to help answering challenges to conduct conformity assessment. The objective is that attendees cascade the info into their organisation to reach all reviewers.