Members

Administrative Committee

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www.team-nb.org

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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 2020 the association has 23 members representing 13 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 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
- ✓ Participate and support the implementation of actions in relation to ensuring continued public safety in relation to medical devices
- ✓ Involv and support and participate on the implementation of the new Regulations by among others supporting the creation and pragmatic update of guidances
- ✓ Improve stakeholder perception and understanding of the work of responsible Notified Bodies
- ✓ Inform members on trends concerning new regulations, guidelines, … and help in their formulation.

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 with 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 both regulations.

Certification system

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

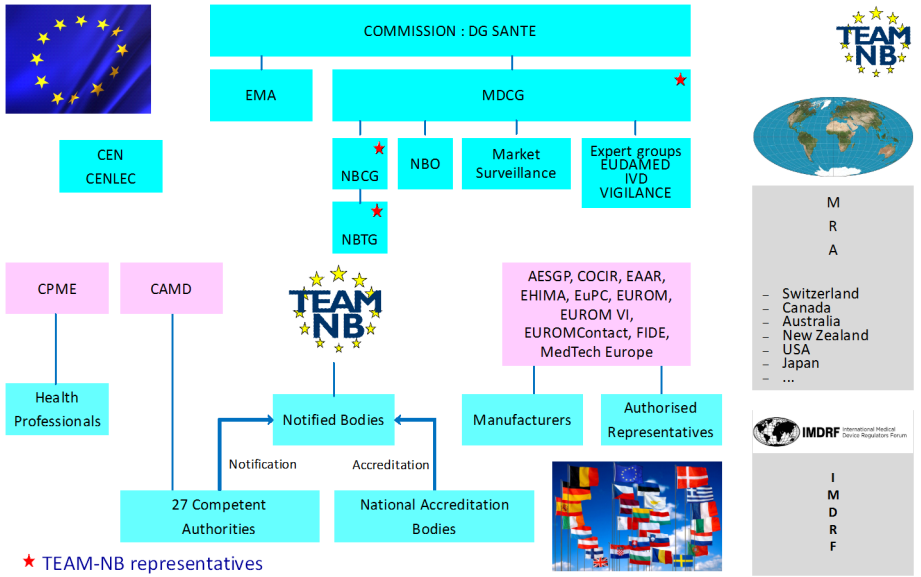
These regulatory controls are based on a risk-based approach. The level of regulatory control increases with increasing degree of risk for the public Health.

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 on a worldwide basis.

TEAM-NB context



TEAM-NB initiative:

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"

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 initiative:

Training academy

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

Another purpose of these trainings 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.