Members

Administrative Committee

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www.team-nb.org

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TEAM NB

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 2014 the association has 26 members representing 14 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.

Our aims are :

- Demonstrate commitment of Team NB members in improving Public Safety in relation to medical devices
- To participate and support the implementation of Interim Action in relation to ensuring continued public safety in relation to medical devices
- Support and participate in the finalization of the new Regulations
- 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 recommendations, position papers or other useful information with news and events.

Medical Devices CE marking system

Legislative framework: 3 Medical Devices Directives

90/385/EEC -> Active Implantable Medical devices
93/42/EEC -> Medical devices
98/79/EC -> In vitro Diagnostics Medical devices

This legislative framework is in recast. Two regulations are expected to replace the 3 above directives. The vote for this 2 new regulations could take place in 2014-15 and could need to be implemented in 2017-18.

Certification system

notifies certifies

National Competent Authority | Notified Body | Manufacturer

monitors assess

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 expertises. The list of Notified Bodies and their scope of notification are available on the Nando web site.

Conformity assessment procedures

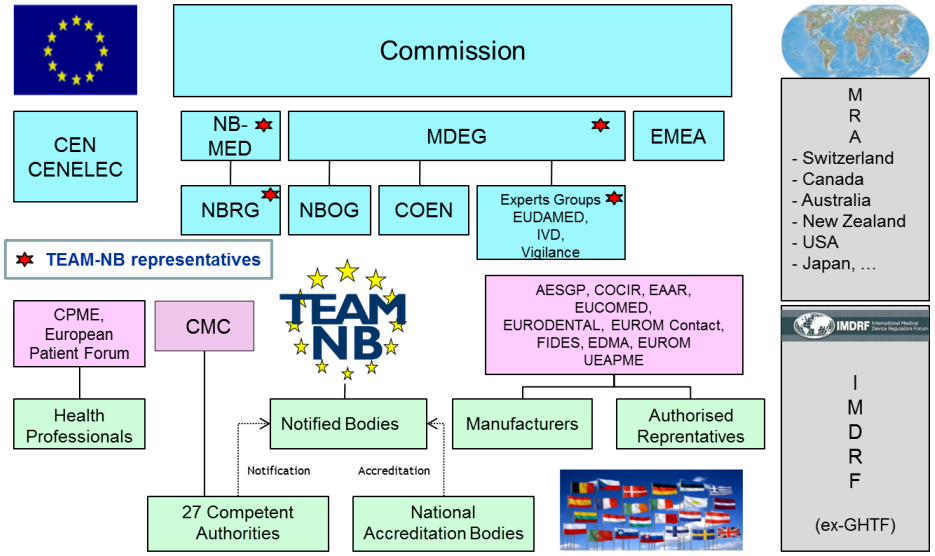
These regulatory controls are based on a risk-based approach. The level of regulatory control increases with increasing degree of risk for the public Health.

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. European patients have a two-year advantage over US patients in terms of access to the latest medical devices
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 and 98/79/EC
"Improving the implementation and harmonization of the European CE marking of medical devices and the quality and competence of Notified Bodies"

This Code of Conduct is mandatory for all Team-NB members.
The document's purpose is to improve the implementation of the European CE certification of medical devices by the member of Team-NB through defined organizational criteria and assessment competence.

This document contains the following topics :

1. Implementation and monitoring of the Code of Conduct
2. Qualification and Assignment of Notified Body Assessment Personnel
3. Minimum time for Notified Body assessments
4. Unannounced inspections
5. Sampling of class IIa and IIb technical files
6. Design Dossier Reviews
7. Verification of Manufactured Products for the IVD Directive
8. Rules for subcontracting
9. Rules for Certification Decisions

Further revisions will be made to be in line with new requirements.