Presentation of the changes and impact of the upcoming Medical Device regulations

Françoise Schlemmer, Team-NB Director
Euromcontact, December 9th, 2015
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
TEAM-NB

Members

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<tr>
<th>Year</th>
<th>Members</th>
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<tr>
<td>2001</td>
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<td>2013</td>
<td>26</td>
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<td>2014</td>
<td>25</td>
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Context of TEAM-NB

TEAM-NB representatives

Commission

CEN CENELEC

EMA NB-MED MDEG

NBRG NBOG COEN

Experts Groups EUDAMED, IVD, Vigilance

CPME
CMC

Health Professionals

Notified Bodies

28 Competent Authorities

Manufacturers

National Accreditation Bodies

Authorised Representatives

EUROMContact, EUCOMED, MedTech, FIDES, EDMA, EUROM UEAPME, Eur Assoc of Auth Repr

Notification Accreditation

- Switzerland
- Canada
- Australia
- New Zealand
- USA
- Japan, …
Code of Conduct V 3.3

- Mandatory to sign for TEAM-NB members
- Available on website www.team-nb.org
- New version includes:
  - Peer assessment
  - Unannounced Visits
  - Details on Code of Conduct Compliance Audits by TEAM-NB auditors
- Version 3.4 in progress:
  - raising qualification levels
Code of Conduct: detailed content

- Implementation, enforcement and monitoring of the Code of Conduct
- Unannounced visits
- Qualification and Assignment of NB Assessment Personnel
- Minimum time for Notified Body assessments
- Sampling of class IIa and IIb technical files
- Design Dossier Reviews
- Rules for subcontracting
- Rules for Certification Decisions
Code of Conduct : peer review audits

◆ Code of Conduct audit

❖ Cycle

- 1\textsuperscript{st} cycle : 3 years 2013-2015
- 2\textsuperscript{nd} cycle : 2 years 2016-2017

❖ Audits

- 1 audit of a NB member/cycle
- 2 auditors in 1 day by audit
- Standard : Code of Conduct

❖ Pool of 5 auditors

Mainly young retired experience people coming from :

- Consultancy
- Notified Bodies
- Competent Authorities
Key Elements on Product assessment
- Essential safety and health requirements
- All risks evaluated; Preclinical, Clinical, PMCF

Key Elements on quality system assessment
- Manufacturer’s premises (incl. subcontractors or suppliers)
- Critical processes
- Obligations in case of outsourcing
Key elements on unannounced audits

- 1 day two auditors
- All manufacturers
  - or critical subcontractors
  - or crucial suppliers
- Sampling of a recent production
  - Technical documentation, forms
  - Sample 3 < 99
  - Testing on site or in a lab
- 2 critical processes audited
Key elements on unannounced audits

- Frequency table of visits in a 3 year period
  (only guidance, NB-Med Consensus Version 20140812)

  - Class I sterile, measuring function & Class II a / IVD self testing
    (under Annex IV)

    | Suspicion (*) | None | Yes |
    |--------------|------|-----|
    | NC rare      | 1    | 2   |
    | NC frequent  | 2    | 2   |

  - Class II b / List B IVD & Class III / AIMD / List A IVD

    | Suspicion (*) | None | Yes |
    |--------------|------|-----|
    | NC rare      | 1    | 2   |
    | NC frequent  | 2    | 3   |

(*) Suspicion: specific indicators to suspect nonconformities
UAVs working group topics

• Access to countries with difficult entry requirements
• Ensure UAVs are truly unannounced
• Costs for UAVs (travel)
• Impact for small companies
• Manufacturers under more than 1 directive (several UAVs?)
• UAVs for large companies (number of days?)
• UAVs at supplier / subcontractors premises?
• Selection of tests to be witness (not class III); to be done in accredited lab
• Feedback to NBOG on open issues / unclear requirements
# New regulations positions

## State of play just after start of Trilogue

<table>
<thead>
<tr>
<th>Commission</th>
<th>Parliament</th>
<th>Council</th>
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<tbody>
<tr>
<td>• UDI</td>
<td>• UDI: single system; to be updated with PMCF data</td>
<td>• UDI on label, packaging, DoC; included in implant card, stored by health institutes; on NB certificates IIb implants and III</td>
</tr>
<tr>
<td>• High risk: Summary on safety and performance data</td>
<td>• Safety and full clinical performance report + layman's summary</td>
<td>• Detailed requirements on summary</td>
</tr>
<tr>
<td>• EUDAMED: Public access</td>
<td>• EUDAMED: public access to vigilance and market surveillance data</td>
<td></td>
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<tr>
<td>• Manufacturer/AR, importers registered</td>
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New regulations positions

Legal Manufacturer

• Full control of the distributor
  ✓ Regular audits
  ✓ Incoming inspection process

• Control against MDR/IVDR

Distributor

• Control against MDR/IVDR of the Manufacturer
  - Article 12: General obligations of distributors
    ✓ CE marking
    ✓ Instruction For Use
    ✓ UDI
    ✓ etc...
Step Change in requirements for the medical devices sector

2010

Guidance and interpretation

2013

Audits and supervision

Now

Regulation (Joint audits)

Recommendation (UAVs)

CoC audits

2016-2018

MDR / IVDR

NBs scope (competencies)

EU oversight

UDI

EUDAMED

Risks analysis

Clinical datas

Electronic submission

Industry in Spotlight

and MORE….
Contacts

Management:

- **Gert Bos** (gert.bos@bsigroup.com) – president
- **Hans Heiner Junker** (hans-heiner.junker@tuev-sued.de) – vice president
- **Guy Buijzen** (guy.buijzen@dekerja.com) – assistant vice-president
- **Cecilie Gudesen Torp** (Cecilie.Gudesen.Torp@presafe.com) - treasurer
- **Corinne Delorme** (corinne.delorme@lne.fr) – secretary
- **Kevin Butcher** (kevin.butcher@sgs.com) – CoC board president
- **Françoise Schlemmer** (schlemmer@quasys.com) - Director and Secretariat

www.team-nb.org
Members