Scientific expertise for evaluating clinical evidence – needs of the Notified Bodies

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Disclaimer

This presentation is based on information available as of today and prepared to my best knowledge as subject matter expert.

This presentation presents my personal understanding of the medical device requirements in Europe and is not reflecting the view of TÜV SÜD PS.
TÜV SÜD at a glance

- 150+ years of quality, safety & sustainability
- 1,000 locations worldwide
- €2.3 billion in annual revenue
- 24,000 employees
- 574,000 certificates
- 100% independent & impartial
- 1-stop solutions provider

Note: Figures have been rounded off.
Independence and impartiality

TÜV SÜD e.V. 74.9%  TÜV SÜD Foundation 25.1%

Gesellschafterausschuss GbR (Shareholder committee)

TÜV SÜD AG

INDUSTRY  MOBILITY  CERTIFICATION

Subsidiaries in GERMANY  Subsidiaries in MIDDLE-EAST & AFRICA

Subsidiaries in CENTRAL & EASTERN EUROPE  Subsidiaries in the ASIA-PACIFIC REGION

Subsidiaries in WESTERN EUROPE  Subsidiaries in the AMERICAS
What is happening when…

- **2008**: Commission: consultation on medical device framework
- **2012**: Commission: proposal for new MDR
- **2014 Q2**: Parliament: position on MDR
- **2015 Q3**: Council position on proposed Regulation
- **2015 Q4**: Trilogue: Commission, Parliament, Council
- **2017**: MDR published on May 5, 2017
- **2020**: End of three-year transition on May 26, 2020

**Medical Device Regulation**

- **Devices falling in the scope of the MDR**
  - Compliance from: 26 May 2020
- **Class I and upclassified devices without certificates based on directives**
  - Compliance from: 26 May 2020

- **Confidentiality**
  - Apply: 26 May 2018
  - Void: 26 May 2020

- **EUDAMED**
  - End of planning phase / road map: May 2018
  - Initial release: March 2020

- **Acceptance of NB Applications**
  - 26 November 2017

- **Current Notification of NBs**
  - Void: 26 May 2020
Additional documents to be expected

- Delegating Acts
- Implementing Acts
- Common Specification
- Harmonized Standards

Other guidance documents either as MEDDEV or similar (e.g. CAMD)
Structure of the MDR

New chapters

**Chapter I (Art. 1-3):**
Scope & definitions

**Chapter III (Art. 25-34):**
Identification and traceability of devices, registration of devices and of economic operators, summary of safety and clinical performance (SSCP), European database on medical devices

**Chapter V (Art. 51-60):**
Classification and conformity assessment, consultations, scrutiny

**Chapter VII (Art. 83-100):**
Post-market surveillance (PMS), post market clinical follow up (PMCF), vigilance, market surveillance, trends, periodic safety update report (PSUR)

**Chapter IV (Art. 109-113):**
Confidentiality, data protection, funding, penalties

**Chapter II (Art. 5-24):**
Making available on the market and putting into service of devices, obligations of economic operators, reprocessing, CE marking, free movement

**Chapter IV (Art. 35-50):**
Notified bodies

**Chapter VI (Art. 61-82):**
Clinical evaluation & clinical investigation

**Chapter VIII (Art. 101-108):**
Cooperation between member states, expert laboratories, medical device coordination group, expert panels, device registers

**Chapter X (Art. 114-123):**
Final provisions
State of the Art Expectations (e.g. MEDDEV 2.7.1 rev. 4)

Who should perform a clinical evaluation and who should assess it?

Least experiences in relevant field for medical device manufacturer

- A higher degree & 5 years of documented professional experience
- 10 years of documented professional experience (if higher degree is not a prerequisite)

Experience expectations on notified bodies

- Notified bodies should establish and implement internal policies and procedures for the assessment of clinical evaluation reports and associated data
- Such expertise should be sufficient to conduct a complete review of the clinical data and clinical evaluation presented for a particular device, to identify and estimate the risks and benefits associated with the use of the medical devices and to identify what, if any, specific clinical expertise is required for the full assessment of the device.
- The assessment team should have sufficient expertise in the device technology as the associated medical procedures.
- Such an assessment requires input from a qualified medical practitioner (for example physician, dentist, nurse, etc.), as appropriate for the particular device, who has clinical experience in using the device or similar devices, the pathology of the condition being treated, the usual treatment, other medical alternatives, etc.
- The notified body clinical assessor may work with external clinical experts. The notified body clinical assessor should ensure that any experts are appropriately aware of the relevant legislation, guidance and standards and to identify specific aspects of the clinical data evaluation for their specific review.

Note: There may be circumstances where the level of evaluator expertise may be less or different; this should be documented and duly justified.
Notified Bodies shall have

permanent availability of sufficient administrative, technical and scientific personnel in accordance with Section 3.1.1 of Annex VII and personnel with relevant clinical expertise in accordance with Section 3.2.4 of Annex VII, where possible employed by the notified body itself.
The Notified Body shall establish and document qualification criteria and procedures for selection and authorisation of persons involved in conformity assessment activities [...] The qualification criteria shall address the various functions within the conformity assessment process, such [...] clinical evaluation, covered by the scope of designation.
Specific qualification criteria shall be defined at least for the assessment of:

- the pre-clinical evaluation
- clinical evaluation
- tissues and cells of human and animal origin
- functional safety
- Software
- Packaging
- devices that incorporate as an integral part a medicinal product
- devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body and
- the different types of sterilisation processes.
The notified body shall have permanent availability of personnel with relevant clinical expertise and where possible such personnel shall be employed by the notified body itself. Such personnel shall be integrated throughout the notified body's assessment and decision-making process in order to:

- Be able to review and challenge the clinical data
- Be able to scientifically evaluate and challenge the opinion of the external clinical expert (if applicable)
- Identify when specialist input is required
- Appropriately train external clinical experts
- Be able to ascertain the comparability and consistency of the assessments
- Document, report and make a recommendation to decision makers
The personnel responsible for carrying out product-related reviews (product reviewers) [...] shall have all of the following proven qualifications:

- successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, pharmacy, engineering or other relevant sciences
- **four years'** professional experience in the field of healthcare products or related activities, such as in manufacturing, auditing or research, of which **two years** shall be in the design, manufacture, testing or use of the device or technology to be assessed or related to the scientific aspects to be assessed
- knowledge of device legislation, including the general safety and performance requirements set out in Annex I
- appropriate knowledge and experience of relevant harmonised standards, CS and guidance documents
- appropriate knowledge and experience of risk management and related device standards and guidance documents
- appropriate knowledge and experience of clinical evaluation
- appropriate knowledge of the devices which they are assessing
- appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes IX to XI, in particular of the aspects of those procedures for which they are responsible, and adequate authorisation for carrying out those assessments
- the ability to draw up records and reports demonstrating that the relevant conformity assessment activities have been appropriately carried out.
The notified body shall employ device reviewers with *sufficient clinical expertise* and, if necessary, use external clinical experts with direct and current experience relating to the device in question or to the clinical condition in which it is utilised, for the purposes of that review.
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