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Conformity Assessment Procedures and Premarket Scrutiny

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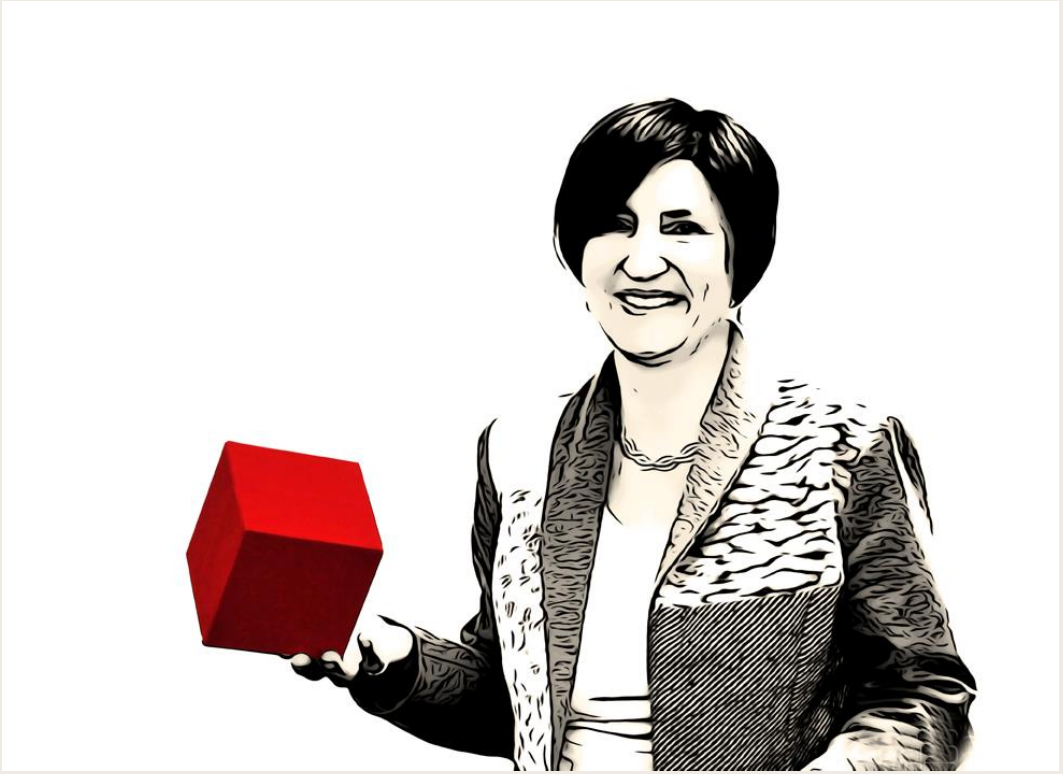
Before she was Head of Regulatory Affairs and Quality Assurance and member of the executive board at SenTec AG, a medium sized medical device manufacturer of patient monitoring systems.
From 1997 to 2004 she worked in various positions in device development and technical documentation an Metrohm AG, a manufacturer of devices for ion analytics.
Sabine Nieba studied Chemistry and Biochemistry and obtained her Ph.D. from the University of Zürich (Department of Biochemistry).



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MDR References

MDR References

- Conformity assessment procedures depending on the product classification are specified in Chapter V, Section 1, Article 52.
- The involvement of notified bodies (NBs) in the conformity assessment is described in Article 53.
- Article 54 contains the scrutiny mechanisms for certain class III and class IIb devices.
- Annex IX, X and XI describe the different conformity assessment procedures.

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Key changes

Key changes

- Full quality assurance system (MDD Annex II – MDR Annex IX):
  TD sampling: Increased number of Technical Documentations to be assessed by the NB (MDR Article 52).
- EC product verification (MDD Annex IV – MDR Annex XI Part B):
  every product needs to be tested (no sampling)
- Production quality system assurance (MDD Annex V in connection with Annex III – MDR Annex XI Part A): not for class III devices any more
- Product quality assurance (MDD Annex VI):
  deleted
- New pre-market scrutiny and special procedures for high-risk devices

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New and changed requirements

New and changed requirements (1)

MDD	MDR	Changes
Annex II **excl. Point 4** Full quality assurance system	**Annex IX** Quality management system + Technical documentation (TD) assessment	TD assessment: Class IIa: at least one representative device for each category of devices Class IIb: at least one representative device per generic device group Class IIb implantable: every device (with exception of certain devices like sutures, wires, clips…; list can be amended by delegated acts)
Annex II Full quality assurance system + Design dossier	**Annex IX** Quality management system + TD assessment + Special scrutiny	TD assessment: Class III: every device Special scrutiny for certain device types (e.g. drug delivery devices)

New and changed requirements (2)

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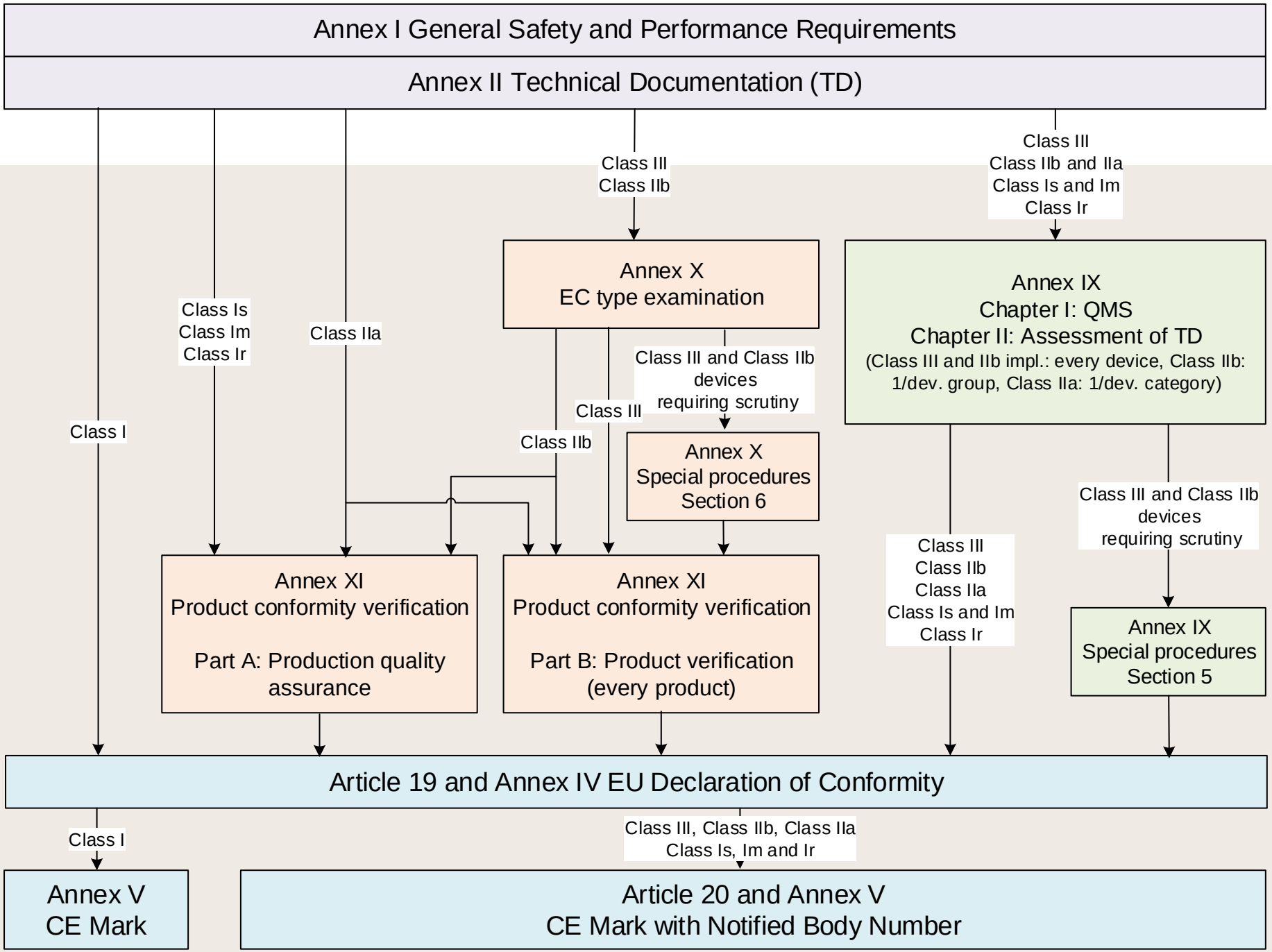
MDD	MDR	Changes
Annex III + Annex IV EC type-examination + EC product verification	**Annex X + Annex XI, Part B** EC type-examination Product verification	No sampling anymore Testing of **all** produced devices
Annex III + Annex V EC type-examination + Production quality system assurance	**Annex X + Annex XI, Part A** EC type-examination Production quality assurance	Not possible for class III devices any more
Annex III + Annex VI EC type-examination + Product quality assurance	n.a.	Not available any more

New and changed requirements (3)

MDD	MDR	Changes
Annex VII EC declaration of conformity (DoC)	**Annex IV** EU declaration of conformity (DoC)	Annex IV in the MDR does not describe the conformity assessment procedure but the content of the DoC. It applies to all conformity assessment procedures.
Annex VII + Annex IV EC DoC + EC product verification	n.a.	Not available any more

New and changed requirements (4)

MDD	MDR	Changes
Annex VII + Annex V EC DoC + Production quality system assurance	**Annex XI, Part A** Production quality assurance	NB involvement also required for class I reusable surgical instruments
Annex VII + Annex VI EC type-examination + Product quality assurance	n.a.	Not available any more


Annex I General Safety and Performance Requirements
Annex II Technical Documentation (TD)
Class I
Class Is
Class Im
Class Ir
Class IIa
Class III
Class IIb
Annex X
EC type examination
Class III and Class IIb devices requiring scrutiny
Annex X
Special procedures
Section 6
Class III
Class IIb and IIa
Class Is and Im
Class Ir
Annex IX
Chapter I: QMS
Chapter II: Assessment of TD
(Class III and IIb impl.: every device, Class IIb: 1/dev. group, Class IIa: 1/dev. category)
Class III and Class IIb devices requiring scrutiny
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Class III, Class IIb, Class IIa
Class Is, Im and Ir
Annex V
CE Mark
Article 20 and Annex V
CE Mark with Notified Body Number

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New and changed requirements (6)

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Devices	Changes
Custom made devices	Article 52(8) and Annex XIII (Procedure for custom-made devices) Statement similar to the one required by the MDD
Investigational devices	Articles 62-80 and 82, Annex XV
Devices for demonstration (exhibitions etc.)	New requirement in Article 21: visible sign clearly indicates that such devices are intended for presentation or demonstration purposes only
Devices with no medical purpose as listed in Annex XVI (e.g. Laser devices for tattoo removal)	New Classification according to rules in Annex VIII > Conformity assessment procedures identical to those for devices with medical purpose
OEM / OBL	OBL must have a QMS and hold the technical documentation.

New and changed requirements (7)

New premarket scrutiny requirements (1)

- For class III implantable devices and class IIb active devices intended to administer and/or remove a medicinal product, notified bodies should, except in certain cases, be obliged to request expert panels to scrutinize their clinical evaluation assessment report.
- The clinical evaluation consultation procedure is described in Article 54 of the MDR, and Annex IX, Section 5.1.
- Not required in case of
  - Renewal of the certificate
  - Modification of already marketed device by same manufacturer for same intended purpose
  - Common Specification available that addresses principle of clinical evaluation for the device type

New and changed requirements (8)

New premarket scrutiny requirements (2)

Clinical evaluation consultation procedure

- The **notified body** shall:
  - verify the quality of clinical data supporting the clinical evaluation report of the manufacturer
  - prepare a clinical evaluation assessment report (CEAR) which concludes on:
    - the **clinical evidence** provided by the manufacturer
    - the **consistency with the intended purpose**, including the medical indication(s)
    - the **plan for the Post-Market Clinical Follow-Up** (PMCF)
  - transmit its clinical evaluation assessment report, along with the clinical evaluation documentation of the manufacturer to the Commission.
- The **Commission** shall immediately transmit these documents to the relevant expert panel. (The notified body may be requested to present its conclusion to the expert panel concerned.)

New and changed requirements (9)

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New premarket scrutiny requirements (3)

Clinical evaluation consultation procedure (f)

- The **expert panel** shall:
  - Decide under the supervision of the Commission on the basis of the following criteria:
    - the novelty of the device or the related clinical procedure involved with possible major clinical or health impact;
    - a significantly adverse change in the risk-benefit profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in the case of failure;
    - a significantly increased rate of serious incidents reported in accordance with Article 87 in respect of a specific category or group of devices,

whether to provide a scientific opinion on the CEAR.

New and changed requirements (10)

New premarket scrutiny requirements (4)

Clinical evaluation consultation procedure (ff)

- The **expert panel** may decide not to provide a scientific opinion, in which case it shall inform the notified body and the Commission as soon as possible and in any event within 21 days after receipt of the documents from the Commission.
- The **expert panel** shall provide the scientific opinion within a period of 60 days.
- Where no opinion has been delivered within a period of 60 days, the **notified body** may proceed with the certification procedure of that device.

New and changed requirements (11)

New premarket scrutiny requirements (6)

Special procedures for specific high risk devices

- Devices incorporating a medicinal substance (Annex IX, Section 5.2):
  > NB shall consult medicinal products authority
- Devices manufactured utilizing, or incorporating tissues or cells of human origin (non-viable) (Annex IX, Section 5.3.1):
  > NB shall consult "human tissues and cells competent authority"
- Devices manufactured utilizing, or incorporating tissues or cells of animal origin (non-viable) (Annex IX, Section 5.3.2):
  > NB shall apply Regulation (EU) No 722/2012

New and changed requirements (12)

New premarket scrutiny requirements (7)

Special procedures for specific high risk devices (f)

- Devices that are composed of substances or combinations of substances that are absorbed by or locally dispersed in the human body (Annex IX, Section 5.4):
  > Apply Annex I of Directive 2001/83/EC, NB shall consult medicinal products authority for products that are systemically absorbed by the human body

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Actions required

Actions required

- Check, whether conformity assessment procedure applied is still possible

- Consult early with NB, to assure that NB will be able to provide required conformity assessment procedure