

DEVELOPMENT AND CERTIFICATION OF MEDICAL DEVICES - STANDARDIZATION IN THE MEDICAL DEVICES TECHNOLOGY

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The medical equipment market is highly regulated in most countries. To introduce a medical device on the market in one specific country, a certification process is necessary. Different countries have different certification processes and slightly different requirements (national deviations).

To receive a CE certification, the product must comply with:

- the requirements of the 93/42 Medical Device Directive,
- the harmonised standards,
- the national regulations of the manufacturers/importers country.

To receive US certification, the product must fulfill the FDA (Food and Drug Administration) requirements

The fulfilling of further standards like UL (Underwriters Laboratory) are recommended in different cases.

Independent of the market, the key requirements for medical devices are safety and clinical effectiveness.

The medical device manufacturer has to comply with a specific Quality Management System, which requires specific processes for the whole product life cycle of the medical devices. This includes the product development, distribution, after sales service and the product monitoring through the whole product life.

The product development life cycle requires fulfillment of process norms as for usability, risk management and software development. In addition, every product has to fulfill specific product standards.

To comply with all process and product regulations, medical equipment manufacturers have to install a detailed product development process.

The paper shows an overview of the most important standards for the product development and the interaction between them. Further, it describes an example of a product development process consisting of the following phases:

- Product definition
- Concept
- Functional models
- Prototyping
- Transfer to production
- Zero series

For each phase, the most important activities and deliverables are mentioned.