Guidance

Tech-Doc

Basic Requirements Technical Documentation

- Unambiguousness
  - Structure
  - Phrasing
  - Objective Evidence
- Uniformity / Continuity within all Documents
- Clarity (clearly structured)
  - Template (unambiguous Format)
  - File Structure of Document Management System
  - Table of Content
- Completeness
- Orthography / Spelling Check
- Final Release (Individual- / Entire Document)
- Searchability (pdf / OCR)
- Revision Status / Traceability of Changes

Annex II Chapter 4 refers to Annex I: Essential Safety and Performance Requirements

ANNEX I

Chapter I – General Requirements

ChapterII – Requirements regarding Design and Manufacturing

10. Chemical, physical und biological properties
11. Infection und microbial Contamination
12. Devices incorporating a substance consideres medicinal product
13. Devices incorporating materials of biological origin
14. Construction of devices and interaction with their environment
15. Devices with a diagnostic or measuring function
16. Protection against radiation
17. Electronic programmable Systems and Software
18. Active devices an devices connected to them
19. Particular requirements for active implantable Devices
20. Protection against mechanical and thermal Risks
21. Protection against the Risks posed to the patient or user by devices supplying energy or substances
22. Protection against the Risks posed by medical devices intended by the manufacturer for use by lay persons

Chapter III – Requirementsregardingthe information supplied with the device

23. Label and Instructions for use

- **Reasoning for non-applicability**
- **Evidence of Methods applied**
- **Applied harmonised Standards, CTS oder other means**
- **Detailled denomination of controlled documents incl. linking to their storage location**

Annex I: Essential Safety and Performance Requirements

I. General Requirements

- Suitability and compliance for medical purpose
- Application of State of the technology
- Risk Management System: iterative Process during entire Life-cycle
- Evidence for Lifetime
- Evidence for Transport- and Warehouse conditions
- Benefit Assessment
- Products w/o medical purpose: Focus on Safety aspects

II. Requirements for Design and Production

10.Chemical, physical and biological Properties

- Designed & Produced
- Assessment of the used Substances & Materials (Toxicity / Flammability)
- Mutual Compatibility
- Effect on Processes on Material Properties
- Mechanical Properties
- Surface properties and conditions
- Evidence Chemical +/o physical Specifications
- Evidence of reduced Risks on harmful substances
- Reasoning for existence of „CMR-Substances“ (carcinogenic , mutagenic or reprotoxic) substances of the device
- Risks, associated with Size / Properties of the device. Attention: Nanomaterials
- Guidance on Phthalates
- Guidance für CMR- and endocrinal Substances
- Identification of harmful substances

Annex I: Essential Safety and Performance Requirements

11. Infection und microbial contamination

- Devices and their manufacturing processes designed to eliminate or to reduce as far as possible the risk of infection
- Designed to facilitate their safe cleaning, disinfection, and/or re-sterilisation.
- Labelling of the microbial Status
- Sterility confirmation on Packing and Labelling, etc.
- Integrity of packaging is clearly evident to the final user.
- The labelling of the device shall distinguish between devices in both a sterile and a non-sterile condition

12. Devices incorporating a substance considered to be a medicinal product and devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body.

- Evidence of Quality, Safety and Benefit of medicinal Sustance acc. to 2001/83/EC
- Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body, and that are absorbed by or locally dispersed in the human body have to hall comply, where applicable and in a manner limited to the aspects not covered by this Regulation, with the relevant requirements laid down in Annex I to Directive 2001/83/EC

13. Devices incorporating materials of biological origin

- Evidence for devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable covered by this Regulation
- Evidence for devices manufactured utilising non-viable biological substances

14. Construction of devices and interaction with their environment

- Intended for use in combination with other devices or equipment
- Connection system shall be safe and shall not impair the specified performance of the devices.
- Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Connections shall be designed to minimise all possible risks, such as misconnection.
- Combination of Medical-/ Non-Medical Devices
- Procedure for safe disposal in IFU

Annex I: Essential Safety and Performance Requirements

15. Devices with a diagnostic or measuring function

- Sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods.
- The limits of accuracy shall be indicated by the manufacturer.
- measuring function shall be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC

16. Protection against Radiation

- exposure of patients, users and other persons to radiation is reduced as far as possible
- Operating instructions contain detailed information as to the nature of the emitted radiation, the means of protecting the patient and the user, and on ways of avoiding misuse
- Intended levels of ionizing and/or non- ionizing radiation necessary for a specific medical purpose
- Requirements of the Directive 2013/59/Euratom laying down basic safety standards for Design and Production

17. Electronic programmable systems — devices that incorporate electronic programmable systems and software

- Objective Evidence for Software lifecycle, Risk Management, Information security, Verification and Validation
- Objective Evidence for mobile Computer e.g. Light, Size, Aspect ratio, Noise
- Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.

18. Active devices and devices connected to them

- Active non-implantable Devices : Single Fault Safety concept
- Internal power supply equipped with a means of determining the state and warning when the capacity becomes critical
- Devices where the safety of the patient depends on external power supply shall include an alarm system to signal power failure.
- Test report for EMC Compliance
- avoid, as far as possible, the risk of accidental electric shocks to the patient, user or any other person, both during normal use and in the event of a single fault condition in the device,
- Protection against unauthorised Access

Annex I: Essential Safety and Performance Requirements

19. Particular requirements for active implantable devices

- designed and manufactured in such a way as to remove or minimize risk as far as possible
- Code for Identification of active Implant without surgical intervention

20. Protection against mechanical and thermal risks

- Protection against mechanical risks connected with, for example, resistance to movement, instability and moving parts
  Protection against mechanical vibration
- Protection against Noise
- Protection in case of connection to Energy sources and Gas
- Protection against Mix-Ups during assembly
- Labelling (safety signs) for Risk prevention
- Protection against excessive Temperatures

21. Protection against the risks posed to the patient or user by devices supplying energy or substances

- Amount to be delivered can be set and maintained accurately enough
- Operating or adjustment parameters by visual system shall be understandable

22. Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons

- User related Protection (by design, descriptive, Handling, Training)
- Protection against Injection
- Procedure by which the user can verify at the time of use, that the device will perform as intended by the manufacturer,

III. Requirements regarding the information supplied with the device

23. Label and instructions for use, sterile packaging

- UDI carrier, time limit for using or implanting the device

Objective Evidence for Compliance to Essential Safety and Performance Requirements

MDR Req.

Standards, Regulations, etc.

Records named

Unambiguous Identification of Evidence

General Safety and Performance Requirement Regulation EU 2017/745 ANNEX I: GENERAL SAFETY AND PERFORMANCE REQUIREMENTS	applicable	Method applied	Evidence document, remarks	Doc. no.	Version	Date	Comments
I. GENERAL REQUIREMENTS							
1. Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose.							
They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.							