Medical Device Regulation
Technical Documentation

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General requirement

- technical documentation and the summary
  - Clear
  - Organised
  - **readily searchable**
  - unambiguous
- include in particular the elements listed in this Annex I

Technical Documentation

- Annex II
  - Device description and specification
  - Reference to previous and similar generations of the device
  - Information supplied by the manufacturer
  - Design and manufacturing information
  - General safety and performance requirements
  - Risk/benefit analysis and risk management
  - Product verification and validation
    - Pre-clinical and clinical data / Clinical Performance data
    - Additional information in specific cases
- Annex III
  - PMS plan
  - PSUR (Periodic Safety Update Report)
  - PMS report

Device description and specification

- Product or trade name and a general description of the device
  - including its intended purpose and intended user;
- Basic UDI device identifier attributed by the manufacturer
  - identification of this device shall be based on a UDI system
  - otherwise clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability
- Intended patient population and medical conditions
  - to be diagnosed, treated and/or monitored
  - other considerations such as patient selection criteria, indications, contraindications, warnings
- Principles of operation of the device and its mode of action, scientifically demonstrated if necessary
- Rationale for the qualification of the product as a device
- Risk class of the device and the justification of the classification rule(s) applied
- Explanation of any novel features

Device description and specification

- Description of the accessories, other MD and other products that are not MD, which are intended to be used in combination with it
- A description or complete list of the various configurations/variants of the device that will be made available
- General description of key functional elements
  - parts/components (including software if appropriate), formulation, composition, functionality
  - qualitative and quantitative composition
    - labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components
    - sufficient explanation to understand the drawings and diagrams;
- Description of (raw) materials incorporated into key functional elements
  - making either direct contact with human body or indirect contact with body, e.g., during extracorporeal circulation of body fluids
- Technical specifications
  - features, dimensions and performance attributes of MD
  - any variants/configurations and accessories that would typically appear in product specification made available to user, e.g. in brochures, catalogues and the like

Reference to previous and similar generations of the device

- an overview of the manufacturer’s previous generation(s) of the device, if such exist
- an overview of identified similar devices available on the EU or international markets, if such exist

Information supplied by the manufacturer

- A complete set of the label(s)
  - on the device and on its packaging (single unit packaging, sales packaging, transport packaging in case of specific management conditions)
  - in the languages accepted in the Member States where the device is envisaged to be sold
- Instructions for use in the languages accepted in the Member States where the device is envisaged to be sold

Design and manufacturing information

- Information to allow the understanding of the design stages applied to the device
- Complete information and specifications
  - manufacturing processes and their validation, their adjuvants
  - continuous monitoring and the final product testing
  - data shall be fully included in the technical documentation
- Identification of all sites
  - suppliers and sub-contractors, where design and manufacturing activities are performed

General safety and performance requirements

- General safety and performance requirements (Annex 1) that apply to the device and why others do not apply
- Method(s) used to demonstrate conformity with each applicable general safety and performance requirement
- Harmonised standards or CS applied or other solutions employed
- Precise identity of the controlled documents
  - evidence of conformity with each harmonised standard, CS
  - other method employed
  - this information shall incorporate a **cross-reference** to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation

Benefit/risk analysis and risk management

- Benefit/risk analysis referred to in Sections 1 and 8 of Annex I
- Solutions adopted and the results of the risk management referred to in Section 3 of Annex I

Product verification and validation

- Results and critical analyses of all verifications and validation tests
- Studies undertaken to demonstrate conformity of the device with the requirements of
  - this Regulation
  - applicable general safety and performance requirements

Pre-clinical and clinical data

- Pre-clinical data
  - results of (engineering, laboratory, simulated use, animal) tests
  - Evaluation of published literature applicable to the device
    - taking into account its intended purpose or similar devices regarding pre-clinical safety of device and its conformity with the specifications
- Detailed information regarding test design, complete test or study protocols, methods of data analysis, data summaries and test conclusions
  - biocompatibility of the device
    - identification of all materials in direct or indirect contact with the patient or user
  - physical, chemical and microbiological characterisation
  - electrical safety and electromagnetic compatibility
  - software verification and validation
    - software design and development process and evidence of validation of software, as used in finished device
    - summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release.
    - address all of the different hardware configurations and operating systems identified in the information supplied by the manufacturer
  - stability/shelf life
  - performance and safety

Pre-clinical and clinical data

- Conformity with
  - Directive 2004/10/EC of the European Parliament
  - Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions
  - relating to the application of the principles of GLP and the verification of their applications for tests on chemical substances
- Where no new testing has been undertaken, the documentation shall incorporate a rationale for that decision
  - biocompatibility testing on the identical materials was conducted when these were incorporated in a previous version of the device that has been legally placed on the market or put into service
- the clinical evaluation report and its updates and clinical evaluation plan in accordance with Article 61(12) and Part A of Annex XIV
- PMCF plan and PMCF evaluation report in accordance with Part B of Annex XIV or any justification why a PMCF is not applicable

Additional information in specific cases

- Medicinal product
  - device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product
  - a medicinal product derived from human blood or human plasma
  - a statement indicating this fact
  - identify the source of that substance and contain the data of the tests conducted to assess its safety, quality and usefulness, taking account of the intended purpose of the device
- A device is manufactured utilising tissues or cells of human or animal origin, or their derivatives
  - a statement indicating this fact
  - the documentation shall identify all materials of human or animal origin used and provide detailed information concerning the conformity

Additional information in specific cases

- Devices that are composed of substances or combination of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body
  - detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions, or otherwise justification for the absence of such studies, regarding:
    - absorption, distribution, metabolism and excretion;
    - possible interactions, or of their products of metabolism, with other devices, medicinal products or other substances, considering the target population, and their associated medical conditions
    - local tolerance
    - toxicity, including single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity and reproductive and developmental toxicity, as applicable according to total exposure to the device

Additional information in specific cases

- Devices containing CMR or endocrine-disrupting substances referred to in Section 10.4.1 of Annex I, the justification referred to in Section 10.4.2 of that Annex
- MD in a sterile or defined microbiological condition
  - description of the environmental conditions for the relevant manufacturing steps.
- MD in a sterile condition
  - description of the methods used
    - validation reports, with respect to packaging, sterilisation and maintenance of sterility.
    - validation report shall address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues
- MD with a measuring function
  - description of the methods used in order to ensure the accuracy as given in the specifications.
- If MD is to be connected to other device to operate as intended
  - description of this combination/configuration including proof that it conforms to the general safety and performance requirements when connected to any such device(s)

Technical documentation on post-market surveillance plan

- shall address the collection and utilization of available information
  - Information concerning serious incidents
    - information from periodic safety update reports, and field safety corrective actions
  - Records referring to non-serious incidents and data on any undesirable side effects
  - Information from trend reporting
  - Relevant specialist or technical literature, databases and/or registers
  - Information, including feedbacks and complaints, provided by users, distributors and importers,
  - Publicly available information about similar medical devices

Technical documentation on post-market surveillance plan

- cover at least
  - Proactive and systematic process to collect any information referred to above.
    - Process shall allow a correct characterization of performance of devices also comparing device with similar products available on market
  - Effective and appropriate methods and processes to assess the collected data
  - Suitable indicators and threshold values to be used in continuous reassessment of risk benefit analysis and of risk management
  - Effective and appropriate methods and tools to investigate complaints or market experiences collected in the field
  - Methods and protocols to manage the events subject to trend report
    - including those to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period

Technical documentation on post-market surveillance plan

- cover at least
  - Methods and protocols to communicate effectively with CA, NB, economic operators and users
  - Reference to procedures to fulfil the manufacturers obligations laid down in Articles 83, 84 and 86
  - Systematic procedures to identify and initiate appropriate measures including corrective actions
  - Effective tools to trace and identify devices for which corrective actions might be necessary
  - PMCF plan, or a justification why PMCF is not applicable
- PSUR (Article 86) and PMS report (Article 85)