F36A NR Minimal Requirements for Content of the Technical Files of Medical Devices according to the MDR

0/ ADMINISTRATIVE DATA
Name and address of the Manufacturer
Name and address of Notified Body
Name and address of the EU Authorised Representative
Contract with EU Authorised Representative
Company Profile
Certificates
Identification of Technical Documentation (number, date of issue, revision)
Revision History
Manufacturers declarations
1/ MD DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES
1.1/ MD description and specification
Name or trade name of the medical device (MD)
General description of the MD
Internationally recognized nomenclature code of MD (GMDN or UMDNS or EDMA)
Intended purpose
Intended users
Basic UDI-DI (according to the part C of Annex VI)
Intended patient population
Medical conditions to be diagnosed, treated and/or monitored
Indications, contra-indications, warnings
Principles of operation of the MD and its mode of action (main active substance)
The rationale for the qualification of the product as a MD
MD classification (the risk class) and the justification for the classification rule(s) applied
Conformity assessment procedure
An explanation of any novel features of the MD (innovations, new characteristics, new intended purposes / markings)
A description of the accessories for a MD / pack
A description of the various configurations/variants of the MD
A description of the key functional elements with drawings
A description of the raw materials
Technical specifications
1.2/ Reference to previous and similar generations of the MD
An overview of the previous generation or generations of the MD produced by the manufacturer
An overview of identified equivalent or similar MDs available
2/ INFORMATION TO BE SUPPLIED BY THE MANUFACTURER
Label of the MD (on the device and its packaging, e.g. label, single unit packaging, sales packaging, transport packaging; in the languages accepted in the Member States where the MD is envisaged to be sold)
The instructions for use (in the languages accepted in the Member States where the MD is envisaged to be sold)
3/ DESIGN AND MANUFACTURING INFORMATION
A description of MD design (design stages applied to the MD, summary of results)
Identification of MD design sites (identification of all sites, including suppliers and sub-contractors, where design activities are performed, e.g. outsourced design units, research sites, etc.)
A description of manufacturing process (e.g. procedures, flow diagrams, protocols, ...)
Identification of MD manufacturing process sites (identification of all sites, including information of manufacturing stages, suppliers and sub-contractors, where manufacturing activities are performed)

Information and specifications including manufacturing processes and their validations (e.g. coating processes, injection moulding, bonding, welding, cleaning, rinsing, sterilisation packaging, software processes, etc.)
Specification of final product and testing
A description of quality control (incoming control, in-process control and final testing)
Quality assurance agreements with subcontractors (in case of sterile MDs contract with sterilisation company)
Working environment control
Suppliers and subcontractors (name and address of the company, evidence of qualification of subcontractors, e.g. certificates, accreditation certificate, etc.)
4/ GENERAL SAFETY AND PERFORMANCE REQUIREMENTS
The general safety and performance requirements, including: - justification of (non)applicability of each requirement - reference to applied common specifications („CS“), standards or parts thereof (specific reference to the applied date of issue) - reference to controlled documents and records as evidence of conformity - evaluations if the requirements are fulfilled - approval by responsible person (date, signature).
List of applied standards and common specifications („CS“)
5/ BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT
The benefit-risk analysis (referred to in Sections 1 and 8 of Annex I)
Risk analysis and risk management (application of EN ISO 14971), including documentation regarding risk management: - risk management plan - risk analysis including risk control measures - risk management report including the evaluation of residual risks and evaluation of benefit-risk ratio
6/ PRODUCT VERIFICATION AND VALIDATION
6.1/ Pre-clinical and clinical data
Pre-clinical safety of the MD (results of technical and laboratory tests, tests of the simulated use and animal tests as well as their evaluation)
Biocompatibility of the MD (identification of all materials in direct or indirect contact with patient or user): - chemical characterisation of materials - literature research - test reports of performed biological tests - summary evaluation of all data and test results for the finished product
Physical, chemical and microbiological tests (evidence of characterisation and pre-clinical suitability of MD with regard to applicable test parameters (e.g. physical composition, chemical characterisation and purity of raw materials and finished product, microbiological condition of final product, etc.): - planning and overview of tests performed - test reports of tests performed - evaluation of data and test results
Tests of electrical safety and electromagnetic compatibility: - planning and overview of tests performed - test reports of tests performed - evaluation of data and test results - a description of requirements related to the recurrent tests and tests after repairs (e.g. EN 62353)
Software verification and validation: - a description of software life cycle (e.g. EN 62304) - a description of software design (e.g. EN 62304, EN 62366)

- validation of the software as used in the finished MD (e.g. the summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment)

Stability, including shelf life (evidence that MD meets defined requirements during the defined shelf life):
- planning and overview of tests performed
- stability of product during shelf life (accelerated ageing studies, long-term stability studies)
- transport stability in-use stability
- evaluation of data and test results

Packaging and transport of MD

The MD clinical evaluation report and its updates (in the case of Directive 93/42/EEC according to the MEDDEV 2.7/1 rev.4), including information on the qualification of the author

The clinical evaluation plan

Clinical trials (if necessary)

Post-market activities - PMCF plan and PMCF evaluation report (or a justification as to why a PMCF is not applicable)

Summary of Safety and Clinical Performance (SSCP) according to the Art. 32 MDR
For implantable MDs and for class III MDs, other than custom-made or investigational MDs, the manufacturer shall draw up a SSCP.
- SSCP shall be written in a way that is clear to the intended user and, if relevant, to the patient and shall be made available to the public via Eudamed,
- the draft of the SSCP shall be part of the documentation and shall be validated by the notified body and uploaded to the Eudamed,
- the manufacturer shall mention on the label or instructions for use where the SSCP is available,
- the SSCP shall be updated at least annually (Art. 61 MDR), update shall be identified in the PMS plan.

6.2/ Additional information required in specific cases

Medicinal products according to the Directive 2001/83/EC (consultation procedure with medicinal agency)
Documentation shall contain:
- general information,
- description of active substance(s) composition,
- statement regarding the reasonableness of the pharmaceutical content,
- GMP certificate for the manufacturing of the medicinal product(s),
- description of the manufacturing steps in relation to manufacturing of medicinal product(s),
- control of the active substances (e.g. declaration for the pharmaceutical quality),
- description of the in-process-controls of the MD relating to the medicinal product,
- description of the final quality controls of the MD (e.g. identity, purity, content, release, compatibility),
- stability tests (or reference to relevant TD chapter),
- toxicity – pharmacological/ toxicological profile,
- pharmacokinetics,
- local compatibility,
- clinical documentation (or reference to relevant TD chapter),
- MD label / Instructions for use (or reference to relevant TD chapter),
- ASMF (or DMF) or EDQM Certificate of Suitability.

MD manufactured utilising tissues or cells of animal origin, or their derivatives
Documentation shall contain:
- explanation / justification of use of animal origin material in comparison with alternative products other than animal origin,
- evidence on the origin, rearing, feeding and age of animals,
- evidence on animal slaughtering and preparation / handling of tissues,
- evidence on elimination or inactivation of transmissible pathogens,
- description related to the traceability of products,
- evidence on compliance with EN 22442-1, -2 and -3 and Regulation (EU) 722/2012 (not in the scope of 3EC notification).

MDs that are composed of substances or 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

Documentation shall contain detailed information, including test design, complete test or study protocols, methods of data analysis, and data summaries and test conclusions, regarding studies in relation to:

- absorption, distribution, metabolism and excretion,
- possible interactions of those substances, or of their products of metabolism in the human body, with other MDs, medicinal products or other substances, considering the target population, and its associated medical conditions,
- local tolerance,
- toxicity, including single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity and reproductive and developmental toxicity, as applicable depending on the level and nature of exposure to the MD.

In the absence of such studies, a justification shall be provided.

CMR substances (carcinogenic, mutagenic or toxic to reproduction) **substances having endocrine-disrupting properties**

- planning and overview of tests performed,
- test reports of on tests performed,
- evaluation of data and test results.

Sterile medical MDs and MDs to be sterilised (description of the sterilisation method used, contract with sterilisation company, results)

- description of working environment conditions during production, cleaning and packaging (validation, cleaning process or reference to relevant TD chapter),
- description and validation of packaging process,
- bioburden before sterilisation (EN ISO 11737-1),
- pyrogen testing, testing for sterilant residues (endotoxins),
- description of the sterilisation method used, including the validation of sterilisation (if applicable).

MDs with measuring function

- planning and overview of tests performed,
- test reports of tests performed,
- evaluation of data and test results,
- description of scope and interval of metrological inspections.

Combination/configuration of MDs connected with other MDs

- planning and overview of tests performed,
- test reports of tests performed,
- evaluation of data and test results.

7/ EU DECLARATION OF CONFORMITY

Draft of EU Declaration of conformity in line with Annex IV MDR

8/ QUALITY MANAGEMENT DOCUMENTATION (Article 10 sec.9 MDR)

Manufacturers of MDs shall **establish, document, implement, maintain, keep up to date and continually improve a quality management system** that shall ensure compliance with this Regulation in the most effective manner and in a manner that is proportionate to the risk class and the type of MD.

The **Quality Management System shall cover all parts and elements of a manufacturer's organisation** dealing with the quality of processes, procedures and MDs. It shall govern the structure, responsibilities, procedures, processes and management resources required to implement the principles and actions necessary to achieve compliance with the provisions of this Regulation.

The quality management system shall address at least the following aspects:

a) a **strategy** for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the MDs covered by the system;

(b) identification of applicable **general safety and performance requirements** and exploration of options to address those requirements;

(c) **responsibility** of the management;

(d) **resource management**, including selection and control of suppliers and sub-contractors;

(e) **risk management** as set out in in Section 3 of Annex I;

(f) **clinical evaluation** in accordance with Article 61 and Annex XIV, **including PMCF**;

(g) **product realisation**, including planning, design, development, production and service provision;
(h) **verification of the UDI** assignments made in accordance with Article 27(3) to all relevant MDs and ensuring consistency and validity of information provided in accordance with Article 29;
(i) **setting-up, implementation and maintenance of a post-market surveillance system**, in accordance with Article 83;
(j) **handling communication** with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;
(k) **processes for reporting of serious incidents** and field safety corrective actions in the context of **vigilance**;
(l) **management of corrective and preventive actions** and verification of their effectiveness;
(m) **processes for monitoring and measurement of output, data analysis** and product improvement.
9/ TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE MDR Chapter VII and Annex III
Article 83 Post-market surveillance system of the manufacturer
1. For each MD, manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of MD. That system shall be an integral part of the manufacturer's quality management system referred to in Article 10(9).
2. The post-market surveillance system shall be suited to actively and systematically gathering, recording and analysing relevant data on the quality, performance and safety of a MD throughout its entire lifetime, and to drawing the necessary conclusions and to determining, implementing and monitoring any preventive and corrective actions.
3. Data gathered by the manufacturer's post-market surveillance system shall in particular be used: (a) to update the benefit-risk determination and to improve the risk management as referred to in Chapter I of Annex I; (b) to update the design and manufacturing information, the instructions for use and the labelling; (c) to update the clinical evaluation; (d) to update the summary of safety and clinical performance referred to in Article 32; (e) for the identification of needs for preventive, corrective or field safety corrective action; (f) for the identification of options to improve the usability, performance and safety of the MD; (g) when relevant, to contribute to the post-market surveillance of other MDs; and (h) to detect and report trends in accordance with Article 88. The technical documentation shall be updated accordingly.
ANNEX III TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE
1.1 The post-market surveillance plan drawn up in accordance with Article 84. The manufacturer shall prove in a post-market surveillance plan that it complies with the obligation referred to in Article 83. (a) The post-market surveillance plan shall address the collection and utilization of available information, in particular: - information concerning serious incidents, including information from PSURs, 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; and - publicly available information about similar MDs. (b) The post-market surveillance plan shall cover at least: - a proactive and systematic process to collect any information referred to in point (a). The process shall allow a correct characterisation of the performance of the MDs and shall also allow a comparison to be made between the MD and similar products available on the market; - effective and appropriate methods and processes to assess the collected data;

- suitable indicators and threshold values that shall be used in the continuous reassessment of the benefit-risk analysis and of the risk management as referred to in Section 3 of Annex I; - effective and appropriate methods and tools to investigate complaints and analyse market-related experience collected in the field; - methods and protocols to manage the incidents subject to the trend report as provided for in Article 88, including the methods and protocols to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period; - methods and protocols to communicate effectively with competent authorities, notified bodies, 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 MDs for which corrective actions might be necessary; and - a PMCF plan as referred to in Part B of Annex XIV, or a justification as to why a PMCF is not applicable.
1.2 The PSUR referred to in Article 86 and the post-market surveillance report referred to in Article 85.