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Med-Info

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for the medical device industry

Design Dossiers

Design Dossiers are technical files for Class III devices and comprehensively examined by the notified body.

Medical Device Directive (MDD) Annex II

Section 4.2 states that an application for examination of the design of the product must include the documents needed to assess whether the product conforms to the requirements of the MDD. Design Dossiers have to be submitted to the notified body for review prior to CE marking of the product. We will assign a project coordinator who will entrust one or more further experts with the review of particular modules. After successful review, the notified body issues a design examination certificate according to Annex II.4 of the Council Directive 93/42/EEC certifying compliance with the relevant provisions of Annex I of the MDD.

Product documentation

- According to MDD Article 11 Section 12, the file shall be in an official language of the EC member state where the chosen notified body is located and/or in another community language the notified body agrees to.
- Once completed, the Design Dossier has to be a controlled document. It does not need to be under document control, but it still needs to be controlled in some manner. Therefore, a complete pagination of the Design Dossier is indicated.

It is recommended to compile a Design Dossier or technical file as follows

(see also NB-MED/2.5.1 and GHTF document GHTF/SG1/N063)

Part A: Technical file

1. Table of content

2. Introduction

- Revision history of Design Dossier
- Regulatory information, e.g. classification of the device including the product code according to the Universal Medical Device Nomenclature System and/or Global Medical Device Nomenclature (UMDNS, GMDN)
- OEM and critical component supplier as well as certificates
- Outsourced critical processes
- Brief description of the product: Intended use, model numbers and names, variants, list of accessories or equipment intended to be used in combination with the device, applied standards, etc.
- History of the device: Market release, items sold, history of the materials used, change notifications, techniques applied including existing regulatory approvals (i.e. FDA 510(k) or PMA clearance)
- Brief description of design process, design control, input/output, verification, validation

3. Design Dossier/technical file summary information

(Reference to supporting documents filed in Part B)

- Comprehensive description of the system and each functional component of the device and the related accessories
- Summary of the essential data and results as detailed in Part B

Part B: Annexes

1. Essential Requirements (ER) checklist

- Table format: Essential Requirements, applicability of requirements, standards or methods utilized to show compliance, location of supporting documentation, rationale or comments
- List of standards applied by the manufacturer

2. Risk analysis (Annex I.1 to I.6)

- All hazards known or reasonably foreseeable in both normal and fault condition, together with the likelihood and consequences of occurrence and measures taken to reduce the resulting risk as far as possible
- Demonstration of appropriate risk analysis; conclusion that the remaining risks are acceptable when weighed against the benefits; results to be reviewed and approved
- Acceptance criteria for the overall residual risk according to EN ISO 14971, EN ISO 22442-1/2/3
- Usability engineering documentation according to EN/IEC 62366 in relation to the accompanying documents (instructions for use (IFU), labeling) and use scenario of the medical device

3. Drawings, design and product specifications

- Most important technical data (to be specified), reports, attachments, photographs, blueprints, flowcharts, product samples

4. Chemical, physical (mechanical safety and performance) and biological tests (Annex I.3, I.7, I.9)

4.1 In vitro testing – preclinical studies

- Use of finished (sterilized) and aged (according to shelf life claim) product
- If applicable, visual, chemical, biological (see also 4.3), physical/mechanical testing (i.e. tensile strength, durability, corrosion, fatigue, long-term stability), efficacy/performance testing, simulated use, finite element analysis (FEA), compatibility to drugs or chemicals, nanoparticle technology

- Description of solutions adopted to fulfill the ER
- Test protocols: Purpose, objective, applicable standards, sample size rationale, aging conditions, test description, parameters, equipment, calibration, acceptance criteria, statistics
- Test reports: Deviations and amendments including justification, reference to raw data, statistical analysis, interpretation and conclusion(s), signature(s)
- Justification is required should any of the above not apply

4.2 In vivo testing – preclinical studies

- Good laboratory practice (GLP) animal studies
- Objectives, methodology, rationale, transferability to humans, limitations
- Pharmacological/pharmacokinetic/toxicological studies, see also 4.3
- Results, analyses of the functional effectiveness and the device's interactions with animal fluids and tissues, statistical analysis, conclusions, see also 4.3

4.3 Biological evaluation (Annex I.7)

- Purpose, scope, strategy, relevant standards
- Categorization of the device according to the nature and duration of body contact
- List of components/materials having direct or indirect body contact including their characteristics, additives, total contacting surface area, description of tested item(s), sterile state, extract preparation, rationale
- Chemical characterization
- List of known possible biological hazards
- Tests performed (qualification of the test laboratory; accreditation) according to EN ISO 10993-1 and GLP
- Action taken on positive results
- Justification for tests not performed, waiving of tests to be recorded
- Overall residual risk-benefit evaluation for biological safety
- Interpretation and conclusion and final statement of manufacturer
- see also Med-Info "Biological evaluation"

4.4 Biostability tests

Influence of the biological matrix on the device (see also 4.3)

4.5 Microbiological safety, animal origin tissue (Annex I.8.2)

For all medical devices utilizing material of animal origin, three separate Med-Infos are available. These documents provide current information on the requirements of the documentation for this type of devices, issues of viral safety, and the validity of European Directorate for the Quality of Medicines (EDQM) certificates of suitability.

Different types of medical devices utilizing material of animal origin are to be considered:

- Devices consisting of material of animal origin (e.g. heart valves, hemostyptica)
- Devices being coated with material of animal origin (e.g. blood vessel replacements)
- Devices that have been manufactured using material of animal origin (e.g. fermentation products)

4.6 Drug/medical device combination products (Annex I.7.4)

Considerations for the consultation procedure to the competent bodies of the member states or the European Medicines Agency (EMA) regarding the assessment of usefulness and safety applied to a medicinal substance, which is of ancillary purpose, in a drug-device combination. This type of product consists of a medical device component and one or more of the following elements:

- Medicinal substance (2001/83/EC; 2004/27/EC; MEDDEV 2.1/3)
- Human blood or human plasma derivative (2000/70/EC; 2001/83/EC; 2002/98/EC; 2004/33/EC; MEDDEV 2.1/3; EMA/CHMP/578661/2010)
- Advanced therapy medicinal product (gene therapeutics, somatic cells or tissue engineering products)

4.7 Human blood derivatives, human tissue/ medical device combination

See above.

4.8 Coated medical devices (biomimicry)

Stability of coating in biological matrix, physiological/pathologic reactions, microbiological evaluation (see also 4.3)

5. Clinical data (Annex I.1, I.6)

- Data from market experience of the same or similar devices, clinical investigations and information from scientific literature
- MDD Annex X, EN ISO 14155-1+2, MEDDEV 2.7.1

For further information, separate Med-Infos on clinical data are available.

6. Labels and IFU, patient information, advertising material (Annex I.13)

- Requirements of the MDD (Annex I.13), EN 980, EN ISO 15223, EN1041
- Description of the product, indication for use, contraindications, warnings, precautions, adverse events, operation

- Disposal information and safety information (Annex I.1 to I.6)
- Risk statement on reuse of single use devices (13.6 h)

7. Manufacturing

- Multiple facilities, critical suppliers, contract sterilizers, etc., copies of relevant certificates
- Flowcharts
- Inspection and preventive monitoring steps (bioburden, particles, pyrogens), deactivation, labeling control, traceability
- Control specifications for incoming critical material/components, in-process controls
- Summary of manufacturing methods (molding, extrusion, chemical process, assembly, etc.)
- Final product release criteria

8. Packaging and shelf life (Annex I.4, I.5, I.8.3, I.8.5, I.8.6, I.8.7)

- Detailed description of the packaging and packaging materials, supplier certificates
- Physical package qualification, performance of the product after real-time and/or accelerated aging, shelf life (expiration date) according to EN 868-2 ff, EN ISO 11607-1+2
- Testing shelf life of the device

9. Sterilization (Annex I.8)

- Installation qualification and validation summary (SAL of 10⁻⁶)
- Process validation report with physical and microbiological performance qualification
- Sterilization plant certified by a notified body (EN ISO 13485, EN 556, ISO 11135-1, ISO 11137, ISO 17665-1)
- Aseptic filling: Validation plan, risk management strategy, identification and evaluation concerning contamination risks, monitoring and evidence/prevention of contamination, definition of aseptic process according to EN ISO 13408-1
- Reprocessing of resterilizable medical devices: Documentation according EN ISO 17664 and EN ISO 15883

10. Measuring function (Annex I.10)

- Sufficient accuracy and stability within appropriate limits of accuracy
- Council Directive 80/181/EWG; MEDDEV 2.1/5

11. Combination with other medical devices (Annex I.9.1)

The whole combination must be safe and must not impair the specified performances of the devices (e.g. electrical safety by combination with active medical devices, Annex I.9.1).

12. Compatibility to drugs (Annex I.7.3)

Devices must be compatible with the medicinal products concerned according to the provisions and restrictions governing these products.

13. Other applicable directives and regulations

- Personal Protective Equipment Directive (89/686/EEC)
- Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH; Regulation (EC) No. 1907/2006)
- Dangerous Preparations (1999/45/EC)
- Brief description of applicability and summary of compliance with regulation

14. Conclusion

Summary of the Design Dossier data including a risk-benefit statement, signature of company representative

15. Declaration of conformity (draft only!)

Important note:

This leaflet provides a rough overview only!

Your contact partner at TÜV SÜD Product Service can provide further information.

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