

Design Dossiers

Design dossiers are considered to be technical files for class III devices and are comprehensively examined by the Notified Body.

Medical Device Directive (MDD) Annex II

Section 4.2 states that an application for examination of the design dossier relating to 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 manager who will entrust one or more further experts with the review of particular modules. All experts are at your disposal directly or indirectly through the project manager. 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.

1. Product documentation

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

2. Description of the medical device

- General description (design, characteristics, mechanism, current instruction for use)
- Summary of manufacturing method (moulding, extrusion, chemical process, assembly, etc.)
- Final product release criteria
- Classification of the device including classification rule according to Universal Medical Device Nomenclature System (UMDNS)

3. Variants

Model number(s) and model name(s) where appropriate.

4. Accessories (integral part of package)

List of accessories or equipment intended to be used in combination with the device system.

5. Material of animal origin (Annex I.8)

For all medical devices utilizing material of animal origin three separate Med-Infos are available. These documents provide current information on the requirements on the documentation for this type of device, issues of viral safety and the validity of 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 replacement)
- devices that have been manufactured using material of animal origin (e.g. fermentation products)

6. Combination products (Annex I.7.4)

This type of product consists of a medical device component and one or more of the following elements:

- a medicinal substance
- a blood product/blood derivative
- an advanced therapy medicinal product (gene therapeutics, somatic cells or tissue engineering products)

The requirements for the documentation on this type of product are detailed in separate Med-Infos.

7. Blood derivatives, human tissue/medical device combination

See above.

8. Measuring function (Annex I.10)

- Sufficient accuracy and stability within appropriate limits of accuracy
- Council Directive 80/181/EEC

9. Emission of radiation (Annex I.11)

- Exposure of patients, users and other persons to be reduced as far as possible
- Compatible with intended purpose

10. 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.

11. Biological requirements/chemical requirements (Annex I.7)

- Categorization of the device according to the nature and duration of body contact
- Tests performed (qualification of the test laboratory; accreditation) according to ISO 10993-1
- Justification for tests not performed
- Final statement of the manufacturer

12. Compatibility with drugs

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

13. Mechanical safety (Annex I.2, I.12)

- Pre-defined protocol: test method, applicable standards, parameters, equipment, calibration arrangements, acceptance criteria, and statistics
- Test report: deviations from the protocols and respective justification, raw data, statistical analysis, interpretation of data, and conclusion(s), approval signature(s)

14. In vivo testing - preclinical studies

Preclinical animal studies used to support the probability of effectiveness in humans:

- GLP, objectives, methodology, rationale for animal model including transferability to humans and limitations
- results, analysis of the functional effectiveness and the device's interactions with animal fluids and tissues
- manufacturer's conclusions

15. Clinical data (Annex I.1, I.6, I.14)

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

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

16. Packaging and shelf life (Annex I.4, I.5, 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), EN 868-1 ff, ISO 11607

17. Sterility (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 (ISO 13485/8, EN 550 ff, ISO 11130 ff)

18. Labeling (Annex I.13)

Requirements of the MDD (Annex I.13), EN 980, ISO 15223, EN1041

19. Instructions for use (Annex I.13)

Description, indication for use, contraindications, warnings, precautions, adverse events, operation

20. 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 risks to acceptable levels
- Demonstration of appropriate risk analysis; conclusion that the remaining risks are acceptable when weighed against the benefits. Results to be reviewed and approved.
- EN ISO 14971, EN 12442-1/2/3, MEDDEV 2.5-8

21. Essential requirements checklist

Table format: essential requirements, applicability of requirements, standards or methods utilized to show compliance, location of supporting documentation, rationale or comments.

22. History of the device

Market release, items sold, history of the materials used, techniques applied including existing regulatory approvals (i.e. FDA 510(k) or PMA clearance)

23. Conclusion

Summary of the design dossier data including a risk vs. benefit statement.

24. Declaration of conformity (draft only!)



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Important note: This leaflet provides a rough overview only!

Prior to the compilation of design dossiers please contact for detailed scientific advice:

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