MDR Technical File

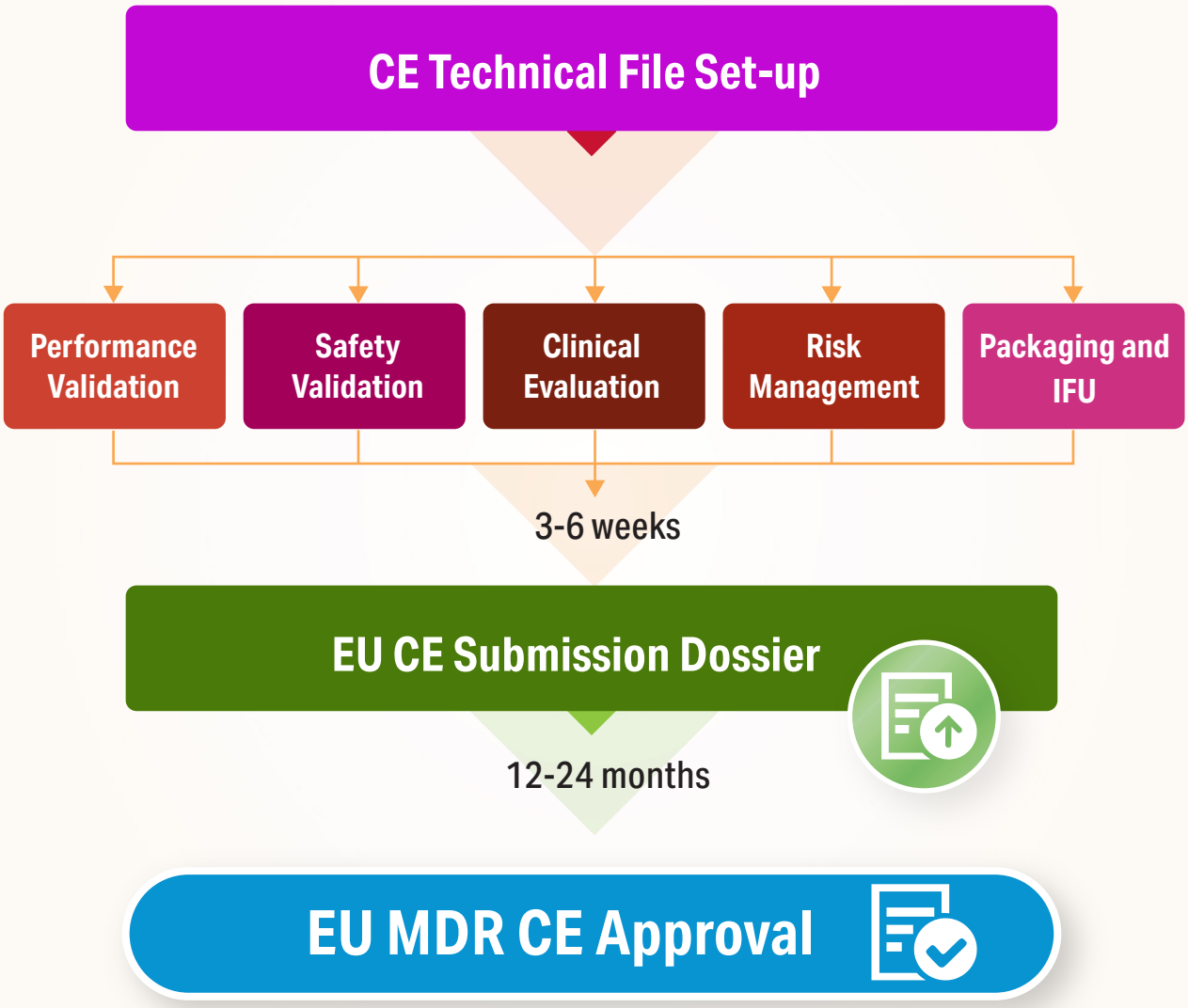
Global Medical Device Consulting

VEE CARE (ASIA) LTD

bsi ISO 13485 Quality Management for Medical Devices CERTIFIED

MD 653109

MDR TECHNICAL FILE DEVELOPMENT PROCESS



TECHNICAL FILE CONTENT

1. DEVICE DESCRIPTION AND SPECIFICATION

1.1 GENERAL DESCRIPTION OF THE DEVICE, ITS VARIANTS, AND ITS INTENDED PURPOSE

1.1.1	Name and address of the manufacturer	☐
1.1.2	Overview of devices/ device groups/device types e.g. table with designation and reference to the REF number, including UDI-DI (if applicable)	☐
1.1.3	All trade names under which the device is placed on the market	☐
1.1.4	Specification of the device including its intended purpose, indication(s), contraindication(s)and warnings, the intended patient group and the medical conditions to be diagnosed / treated / monitored	☐
1.1.5	UMDNS/GMDN classification (if applicable)	☐
1.1.6	Technical specifications of the device, such as characteristics, dimensions and performance attributes of the device	☐
1.1.7	Variants/components/configurations and accessories of the device	☐
1.1.8	Exact software version (if applicable)	☐
1.1.9	Explanations of new characteristics and new intended purposes/indications	☐

1.2 UDI (AS SOON AS IMPLEMENTED OR OBLIGATORY)

Description of the Basic-UDI-DI or (until EUDAMED is fully implemented) description of the traceability by unique identification e.g. by product code, catalogue number or other unambiguous reference. ☐

1.3 DESIGNATION / CLASSIFICATION

Justification for the designation as a medical device and description of the classification of the device including justification for on the applied classification rule(s), exact identification of the applied indent, statement for the classification ☐

1.4 DECLARATION OF CONFORMITY (DOC)

DoC according to Annex IV MDR or according to MDD. For initial certifications (e.g. MDR) the DoC has to be filed in draft status. ☐

TECHNICAL FILE CONTENT

1.5 DESCRIPTION OF THE PRINCIPLES OF OPERATION OF THE DEVICE AND ITS MODE OF ACTION

Description of principles of operation of the device and its mode of action comprehensible to third parties, in combination with other components/accessories if applicable.	☐

1.6 SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

Summary report according to Art. 32 MDR on safety and clinical performance – only necessary for implantable devices and for class III devices except custom-made or investigational devices	☐

1.7 RAW MATERIALS, COMPONENTS, PACKAGING MATERIALS

1.7.1	Overview of all raw materials, components, packaging materials (e.g. bill of materials)	☐
1.7.2	Specifications of raw materials components/subassemblies	☐
1.7.3	Specifications of packaging materials (primary and secondary packaging)	☐
1.7.4	Certificates of analysis from the suppliers, material certificates, inspection certificates	☐
1.7.5	Identification of substances that come into contact with the human body	☐

1.8 DECLARATION ON PARTICULAR SUBSTANCES:

1.8.1	A formal statement in a separate document if the device is manufactured utilizing tissues or cells of human origin, or their derivatives	☐
1.8.2	A formal statement in a separate document if the device is manufactured utilizing tissues or cells of animal origin, or their derivatives	☐
1.8.3	A formal statement in a separate document if the device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as referred to in the first subparagraph of Article 1 (8)	☐

1.9 PREVIOUS AND SIMILAR GENERATIONS

1.9.1	Overview of the previous generation(s) of the device produced by the manufacturer	☐
1.9.2	Overview of the similar generation(s) of the device available on the market in the European Union or on international markets	☐

TECHNICAL FILE CONTENT

1.10 QM-SYSTEM (ONLY FOR MDD PROCEDURES)

Description of the QM-System – typically by submission of the applicable certificates or alternatively by submission of the QM documentation (e.g. Quality manual, etc.).- This aspect is only required for documentation according to MDD. ☐

2. LABELLING / INSTRUCTIONS FOR USE

2.1 LABELLING

Product, single unit packaging, sales packaging and transport packaging in case of specific management conditions) in all languages accepted in the member states where the device is intended to be sold. ☐

2.2 INSTRUCTIONS FOR USE

In all languages accepted in the member states in which the device is intended to be sold. ☐

3. DESIGN AND MANUFACTURING INFORMATION

3.1 DESCRIPTION OF THE DESIGN

3.1.1 Description of the applied design process, the phases (e.g. Milestones) that were applied within the design of the device and a summary of the results of these phases ☐

3.1.2 Identification of all sites where design processes were performed (e.g. Outsourced design units, research sites, etc.) ☐

3.2 DESCRIPTION OF THE MANUFACTURING

3.2.1 Comprehensible description of manufacturing (e.g., Procedures, flow charts, sample batch protocols...) ☐

3.2.2 Addresses of all manufacturing sites with information on the manufacturing steps ☐

3.2.3 Information on specific processes and their validation (e.g., Coating processes, injection moulding, soldering, bonding, welding, lyophilization, cleaning, etc.) ☐

3.2.4 Information on controlled conditions under which certain manufacturing steps take place ☐

TECHNICAL FILE CONTENT

3.3 DESCRIPTION OF QUALITY CONTROL

	Description (e.g. Procedures, flow charts, test specifications, sample test protocols,) of the quality controls (incoming controls, in-process controls and final tests) including acceptance criteria.	☐

3.4 OUTSOURCED PROCESSES, SUBCONTRACTORS

3.4.1	Overview in tabular format of outsourced processes and name/address of the executing companies	☐
3.4.2	Evidence of qualification of subcontractors (e.g. Certificates, and /or accreditation)	☐
3.4.3	Quality assurance agreements with subcontractors for outsourced production steps and in the case of sterile devices for outsourcing of packaging and/or sterilization	☐

4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

4.1 SYSTEMATIC EVIDENCE OF COMPLIANCE WITH THE GENERAL SAFETY AND PERFORMANCE REQUIREMENTS (PREFERABLY IN THE FORM OF A CHECKLIST) :

4.1.1	Justification for applicability / inapplicability of the requirement	☐
4.1.2	Reference to applied common specifications, standards or parts thereof (specific reference to the applied date of issue)	☐
4.1.3	Reference to controlled documents and records as evidence of compliance	☐
4.1.4	Evaluate if the requirements are fulfilled	☐
4.1.5	Approval by a responsible person (date, signature)	☐

4.2 LIST OF APPLIED STANDARDS AND COMMON SPECIFICATIONS

	A current list of applied standards, including the applied issue and, if applicable, an indication of which parts of the standards have not been applied. (This item is part of 4.1 according to MDR, but explicitly required for Directive 93/42/EEC)	☐

5. BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT

The following items must be submitted from the current risk management file covering the whole life cycle:

TECHNICAL FILE CONTENT

5.1 OUTSOURCED PROCESSES, SUBCONTRACTORS

5.2 RISK ANALYSIS, INCLUDING RISK CONTROL MEASURES

5.3 RISK MANAGEMENT REPORT, INCLUDING EXAMINATION OF RESIDUAL RISKS AND BENEFIT-RISK RATIO

6. PRODUCT VERIFICATION AND VALIDATION

For each of the following items, a summary evaluation of the tests or a statement of non-applicability shall be provided. The test reports shall be submitted for the referenced tests. ☐

The performance of testing in an accredited or recognized testing laboratory is not obligatory, but typically facilitates the evidence of suitability.

6.1 BIOCOMPATIBILITY

All components and materials which (can) have direct or indirect contact with the patient or user must be considered ☐

- 6.1.1 Chemical characterization of materials ☐
- 6.1.2 Literature research ☐
- 6.1.3 Test reports of performed biological tests ☐
- 6.1.4 Summary evaluation of all data and test results for the finished product ☐

6.2 PHYSICAL, CHEMICAL AND MICROBIOLOGICAL TESTING

Evidence of characterization and Preclinical suitability of the devices with regard to applicable test parameters (e.g., Physical composition, chemical characterization and purity of raw materials and finished product, microbiological condition of the finished device etc. ☐

- 6.2.1 Planning and overview of performed tests ☐
- 6.2.2 Evaluation of data and test results ☐
- 6.3.3 Test reports of performed tests ☐

TECHNICAL FILE CONTENT

6.3 ELECTRICAL SAFETY AND ELECTROMAGNETIC COMPATIBILITY EMC (IF APPLICABLE)

- 6.3.1 Planning and overview of performed tests ☐
- 6.3.2 Test reports of performed tests ☐
- 6.3.3 Evaluation of data and test results ☐

6.4 SOFTWARE VERIFICATION AND VALIDATION (IF APPLICABLE)

- 6.4.1 Description of the software development process (e.g. according to EN 62304) ☐
- 6.4.2 Description of the software design (e.g. according to EN 62304, EN 62366) ☐
- 6.4.3 Validation of the software as used in the finished device: e.g., a. summary results of verifications, validations and tests performed) ☐

6.5 STABILITY, INCLUDING SHELF LIFE

- 6.5.1 Planning and overview of performed tests ☐
- 6.5.2 Storage stability (accelerated ageing (e.g. Arrhenius equation) and real-time data) ☐
- 6.5.3 Transport stability ☐
- 6.5.4 In-use stability ☐
- 6.5.5 Concept for maintenance and servicing over the entire lifecycle ☐
- 6.5.6 Evaluation of data and test results ☐

6.6 OTHER PRE-CLINICAL TESTS

Other Preclinical tests not addressed under 6.1 to 6.5:

- 6.6.1 Planning and overview of performed tests ☐
- 6.6.2 Test reports of performed tests ☐
- 6.6.3 Evaluation of data and test resultsIn-use stability ☐

6.7 CLINICAL EVALUATION

- 6.7.1 Clinical evaluation ☐
- 6.7.2 Including information on the qualification of the author ☐
- 6.7.3 Reviewed literature ☐

TECHNICAL FILE CONTENT

6.7.4	Evidence of the performed clinical investigations, including	☐
	• Clinical investigation plan	☐
	• Clinical investigation report	☐
	• Vote(s) of the ethics committee(s)	☐
	• Regulatory approval of the clinical investigation	☐
	• Justification for the non-performance of a clinical investigation (class III and implantable devices)	☐
6.7.5	Evidence of performed post-marketing clinical follow-up (PMCF)	☐

6.8 MEDICINAL PRODUCTS WITHIN THE MEANING OF DIRECTIVE 2001/83/EC (IF APPLICABLE PURSUANT TO THE PROVISIONS OF THE CONSULTATION AUTHORITY – FOLLOWING DOCUMENTS PURSUANT TO THE PROVISIONS OF BFARM)

6.8.1	General information	☐
6.8.2	Description of the composition of the active substance(s);	☐
6.8.3	Statement regarding the reasonableness of the pharmaceutical content	☐
6.8.4	GMP-Certificate for the manufacturing of the medicinal product(s)	☐
6.8.4	In-use stability	☐
6.8.5	Description of the manufacturing steps relating to the medicinal product(s)	☐
6.8.6	Control of the active substances (e.g. a declaration for the pharmaceutical quality)	☐
6.8.7	Description of the in-process-controls of the medical device relating to the medicinal product	☐
6.8.8	Description of the final quality controls of the medical device (e.g. identity, purity, content, release, compatibility)	☐
6.8.9	Stability tests (or reference to the information given in chapter 6.5)	☐
6.8.10	Toxicity - pharmacological/toxicological profile	☐
6.8.11	Pharmacokinetics	☐
6.8.12	Local compatibility	☐
6.8.13	Clinical documentation (or reference to chapter 6.7)	☐
6.8.14	Labelling / instruction for use (or reference to chapter 2)	☐

TECHNICAL FILE CONTENT

6.9 OUTSOURCED PROCESSES, SUBCONTRACTORS

- [ ] 6.9.1 Explanation/justification for the use of material of animal origin in comparison to alternative products of non-animal origin
- [ ] 6.9.2 Evidence of the origin, rearing, feeding and age of the animals
- [ ] 6.9.3 Evidence of slaughter of animals and preparation/handling of tissues
- [ ] 6.9.4 Evidence of reduction/removal of transmissible pathogens
- [ ] 6.9.5 Description of the traceability for the products
- [ ] 6.9.5 Evidence of conformity with EN 22442-1, -2 and -3 and Regulation (EU) 722/2012

6.10 SUBSTANCES THAT ARE INTENDED TO BE INTRODUCED INTO THE HUMAN BODY (IF APPLICABLE)

- [ ] 6.10.1 Planning and overview of performed tests
- [ ] 6.10.2 Evidence of absorption, distribution, metabolism and excretion
- [ ] 6.10.3 Testing the interactions of those substances or of their metabolites in the human body with other devices, medicinal products or other substances, considering the target population and its associated medical conditions
- [ ] 6.10.4 Biocompatibility tests – local compatibility, single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity and reproductive toxicity and developmental toxicity

6.11 CMR OR ENDOCRINE-DISRUPTING ACTIVITY (IF APPLICABLE)

- [ ] 6.11.1 Planning and overview of performed tests
- [ ] 6.11.2 Test reports of performed tests
- [ ] 6.11.3 Evaluation of data and test results

6.12 STERILE DEVICES AND TO BE STERILISED (IF APPLICABLE)

- [ ] 6.12.1 Description of environmental conditions during manufacturing
- [ ] 6.12.2 Description of cleaning
- [ ] 6.12.3 Description of packaging
- [ ] 6.12.4 Bioburden (initial microbial count) before sterilisation (EN ISO 11737-1)
- [ ] 6.12.5 Pyrogens / Endotoxins
- [ ] 6.12.6 Description of the sterilization method and validation of sterilization (if applicable)

TECHNICAL FILE CONTENT

6.13 MEASURING FUNCTION (IF APPLICABLE)

- 6.13.1 Planning and overview of performed tests ☐
- 6.13.2 Test reports of performed tests ☐
- 6.13.3 Evaluation of data and test results ☐

6.14 COMBINATION WITH OTHER DEVICES (IF APPLICABLE)

- 6.14.1 Planning and overview of performed tests ☐
- 6.14.2 Test reports of performed tests ☐
- 6.14.3 Evaluation of data and test results ☐

6.15 HYGIENIC (RE-)PROCESSING OF DEVICES (IF APPLICABLE)

- 6.15.1 Validation of cleaning/disinfection processes specified in the instruction for use ☐
- 6.15.2 Validation of sterilisation processes specified in the instruction for use ☐
- 6.15.3 Evidence of numbers of specified reprocessing cycles ☐
- 6.15.4 Evidence of maintenance and functioning control specified in the instruction for use ☐

7. TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE

7.1 POST-MARKET SURVEILLANCE PLAN (PMS-PLAN)

7.2 POST-MARKET CLINICAL FOLLOW-UP PLAN (PMCF-PLAN)

7.3 PERIODIC SAFETY UPDATE REPORT ACCORDING TO ARTICLE 86 (MDR ONLY)

7.4 POST-MARKET SURVEILLANCE REPORT ACCORDING TO ARTICLE 85 (MDR ONLY)

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