Client technical documentation submission checklist

(ALL CLASSES OF DEVICES) MINIMUM REQUIREMENTS

Technical documentation (TD) to be submitted electronically to your SGS contact if possible, with files/documents smaller than 100 MB. All QMS and Technical documentation is required to be provided in an indexed, electronic and text-searchable format. We require them to be available in English. If the documents are in pdf format, then it is best practice is to provide the document with bookmarks. PDF files/attachments should not be file protected or locked.

With all submissions please include a covering letter with a summary that contains sufficient information to identify the type of assessment and why the submission is being made: New technical documentation, transfer, renewal, sampling, significant change (reason for the change). The summary page should also include a Table of Content that refers to all documentation supplied in a clear and comprehensive format.

INSTRUCTIONS:

Client – Complete checklist, confirm the completeness of the Technical Documentation and submit with TD.

SGS Administration – Complete verification that documents are present & legible and when satisfactory inform the product assessor the TD is available for review.

IMPORTANT INFORMATION:

1. This checklist is to support the Client to submit relevant Technical Documentation (TD). Compliance with this checklist does not mean the technical documentation assessment will be fully compliant. Once SGS administration verified the Technical documentation generally includes all appropriate sections, A Product Assessor will review the documentation and any deficiencies will be recorded in the TD assessment report in Non-conformities sections for each relevant part.
2. All non-conformities must be closed before the product can be MDR certified. Please refer to provide guidance non-conformities available on our website: Certification Process and Medical Devices Contact map list https://www.sgs.com/en/life-sciences/ medical-devices/eu-medical-devices-regulations-information-center
3. The time quoted for TD assessment is the minimum time required and it should be noted that poorly organiszed/formatted technical documentation could result in additional time being required to complete the review or termination of the review while manufacturer may still be charged

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To be completed by the Manufacturer per Technical Documentation submitted	
DEVICE NAME:	
MANUFACTURER:	
TECHNICAL DOCUMENTATION (NAME AND IDENTIFICATION):	
DATE SUBMITTED	

REQUIREMENTS	TO BE COMPLETED BY THE MANUFACTURER Indicate File/Folder Name & Section within the TD where documents are located.	SGS ONLY Verification
1 ADMINISTRATION 1. Technical documentation to be subject to document control – indexed, page numbers, authorized.		
2. For devices previously reviewed by Notified Body provide TD Change History identifying all changes since last review with reason for why change was needed and benefit.		
3. Covering letter including Table of Content		
4. In case of Voluntary change of NB, provide previous NB certificate and report.		
2. DEVICE DESCRIPTION 1. Product or trade name and a general description of the device including its intended purpose and intended users for all the variants covered by TD.		
2. Basic UDI- DI, European Medical Device Nomenclature description and code, Implementing regulation 2017/2185 codes and associated rationale		
3. Description of device – the intended patient population, medical condition to be treated, contraindications, principle of operation/mode of action, key performance and safety claims.		
4. Description of how device is used – alone or in combination with other devices or accessories. General description of the key functional elements		
5. List of all accessories.		
6. The rationale for the qualification of the product as a medical device; the risk class of the device and the justification for the classification rule(s).		
7. Conformity assessment route.		
8. Specified pack shelf life		
9. Specified device life in use.		
10. Statements on absence/presence of TSE species derived materials which may also be used in manufacturing processes. Is regulation 722/2012 applicable? Yes or no – provide justification		
11. Statements on absence/presence of medicinal substances according to Directive 2001/83/EC.		
12. Statements on absence/presence of human blood derivatives.		

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13. Statements on absence/presence of phthalates in device or other products that could leak from the device that may be carcinogenic, mutagenic or toxic.		
14. Details of the EU representative if legal manufacturer is located outside of EU		
15. Technical specifications		
16. Description of the raw materials		
3. REFERENCE TO PREVIOUS AND SIMILAR GENERATIONS OF THE DEVICE Overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist; overview of identified similar devices available on the Union or international markets, where such devices exist.		
4. DECLARATION OF CONFORMITY (DoC) 1. If initial submission, the Draft DoC.		
2. DoC to unequivocally identify all variants/models covered by the DoC.		
5. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS (GSPR) 1. Evidence of compliance with GSPR e.g. Checklist with signposting to relevant supporting documentation/reports that identifies how the GSPR is met and relevant standards or CS.		
2. Methods used to demonstrate conformity with each applicable general safety and performance requirement		
3. Justification for GSPRs deemed non-applicable.		
6. STANDARDS 1. Identification of relevant standards, common specifications (CS) with issue date and whether full or partial compliance is claimed.		
2. Justifications required if a key standard is not used, standards are only partially used, or the latest version of a standard is not used which would demonstrate the State of the Art.		
7. RISK MANAGEMENT 1. Risk Management		
2. The benefit-risk analysis referred to in Sections 1 and 8 of Annex I		
3. Risk Management Plan/Protocol and report updated further to Post-Market Surveillance and Clinical Evaluation.		
8. CLINICAL DATA 1. Clinical Evaluation performed according to requirements of MDR Annex XIV part A, including a clinical evaluation plan		
2. Route chosen, Literature, clinical investigation, Literature & Investigation, (MDR Article 61, Section 10)		

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3. 3.1 Literature search protocol with databases to use, search terms, filters to use, inclusion/exclusion criteria, weighting.		
3.2 Documentation of Clinical, biological and technical equivalence if equivalence claimed for safety & performance		
3.3 Clinical hazards identified and included in risk management documents.		
3.4 Copies of literature.		
3.5 Clinical evaluation report, with a critical evaluation of relevant clinical data and how these data support the GSPRs, the performance claims and safety		
3.6 CVs and Declarations of Interest		
4. Where conducted, Clinical Investigation documents demonstrating requirements of Annex XV, Including:		
4.1 Protocol.		
4.2 Letter of no objection/approval		
4.3 Local ethics committee approval.		
4.4 Clinical investigation report.		
4.5 Details of any adverse events in the investigation		
5. Summary of Safety and Clinical Performance (SSCP) – (if relevant – implantable devices and class III devices)		
6. CECP (clinical evaluation consultation procedure)		
9. POST-MARKET SURVEILLANCE: 1. Specific Post-Market Surveillance (PMS) plan for the device subject to TD review.		
2. Post-Market Surveillance Report. Methods for Active and Reactive PMS. PMS report device-specific including per year, sales by geographical areas & complaints/nonconforming product. Evaluation of complaints/trends. Review of information from other sources e.g. literature, databases, regulatory body assessments, data from service reports/repairs. Summary of actions taken – Vigilance reports, FSCA, corrective actions, risk management documents updated, review status of ongoing requirement for PMCF.		
3. Post-Market Clinical Follow up (PMCF) documents per MEDDEV 2.12/2 rev 2, or justification if no PMCF required		
4. Periodic Safety Update Report (PSUR) Article 86		
4.1 Conclusion of risk-benefit determination		
4.2 Main PMCF findings		
4.3 Sales		
10. DESIGN Design procedures and records that applied to the device including changes (design input, design output design verification plan report…)		

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11. MANUFACTURING PROCESSES 1. Detailed description of manufacturing processes with all testing and monitoring and its validation.		
2. Name & addresses for manufacturing sites, suppliers & subcontractors, sterilization provider, external testing facilities with details of their certification/qualification.		
3. Specifications/drawings/Bill of Materials for the critical components and finished manufactured device		
4. Specifications used in manufacturing e.g. for components, sub-assemblies, raw materials, packaging, etc.		
5. Sterile devices – supplier specifications demonstrating suitability of the sterile barrier for the sterilization process that will be used.		
12. PRE-CLINICAL EVALUATION: 1. Results of tests, such as engineering, laboratory, simulated use and animal tests, and evaluation of published literature applicable to the device		
2. Biological evaluation report must be based on the finished device taking account of all materials, manufacturing and sterilization processes, degradation product, leachables, etc		
3. Physical, chemical and microbiological characterization; – electrical safety and electromagnetic compatibility;		
4. Device test reports e.g. to demonstrate compliance to GSPR, finished device specification, claims made, Standards met, verification of Performance Claims.		
5. Report demonstrating device compatibility with any substance that can come into contact with the device e.g. fluids, medicinal substances.		
6. Information on how product cleanliness requirements are met e.g. controlled environment, device cleaning processes, bioburden.		
7. Validation documents for critical manufacturing processes that can affect final product quality e.g. molding, gluing/ bonding, cleaning, sterile barrier sealing, etc.		
8. Report demonstrating suitability when devices used in combination with other devices or accessories.		
9. Report demonstrating accuracy of a measurement function.		
10. Electrical safety and electromagnetic compatibility test reports – EN 60601-1-X series, EN 60601-2-X series from accredited subcontractor		
11. Software verification and validation reports – MEDDEV 2.1/6, EN 62304.		
12. Usability e.g.EN 62366, EN 60601-1-6		
13. USE WITH MEDICINAL PRODUCT: Confirmation that where the device is used with a medicinal product, the regulatory requirements for the medicinal product will be met (e.g. medicinal product marketing authorization/ product license). Use of the medical device should not promote off-label use of the medicinal product.		
14. STABILITY TESTING: 1. Documentation to show the device will meet its specification at the end of its in-use life, including required level of cleanliness or sterility.		
2. Documentation to show device that is reprocessed by the User (e.g. washed, sterilized) will meet its specification after the maximum specified number or reprocesses.		

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3. For sterile devices documentation to show the device and the device pack will remain sterile and in specification after (specified) worst-case sterilization process, and at the end of the pack shelf life		
15. DEVICE SUPPLIED STERILE OR TO BE STERILIZED BY USER: 1. Sterile devices – documentation demonstrating how Sterilization Standards are considered – EN ISO 11135, EN ISO 11137-1, EN ISO 11137-2, EN ISO 17665-1, EN ISO 13408 series.		
2. Devices supplied non-sterile for sterilization by user – validation documentation for sterilization/reprocessing instructions		
3. Technical agreement with sub-contractors – device manufacturer and sterilization company.		
4. Determination of bioburden – validation for test method, and 2 most recent bioburden results.		
5. Manufacturing environmental controls.		
6. Sterility testing – validation of test method.		
7. Ethylene Oxide EO sterilization documents to include validation protocol, validation report, residuals report, information on EO gas specification, biological indicators, last requalification review.		
8. Radiation sterilization documents to include dose setting/ dose substantiation (e.g. Method 1, VDmax & if conducted for a product family rationale for the device being in the family), 2 most recent dose audit reports, process validation protocol and report (dose mapping & if done for a processing category rationale for the device being in the processing category).		
16. TRANSPORTATION AND STORAGE: 1. Documentation to show the device will meet its specification after storage and transportation/shipping.		
2. Defined storage conditions.		
17. INFORMATION MATERIALS: 1. Samples for each group of variants in the TD.		
2. Labels in the form used on the device, primary and secondary packaging.		
3. Instructions for Use (IFU) in the languages accepted in the Member States where the device is envisaged to be sold or justification if no IFU supplied.		
4. Other relevant documentation e.g. implant card (article 18 if relevant), e-labeling.		
5. Verification of translated documents.		
6. Use of symbols.		
7. Marketing brochure/materials.		
8. Labelling information consistent with other TD documents including Risk Management & Clinical Evaluation		
18. OTHER DIRECTIVES: If device also meets the definition of Machinery per 2006/42/ EC or is marketed as PPE per 89/686/EEC documentation required to show how Essential Requirements of these directive are met.		