Medical Device Regulation
Technical Documentation Checklist

	Availability of Document (Yes/No)	Gap description (if applicable)	Applicable Standards	Evidence of compliance OR rationale for non-applicability
Device Description and Product Specifications				
➢ **Device Description Summary**				
1. General description of the device, principles of operation and mode of action				
2. Intended Use, intended users, intended patient population, intended medical field, intended medical condition, indications and contra-indications, warnings, precautions				
3. Device and accessories names, applicable configurations and variants of the device				
➢ **Regulatory Information**				
1. Name, postal address, Notified Body, Certifications, contact person				
2. Conformity Assessment Route per EU-MDR				
3. Device and accessories classification according to MDR Annex VIII				
4. UMDNS and/or GMDN Code				
5. UDI-DI of the device(s) in scope or otherwise a clear identification by catalogue number or other reference allowing traceability.				
6. Product history, approvals market release status of any pending market clearances, country/ies the device(s) are marketed.				
7. OEM and Critical suppliers and subcontractors for outsourced processes				
8. EU Representative, if applicable				
➢ **Applicable Directives, Standards or Regulations**				
The body that recognizes the standard, the revision history of the standard, the name of the standard, a statement indicating whether full or partial compliance with the standard is applicable. Revised or obsolete Standards may require a gap analysis and a statement /rationale which version is used and why				
Labels and Instructions Of Use				
The Manufacturer to provide:				
– product labelling (single unit packaging, sales packaging, transport packaging in case of specific management conditions),				
– sterilization guides				

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– operative techniques				
– marketing material				
Design and Manufacturing Information				
➢ **Development Process Summary and Design Overview**				
1. Design centres location and contact information				
2. Current certification standards for the designing, manufacturing centre				
3. Design Input / Output, Design Control Procedures, Design Verification, Design Validation				
4. Comprehensive description of the system and each functional component of the device and related accessories, including materials or ingredients, packaging, method of sterilization, shelf life, combination with active medical devices, engineering drawings (See Verification/Validation section for more details)				
5. Explanation of novel features (if applicable)				
6. Complete material specifications and certificates of analysis				
7. General statement on functional characteristics and technical performance specifications (mechanical, physical, electrical, biological, chemical, sterility, stability, packaging, transport, storage, combination with other medical devices, accuracy, sensitivity, specificity (for measuring devices) (See Verification/Validation section for more details).				
8. Electrical safety and electromagnetic compatibility (if applicable)				
➢ **Change Notifications**				
Description of all changes in comparison with previous design or manufacturing processes.				
➢ **Manufacturing: Describe in detail the manufacturing process**				
1. Provide information and specifications, including the manufacturing processes and their validation, continuous monitoring and final product testing:				
- Flow charts including inspection and preventive monitoring steps				
- Summary of manufacturing methods				
- Control specifications for incoming critical material/components, in-process controls				
- Final product release criteria				

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2. Identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed:				
– Multiple facilities, critical suppliers, contract sterilizer, etc.: quality assurance certificates issued by an accredited third party inspection body for each facility				
– Manufacturing conditions (provide compliance manufacturing standards)				
– Valid Quality Management Certificate for the manufacturing plant				
– EC-certificate according to Annex II, 3 (Full Quality Assurance System) for the legal manufacturer				
– Labelling control				
– Traceability				
– Product and environmental bioburden, particles				
– Pyrogene testing (if and where applicable)				
General Safety and Performance Requirements				
1. Provide the applicable standards used to evaluate each clause of the checklist				
2. Describe procedures used to demonstrate conformity with each clause.				
3. Provide rationale why a section of the Safety and Performance Requirements Checklist does not apply				
4. For medical devices utilizing animal tissue, the checklist from Commission Regulation (EU) No. 722/2012 must be completed and approved by the identified Divisional Animal Tissue expert				
Benefit-Risk analysis and risk Management				
➢ **Describe the results of the risk management process, including, but not limited to, risk analysis, risk evaluation, mitigation methods and an overall evaluation of residual risk for the design and manufacturing process.**				
1. Description of the risk management procedure of the Manufacturer				
2. Provide the risk management plan				
3. Provide the risk management file				
4. Provide the risk management report				
5. Provide a conclusive statement on:				

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– Completeness of risk evaluation				
– Effectiveness of mitigation measures including a link to the verification documents				
– Overall acceptability of residual risk				
➢ **Usability Studies: studies conducted in accordance with IEC 62366-1. Documentation of use-related hazards**				
1. Provide risk assessment under normal conditions of use and foreseeable misuse in relation to the intended use of the device				
2. Link risk management to usability validation data as evidence for risk verification				
3. Provide market data on use errors including sales volume and complaints received with respect to usability. Not applicable for new devices. Provide potential liaise to PMCF (if applicable)				
4. Statement on any device design changes				
5. Usability validation documentation including:				
– Statement on usability verification of the final design				
– Description of worst case scenario and frequent case scenario of the testing environment and conditions				
– Sampling rationale on amount of users and patients used at validation taking into account the risk reduction stated in the risk management file				
– Acceptance criteria for pass or fail of the usability study				
– Final conclusion with respect to risk management activities				
Product Verification and Validation – Preclinical Data				
➢ **Chemical, Physical, and Biological Testing**				
In Vitro Testing – Preclinical				
6. Adequacy of device response to physiological and pathological stresses, undesirable conditions and forces, long-term use and all known and possible or foreseeable failure modes				
7. Summary of mechanical/physical, visual, biological testing performed to ensure the device is safe and effective. Provide a rationale if any testing was not conducted				
8. If testing is not conducted on a finished sterilized device: Provide a rationale why an alternative item was selected				

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In Vitro Testing – Preclinical animal studies				
1. Description of Good Laboratory Practices with objectives, methodology, rationale of selection for the animal model including transferability to humans and limitations				
2. Results, analysis of functional effectiveness and device interactions with animal fluids and tissues				
3. Pharmacological / pharmacokinetic / toxicological studies. Statement on the device's safety				
Biocompatibility Test				
1. The biological evaluation plan including a purpose of the document and all applied standards, scope/description of the medical device(s). Provide a rationale if some biological effects are not evaluated and/or some test are not performed				
2. Categorization of the medical device(s) based on ISO 10993-1 (nature of body contact and contact duration)				
3. Describe all materials used in the manufacturing processes and evaluated by appropriate ISO Standards including internal materials specification and certificates of analysis and tested items (e.g. finished device, part of device, raw material)				
4. Confirm that testing shall be performed on the final product or representative samples taken from the final product or from materials processed in the same manner as the final product				
5. Rationale for the selection of the sample tested				
6. Statement on the sterile state of the test sample. If the test sample was not sterilized, what is the rationale on why sterilization has no influence on bio-compatibility of the final device				
7. Assurance that no packaging residues may negatively influence the biocompatibility studies				
8. Provide the following information				
– Qualification of the test laboratory, i.e. accreditation				
– Testing is conducted according to GLP				
– Acceptance criteria for qualitative data				
– Biocompatibility test reports				
– Chemical characterization of leachables				
– Conclusive statement on the biological evaluation of the device				
– Relevance of clinical use				

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➢ **Bio-stability Testing:** Influence of the biological matrix on the device				
1. Surface Stress Cracking on Polymers				
2. Corrosion of load-bearing metal screws				
3. Coating Stability				
➢ **Microbiological Safety, Animal Tissue Origin:** If applicable, include:				
1. Geographical origin and boarding of animals: species, country, herd, feeding, age				
2. Origin of material used/nature of starting tissue				
3. Specified risk material: organ, tissue, body fluid				
4. Veterinary control				
– Certificate demonstrating conformance with veterinary inspection criteria indicating that the raw material was fit for human consumption				
– Certificate documenting that the applied techniques for stunning and slaughtering were suitable to avoid cross contamination with specified risk material (EN ISO 22442-2 and respective EC decisions)				
5. Documentation of significant processing steps				
– A flowchart including the starting material and all intermediate and relevant process parameters such as temperature, duration, and pH are required.				
– A detailed description of the manufacturing process including all in-process controls				
– Procedure for reduction or inactivation of potentially existing infectious agents				
➢ **Drug/Medical Device Combinations:** If applicable, provide a rationale whether the assessment route should conform to requirements for the drug-device combinational products. The product in scope consists of a medical device component and one or more of the following elements:				
– Medicinal substance				
– Human blood or human plasma derivative				
– Advanced therapy medicinal product (gene therapeutics, somatic cells, tissue engineering products etc.)				
➢ **Packaging Qualification, Shelf Life, and Aging:** Describe the packaging process and packaging				

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1. Specifications for packaging configurations				
2. Detail description of the packaging materials and discussion of biocompatibility and materials specifications for all packaging materials				
3. Detail description of the packaging process, equipment, and environment the devices are packaged. Supplier certificates				
4. Packaging process validation report including definition of the packaging and sealing equipment				
5. Sampling plan rationale for conducting testing				
6. Shelf Life of the devices. Include statement for accelerated and real time aging if applicable				
7. Discussion of sterile barrier testing				
8. Packaging integrity test (including visual inspection, dye penetration test, creep and burst testing, bubble emission testing), microbial barrier test, seal integrity testing, peel testing (if applicable)				
9. Shipment simulation test and transport validation report				
➢ **Sterilization**				
1. Provide evidence on the sterility assurance of the device				
2. Provide the contract sterilizers information and certification				
3. Provide the methods used for sterilizing the final device				
4. Provide a description of the environmental conditions for the relevant manufacturing steps				
5. Provide a summary of equipment used in the process and their validation				
6. Provide dose mapping and routine sterilization dose information				
7. Provide evidence on bioburdens and their recovery, bacteristasis and fungistasis, endotoxin testing, pyrogen testing, validated microbial methods				
8. Provide a description of worst case scenario				
9. Provide specifications for bioburden limits				
10. Provide information on microbiological performance qualification indicators, supplier's information and specifications				

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Product Verification and Validation - Clinical Data				
1. Clinical Evaluation Plan (CEP)				
2. Clinical Evaluation Report (CER)				
3. Clinical Literature: All literature used to support the Clinical Literature Evaluation including clinical data on benchmark/similar devices				
4. Clinical Development Plan (CDP)				
Post-Market Surveillance				
1. Post-Market Clinical Follow-up (PMCF) Plan according to EU-MDR Annex III				
2. Post-Market Clinical Follow-up (PMCF) Report or a justification why a PMCF is not applicable				
3. Periodic Safety Update Report (PSUR), when applicable				
4. Medical Device Reportable Events: Conduct an adverse event report and provide vigilance reports for all products included in the Technical Documentation				
5. Post Market Surveillance: Include a complaint report of the medical device(s)				
– Include complaints contained in the complaint database, field corrective actions, any open regulatory actions				
– Provide complaint rates as a percentage of sales volume and define the time period covered by the report Note: if the medical device is new, the complaint report should be based on a similar product line for the previous 2-year period if applicable and f available				
– Include a conclusive statement of the types of complaints that were reported				
Additional Information				
1. **Measuring Functions** If applicable, describe the measuring features of the device to the applicable standards and directives				
2. **Combinations with Other Medical Devices** If applicable, describe interactions of the device(s) with compatible devices.				
3. **Compatibility to Drugs** If applicable, describe how the medical device is compatible with drugs.				
4. **Other Applicable Directives and Regulations** Brief description of applicability and summary of compliance with directives and regulations				

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CE Marking of Conformity				
1. Include the legal manufacturer and all manufacturing sites				
2. Include the notified body & notified body number				
3. Include the class of the device(s)				
4. Include any certificate number(s), standard title(s) and date of expiration that the device(s) in the Technical documentation are in conformity with				