Biological Evaluation Submission Form ISO 10993 Part 1

Product Service

Disclaimer: The content of this submission form is subject to changes following the applicable standards and their development. This submission form is only designed to give general guidance without any binding effect for the certification procedure.

Important Note: If a specific point cannot be covered, EN ISO 10993-1 compliance may not be granted. Please note that the order of documentation of this submission form may not represent the chronological order of the process of the respective evaluation steps.

EN ISO 10993-1: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

	Topic	Data	Source of documented evidence	Reference*
1	**General**			
1.1	Legal manufacturer.			Technical File/DesignDossier Content Requirement
1.2	Product (or product family) under evaluation.			Technical File/DesignDossier Content Requirement
1.6	If applicable: Certificate No of product.			
1.9	Which ISO 10993-1 version was applied for biological evaluation? If standard is meanwhile superseded: Provide gap analysis to verify the validity of the evaluation.			General requirement, MDD/AIMD
1.11	Qualification of personnel performing biological evaluation.			EN ISO 10993-1: 4.1, 7
2	**Product description**			

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	Topic	Data	Source of documented evidence	Reference*
2.1	General Product description.			
2.2	What is the intended use of the product (according to the Instructions for Use) and how does it interact with the body?			EN ISO 10993-1: 1, 4.4, 6.2.1 MDD/AIMD Annex I
2.6	10993-1 classification due to nature of body contact and explanation for classification.	Surface-contacting device ☐ Intact skin ☐ Intact mucosal membranes ☐ Breached or otherwise compromised body surfaces External communicating device ☐ Blood path, indirect ☐ Tissue/bone/dentin ☐ Circulating blood Implant devices ☐ Tissue/ bone ☐ Blood Explanation:		EN ISO 10993-1: 5.2
2.12	Describe packaging materials (including labels, ink, desiccants).			EN ISO 10993-1: 4.7 b

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2.13	If applicable: Method of sterilization with key parameters.			EN ISO 10993-1: 6.2.1
3	**Changes –** to be filled out • in case of a planned change (line 1.5 answered with Yes) • in case that changes were made on new products during development that are not already covered by testing/evaluation. In case of certificate extensions, please fill out Appendix E (MED_F_03.10.pdf) to the Application for extension if changes have been made during the last certification period.			
3.1	What type of change(s) was/were introduced to the product?			
3.2	Description of the change(s):			
3.3	Impact on testing/evaluation? If not, please justify.			
4	**Material characterization**			

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4.1	List all materials used in the manufacture having direct or indirect body contact with the appropriate depth of detail with regard to impact on biocompatibility. If appropriate and applicable, specify supplier, Trade name, Source (Distributor), Standard (e.g. AISI etc.), purity, dimensions, etc. In case of novel materials: The identity and quantity of novel materials and chemicals present should be established or measured.			EN ISO 10993-1: 3.2, 4.3, 4.7a MDD/AIMD Annex I Technical File/DesignDossier Content Requirement
4.3	Details of the manufacturing process (including secondary operations) provided in the submission?			EN ISO 10993-1: 4.3 b, 4.8 MDD/AIMD Annex I
4.5	How was material characterization performed? If experimental methods were used, please describe them in Questionnaire Part 18 and 19 and provide a justification on suitability and capability of the respective methods (parameters to be investigated, validation status and limits, LOD etc.).			EN ISO 10993-1: 6.1
4.7	Provide summary of results of material characterization (chemical, physical etc.).			EN ISO 10993-1: 6.1

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4.8	Results of packaging evaluation to assure that no residues from there are negatively influencing biocompatibility of the product.			
5	**Biocompatibility tests**			
5.1	Test item.	*Please fill out submission form part 12.*		EN ISO 10993-1: 6.2.1
5.2	Which tests were performed? Please check boxes. Please provide rationale for selection and/or omission of tests. If tests were performed, please fill out the respective submodule submission form (SF) if available. Available submodules are indicated.			EN ISO 10993-1: 4.4, 4.5, 6.2.1, 6.2.2.1, 7d
☐	Cytotoxicity (SF EN ISO 10993-5)	*Rationale*		EN ISO 10993-1: 6.2.2.2, Annex A
☐	Sensitization (SF EN ISO 10993-10)	*Rationale*		EN ISO 10993-1: 6.2.2.3, Annex A
5.3	Was SF Part 12 filled in for any test performed? If no, provide rationale.			
6	**Risk evaluation**			

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6.1	Confirmation that biological evaluation was carried out within a risk management process in accordance with ISO 14971.			EN ISO 10993-1: 4.1
6.2	Provide a biological risk assessment which considers all known possible biological hazards including: • results of toxicological risk assessment, including the assessment of leachables, degradation products, potential interactive effects etc. • results of evaluation of any existing nonclinical and clinical data or human exposure data, as well as any experience relevant to the medical device.			EN ISO 10993-1: 4.1, 4.5, 7 EN ISO 10993-17
7	**Overall evaluation summary**			
7.1	Overall risk/benefit evaluation.			EN ISO 10993-1: Annex B.2.3 b
7.2	Provide a biological evaluation report according to Annex B.4, including appraisal of the toxicological significance of the data.			EN ISO 10993-1: Annex B.4
8	**Conclusion of the manufacturer**			

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	Topic	Data	Source of documented evidence	Reference*
8.1	Final conclusion on biological safety of the product for its intended use.			EN ISO 10993-1: 7 g

***This submission form is based on the following versions of the standards (including any corrigenda/amendments):**

Standard number (and part number)	Year of issue
EN ISO 10993-1	2009
EN ISO 10993-17	2002
EN ISO 14971	2012

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