Biological Evaluation Submission Forms
General Information

Product Service

The package of submission forms for biological evaluation consists of 17 parts, each covering one standard of the EN ISO 10993 series. The following standards are covered:

EN ISO 10993-1	**EN ISO 10993-10**	**EN ISO 10993-16**
EN ISO 10993-3	**EN ISO 10993-11**	**EN ISO 10993-17**
EN ISO 10993-4	**EN ISO 10993-12**	**EN ISO 10993-18**
EN ISO 10993-5	**EN ISO 10993-13**	**ISO/TS 10993-19**
EN ISO 10993-6	**EN ISO 10993-14**	**ISO/TS 10993-20**
EN ISO 10993-9	**EN ISO 10993-15**	

The EN ISO 10993-2 standard is not represented as a stand-alone form, but requirements are integrated into the respective submission forms. The EN ISO 10993-7 standard is subject of the Submission Form on EO Sterilization Validation, which is also available at TÜV SÜD Product Service.

Bundles available for order:	Price [EUR]
☐ **EN ISO 10993-1 Evaluation and Testing within a Risk Management Process**	**1500**
☐ **Bundle: EN ISO 10993-5 In vitro Cytotoxicity;** **EN ISO 10993-10 Irritation/Sensitization;** **EN ISO 10993-12 Sample Preparation and Reference Materials**	**1500**
☐ **Bundle: EN ISO 10993-18 Chemical Characterization** **EN ISO 10993-17 Allowable Limits** **ISO/TS 10993-19 Physico-chemical/morphological/topographical Characterization**	**1000**
☐ **Bundle: EN ISO 10993-11 Systemic Toxicity** **EN ISO 10993-3 Genotoxicity, Carcinogenicity and Reproductive Toxicity** **EN ISO 10993-6 Local Effects after Implantation**	**1500**
☐ **EN ISO 10993-4 Hemocompatibility**	**1000**
Each of the following:	**500**

☐ **EN ISO 10993-9 Degradation products**	☐ **EN ISO 10993-13 Degrad. Polymers**
☐ **EN ISO 10993-14 Degrad. Ceramics**	☐ **EN ISO 10993-15 Degrad. Metals**
☐ **EN ISO 10993-16 Toxicokinetics**	☐ **EN ISO 10993-20 Immunotoxicology**

The submission forms are delivered as WORD (.docx) files, enabling direct entry of data.

It is strongly recommended to start with Submission Form Part #1. In this part, all other submission forms are referenced, and the manufacturer should indicate which other modules are filled out.

Only the filled form(s) should be sent back to TÜV SÜD Product Service for assessment.

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Product Service

The submission forms are revised upon changes in the respective standards or due to regulatory impact. One update of a module in case of a change of the respective Standard will be provided for free.

For further guidance for preparation of documentation for Biological Evaluation, the manufacturer may refer to http://www.tuev-sued.de/uploads/images/1429795944936471751034/biological-evaluation.pdf

Your contact partner at TÜV SÜD Product Service can provide further information.
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