

# DIN EN ISO 10993-1:2021-05 (E)

Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)

---

Contents	Page
European foreword .....	3
Foreword .....	4
Introduction .....	5
1 Scope .....	6
2 Normative references .....	6
3 Terms and definitions .....	7
4 General principles applying to biological evaluation of medical devices .....	10
5 Categorization of medical devices .....	14
5.1 General .....	14
5.2 Categorization by nature of body contact .....	14
5.2.1 Non-contacting medical devices .....	14
5.2.2 Surface-contacting medical devices .....	15
5.2.3 Externally communicating medical devices .....	15
5.2.4 Implant medical devices .....	16
5.3 Categorization by duration of contact .....	16
5.3.1 Contact duration categories .....	16
5.3.2 Transitory-contacting medical devices .....	16
5.3.3 Medical devices with multiple contact duration categories .....	16
6 Biological evaluation process .....	17
6.1 Physical and chemical information for biological risk analysis .....	17
6.2 Gap analysis and selection of biological endpoints for assessment .....	17
6.3 Biological testing .....	18
6.3.1 General .....	18
6.3.2 Testing for evaluation .....	19
7 Interpretation of biological evaluation data and overall biological risk assessment .....	23
Annex A (informative) Endpoints to be addressed in a biological risk assessment .....	25
Annex B (informative) Guidance on the conduct of biological evaluation within a risk management process .....	30
Annex C (informative) Suggested procedure for literature review .....	43
Bibliography .....	45