

DIN EN ISO 10993-1:2026-03 (E)

Biological evaluation of medical devices - Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process (ISO 10993-1:2025)

Contents		Page
Foreword		v
Introduction		vii
1	Scope	1
2	Normative references	2
3	Terms and definitions	2
4	General principles	8
4.1	Biological evaluation within the ISO 14971 risk management framework	8
4.2	Biological evaluation process	10
4.3	Medical device life cycle	11
4.4	Animal welfare	12
5	Biological evaluation plan	12
6	Biological risk analysis	13
6.1	General approach	13
6.2	Identification of characteristics related to biological safety	14
6.3	Identification of biological hazards, biologically hazardous situations and potential biological harms	14
6.4	Categorization of medical device and determination of scope of evaluation	16
6.4.1	General	16
6.4.2	Exposure duration categories	16
6.4.3	Calculation of exposure duration for categorization of medical devices	17
6.4.4	Body contact and biological effects for consideration	18
6.5	Biological effects for evaluation	21
6.5.1	Overall approach	21
6.5.2	Cytotoxicity	21
6.5.3	Sensitization	22
6.5.4	Irritation	22
6.5.5	Systemic toxicity	22
6.5.6	Local effects after tissue contact	23
6.5.7	Genotoxicity	23
6.5.8	Carcinogenicity	23
6.5.9	Haemocompatibility	24
6.5.10	Other biological effects	24
6.5.11	Other factors to be considered	25
6.6	Gap analysis	28
6.6.1	General	28
6.6.2	Medical devices evaluated using previous versions of this document	28
6.7	Biological equivalence	28
6.8	Testing	30
6.8.1	General principles	30
6.8.2	Biological, physical and chemical testing	31
6.8.3	Degradation testing	32
6.8.4	Toxicokinetic studies	32
6.9	Biological risk estimation	33
7	Biological risk evaluation	33
8	Biological risk control	34
9	Biological evaluation report	34

10	Production and post-production activities	34
Annex A (informative)	Material selection and characterization to support the biological evaluation of a medical device	36
Annex B (informative)	Rationale for key changes in the biological effects listed in Tables 1 to 4	39