

ISO 10993-1:2018 (E)

Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process

Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4	General principles applying to biological evaluation of medical devices
5	Categorization of medical devices
5.1	General
5.2	Categorization by nature of body contact
5.2.1	Non-contacting medical devices
5.2.2	Surface-contacting medical devices
5.2.3	Externally communicating medical devices
5.2.4	Implant medical devices
5.3	Categorization by duration of contact
5.3.1	Contact duration categories
5.3.2	Transitory-contacting medical devices
5.3.3	Medical devices with multiple contact duration categories
6	Biological evaluation process
6.1	Physical and chemical information for biological risk analysis
6.2	Gap analysis and selection of biological endpoints for assessment
6.3	Biological testing
6.3.1	General
6.3.2	Testing for evaluation
6.3.2.1	Cytotoxicity
6.3.2.2	Sensitization
6.3.2.3	Irritation (including intracutaneous reactivity)
6.3.2.4	Haemocompatibility
6.3.2.5	Material-mediated pyrogenicity
6.3.2.6	Acute systemic toxicity
6.3.2.7	Subacute and subchronic toxicity
6.3.2.8	Chronic toxicity
6.3.2.9	Implantation effects
6.3.2.10	Genotoxicity
6.3.2.11	Carcinogenicity
6.3.2.12	Reproductive and developmental toxicity
6.3.2.13	Degradation
6.3.2.14	Toxicokinetic studies
6.3.2.15	Immunotoxicology
7	Interpretation of biological evaluation data and overall biological risk assessment
Annex A	(informative) Endpoints to be addressed in a biological risk assessment
A.1	General
A.2	Rationale for endpoints in Table A.1

Annex B (informative) Guidance on the conduct of biological evaluation within a risk management process

- B.1 Background information**
- B.1.1 General**
- B.1.2 Relationship with other standards, guidance documents and regulatory requirements**
- B.2 Biological evaluation as a risk management practice**
- B.2.1 General**
- B.2.2 The biological evaluation plan**
- B.3 Guidance on risk management**
- B.3.1 Risk assessment**
- B.3.1.1 Introduction**
- B.3.1.2 Risk analysis**
- B.3.1.3 Risk estimation**
- B.3.1.4 Risk evaluation**
- B.3.2 Risk control**
- B.3.3 Evaluation of residual risk acceptability**
- B.3.4 Post production monitoring**
- B.4 Guidance on specific aspects of biological evaluation**
- B.4.1 Material characterization**
- B.4.1.1 Chemical characterization**
- B.4.1.2 Use of chemical characterization data in a biological evaluation**
- B.4.1.3 Proprietary materials formulations**
- B.4.1.4 Physical Characterization**
- B.4.1.5 Effects of manufacturing processes**
- B.4.2 Collection of existing data**
- B.4.3 Device testing considerations**
- B.4.3.1 Tiered approaches to biological testing**
- B.4.3.2 When to do long-term testing (chronic toxicity, reproductive toxicity, degradation and carcinogenicity studies)**
- B.4.3.3 In vitro system pH and osmolality compensation for absorbable materials**
- B.4.4 Biological safety assessment**
- B.4.4.1 Use of clinically relevant data for a risk assessment**
- B.4.4.2 What constitutes “sufficient toxicology data” including dose and route relevance**
- B.4.4.3 Determining the acceptability of the level of leachable (allowable limit) according to ISO 10993-17**
- B.4.4.4 Thresholds of Toxicological Concern (TTC)**
- B.4.4.5 Guidance on mixtures in risk assessment**
- B.4.5 General guidance**
- B.4.5.1 Changes which can require re-evaluation of biological safety**
- B.4.5.2 Good laboratory practice**
- B.4.5.3 Biocompatibility evaluation documentation**

Annex C (informative) Suggested procedure for literature review

- C.1 Introduction**
- C.2 Methodology**
- C.2.1 General**
- C.2.2 Objective(s)**
- C.2.3 Selection criteria for documents**
- C.2.4 Assessment of documents**
- C.2.5 Critical evaluation of the literature**

Page count: 41