

ISO 10993-17:2023-09 (E)

Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents

Contents	Page
Foreword.....	iv
Introduction.....	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Abbreviated terms and symbols	7
5 Toxicological risk assessment within the biological evaluation process	9
5.1 General.....	9
5.1.1 Risk assessment principles.....	9
5.1.2 Hazard identification.....	9
5.1.3 Risk estimation.....	10
5.2 Toxicological risk assessment process.....	12
6 Constituent specific toxicological information	14
6.1 General.....	14
6.2 Identification of hazardous constituents.....	14
6.2.1 General.....	14
6.2.2 Application of the toxicological screening limit.....	16
6.2.3 Identification of human carcinogens or suspected human carcinogens.....	17
6.2.4 Selection of the point of departure.....	17
7 Tolerable contact level, tolerable intake and threshold of toxicological concern	18
7.1 Derivation of TCL and TI.....	18
7.2 Application of TTC.....	18
8 Exposure dose estimation	19
9 Margin of safety	20
9.1 General.....	20
9.2 Calculating the margin of safety.....	20
9.2.1 General.....	20
9.2.2 Combining MoS values to address additivity of harm.....	22
10 Toxicological risk acceptance criteria	23
10.1 General.....	23
10.2 Further risk analysis or risk evaluation or risk control.....	23
11 Reporting requirements	24
Annex A (normative) Evaluation of toxicological data quality when selecting a point of departure	25
Annex B (normative) Derivation of toxicological screening limits	26
Annex C (normative) Derivation of constituent TI or TCL for select endpoints	33
Annex D (informative) Typical assumptions for biological parameters	41
Annex E (normative) Estimation of an exposure dose	44
Annex F (informative) Reporting of toxicological risk assessment information	53
Bibliography	58