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**