ISO 10993-17:2002-12 (E)

Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances

Contents

Page

Foreword iv

Introduction vi

1 Scope 1

2 Normative reference 1

3 Terms and definitions 1

4 General principles for establishing allowable limits 4

5 Establishment of tolerable intake (TI) for specific leachable substances 5
5.1 General 5
5.2 Exposure considerations for TI calculation 7
5.3 Collection and evaluation of data 7
5.4 Set TI for noncancer endpoints 8
5.5 Set TI for cancer endpoints 10
5.6 Establishment of tolerable contact levels (TCLs) 11
5.7 Risk assessment of mixtures 13

6 Calculation of tolerable exposure (TE) 13
6.1 General 13
6.2 Exposure population 14
6.3 Calculation of utilization factor from intended use pattern 14
6.4 Tolerable exposure 15

7 Feasibility evaluation 16

8 Benefit evaluation 16

9 Allowable limits 17

10 Reporting requirements 17

Annex A (informative) Some typical assumptions for biological parameters 18

Annex B (informative) Risk assessment for mixtures of leachable substances 20

Annex C (informative) Conversion of allowable limits for systemic exposure and for body surface contact to maximum dose to patient from a medical device 21

Annex D (informative) Risk analysis report 23

Bibliography 24