

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