

ISO 10993-18 :2005-07 (E)

Biological evaluation of medical devices_ - Part_18: Chemical characterization of materials

Contents

Page

Foreword.....	iv
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions.....	2
4 Symbols and abbreviated terms	3
5 General principles.....	3
6 Characterization procedure	4
6.1 General.....	4
6.2 Step 1 — Qualitative information	5
6.3 Step 2 — Material equivalence	5
6.4 Step 3 — Quantitative information.....	5
6.5 Step 4 — Quantitative risk assessment.....	5
6.6 Step 5 — Estimated clinical exposure to chemicals present.....	6
7 Chemical characterization parameters and methods	6
7.1 General.....	6
7.2 Polymers.....	7
7.3 Metals and alloys	8
7.4 Ceramics.....	8
7.5 Natural macromolecules	9
8 Reporting of data obtained	10
Annex A (normative) Flowchart summarizing the stepwise generation of chemical characterization data for use in toxicological risk assessment	11
Annex B (informative) Information sources for chemical characterization	13
Annex C (informative) Principles for judging toxicological equivalency	16
Bibliography	17