

# 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