

ISO 10993-16:2010-02 (E)

Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables

| Contents | | Page |
|--|--|-------------|
| Foreword | | iv |
| Introduction | | vi |
| 1 | Scope | 1 |
| 2 | Normative references | 1 |
| 3 | Terms and definitions | 1 |
| 4 | Principles for design of toxicokinetic studies | 3 |
| 5 | Guidance on test methods | 4 |
| 5.1 | General considerations | 4 |
| 5.2 | Guidance on specific types of test | 5 |
| 5.2.1 | General | 5 |
| 5.2.2 | Absorption | 5 |
| 5.2.3 | Distribution | 6 |
| 5.2.4 | Metabolism and excretion | 6 |
| Annex A (normative) Circumstances in which toxicokinetic studies shall be considered | | 7 |
| Bibliography | | 8 |