DIN EN ISO 10993-16:2018-02 (E)

Biological evaluation of medical devices - Part 16: Toxicokinetic study d esign for degradation products and leachables (ISO 10993-16:2017)

Contents

Page

European foreword ... **3**

Annex ZA (informative) **Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered** ... **5**

Annex ZB (informative) **Relationship between this European Standard and the essential requirements of Directive 90/385/EEC [OJ L 189] aimed to be covered** ... **7**

Foreword ... **8**

Introduction ... **10**

1 Scope ... **11**

2 Normative references ... **11**

3 Terms and definitions ... **11**

4 Principles for design of toxicokinetic studies ... **13**

5 Guidance on test methods ... **13**

5.1 General considerations ... 13

5.2 Guidance on specific types of test ... 15

5.2.1 General ... 15

5.2.2 Absorption ... 15

5.2.3 Distribution ... 15

5.2.4 Metabolism and excretion ... 16

Annex A (normative) **Circumstances in which toxicokinetic studies shall be considered** ... **17**

Bibliography ... **19**