DIN EN ISO 10993-18:2021-03 (E)

Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020)

Contents

Page

European foreword ... **4**

Annex ZA (informative) **Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered** ... **6**

Annex ZB (informative) Relationship between this European Standard and the essential requirements **of Directive 90/385/EEC [OJ L 189] aimed to be covered** ... **8**

Annex ZC (informative) **Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered** ... **10**

Foreword ... **12**

Introduction ... **13**

1 Scope ... **14**

2 Normative references ... **14**

3 Terms and definitions ... **15**

4 Symbols and abbreviated terms ... **19**

5 Characterization procedure ... **20**
5.1 General ... 20
5.2 Establish medical device configuration and material composition ... 23
5.2.1 General ... 23
5.2.2 Information gathering ... 24
5.2.3 Information generation ... 24
5.3 Assess material/chemical equivalence to a clinically established material or medical device ... 25
5.4 Assess the hypothetical worst-case chemical release based on total exposure to the medical device's chemical constituents ... 26
5.4.1 Establish the hypothetical worst-case chemical release ... 26
5.4.2 Assess the hypothetical worst-case chemical release ... 26
5.5 Establish an analytical evaluation threshold ... 27
5.6 Estimate the chemical release; perform extraction study ... 27
5.7 Assess the estimated chemical release (extractables profile) ... 30
5.8 Determine the actual chemical release; perform leachables study ... 30
5.9 Assess the actual chemical release (leachables profile) ... 32
5.10 Exiting the chemical characterization process ... 32

6 Chemical characterization parameters and methods ... **32**
6.1 General ... 32
6.2 Material composition ... 33
6.3 Extractables and leachables ... 35
6.4 Structural composition or configuration ... 37
6.5 Analytical methods ... 38

7 Reporting of the chemical characterization data ... **39**

Annex A (informative) **General principles of chemical characterization** **40**
Annex B (informative) **Information sources for chemical characterization** **44**
Annex C (informative) **Principles for establishing biological equivalence** **48**
Annex D (informative) **Principles of sample extraction** **51**
Annex E (informative) **Calculation and application of the analytical evaluation threshold (AET)** **63**
Annex F (informative) **Qualification of analytical methods used for extractables/leachables** **71**
Annex G (informative) **Reporting details for analytical methods and chemical data** **74**
Bibliography **77**