ISO 10993-18:2020-01 (E)

Biological evaluation of medical devices - Part 1 8: Chemical characterization of medical device materials within a risk management process

Contents

Page

Foreword ..... **iv**

Introduction ..... **v**

1 Scope **1**

2 Normative references **1**

3 Terms and definitions **2**

4 Symbols and abbreviated terms **6**

5 Characterization procedure **7**

5.1 General 7

5.2 Establish medical device configuration and material composition 10

5.2.1 General 10

5.2.2 Information gathering 11

5.2.3 Information generation 11

5.3 Assess material/chemical equivalence to a clinically established material or medical device 12

5.4 Assess the hypothetical worst-case chemical release based on total exposure to the medical device's chemical constituents 13

5.4.1 Establish the hypothetical worst-case chemical release 13

5.4.2 Assess the hypothetical worst-case chemical release 13

5.5 Establish an analytical evaluation threshold 14

5.6 Estimate the chemical release; perform extraction study 14

5.7 Assess the estimated chemical release (extractables profile) 17

5.8 Determine the actual chemical release; perform leachables study 17

5.9 Assess the actual chemical release (leachables profile) 19

5.10 Exiting the chemical characterization process 19

6 Chemical characterization parameters and methods **19**

6.1 General 19

6.2 Material composition 20

6.3 Extractables and leachables 22

6.4 Structural composition or configuration 24

6.5 Analytical methods 25

7 Reporting of the chemical characterization data **26**

Annex A (informative) **General principles of chemical characterization** **27**

Annex B (informative) **Information sources for chemical characterization** **31**

Annex C (informative) **Principles for establishing biological equivalence** **35**

Annex D (informative) **Principles of sample extraction** **38**

Annex E (informative) **Calculation and application of the analytical evaluation threshold (AET)** **50**

Annex F (informative) **Qualification of analytical methods used for extractables/leachables** **58**

Annex G (informative) **Reporting details for analytical methods and chemical data** **61**

Bibliography **64**