

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