

ISO 10993-1:2009-10 (E)

Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Contents		Page
Foreword		iv
Introduction		vi
1	Scope	1
2	Normative references	1
3	Terms and definitions	2
4	General principles applying to biological evaluation of medical devices	3
5	Categorization of medical devices	6
5.1	General	6
5.2	Categorization by nature of body contact	6
5.3	Categorization by duration of contact	7
6	Biological evaluation process	8
6.1	Material characterization	8
6.2	Biological evaluation tests	8
7	Interpretation of biological evaluation data and overall biological safety assessment	14
Annex A (informative) Biological evaluation tests		15
Annex B (informative) Guidance on the risk management process		16
Annex C (informative) Suggested procedure for literature review		19
Bibliography		21