

ISO 10993-12:2012-07 (E)

Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	General requirements	3
5	Reference materials (RMs)	4
5.1	General	4
5.2	Certification of RMs for biological safety testing	4
6	Use of RMs as experimental controls	4
7	Test sample selection	5
8	Test sample and RM preparation	5
9	Selection of representative portions from a device	5
10	Preparation of extracts of samples	6
10.1	General	6
10.2	Containers for extraction	6
10.3	Extraction conditions and methods	6
10.4	Extraction conditions for hazard identification and risk estimation in the exaggerated-use condition (points to consider in relation to Annex D)	9
11	Records	9
Annex A (informative) Experimental controls		10
Annex B (informative) General principles on, and practices of, test sample preparation and sample selection		12
Annex C (informative) Principles of test sample extraction		14
Annex D (informative) Exhaustive extraction of polymeric materials for biological evaluation		17
Bibliography		19