

DIN EN ISO 10993-12:2021-08 (E)

Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)

| Contents | Page |
|---|------|
| European foreword..... | 3 |
| Annex ZA (informative) Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered..... | 5 |
| Foreword..... | 7 |
| Introduction..... | 8 |
| 1 Scope..... | 9 |
| 2 Normative references..... | 9 |
| 3 Terms and definitions..... | 9 |
| 4 General requirements..... | 11 |
| 5 Reference materials (RMs)..... | 12 |
| 5.1 General..... | 12 |
| 5.2 Certification of RMs for biological safety testing..... | 12 |
| 6 Use of RMs as experimental controls..... | 12 |
| 7 Test sample selection..... | 13 |
| 8 Test sample and RM preparation..... | 13 |
| 9 Selection of representative portions from a medical device..... | 14 |
| 10 Preparation of extracts of samples..... | 14 |
| 10.1 General..... | 14 |
| 10.2 Containers for extraction..... | 14 |
| 10.3 Extraction conditions and methods..... | 15 |
| 10.4 Extraction conditions for materials that polymerize <i>in situ</i> | 18 |
| 11 Records..... | 18 |
| Annex A (informative) Experimental controls..... | 19 |
| Annex B (informative) General principles on, and practices of, test sample preparation and sample selection..... | 21 |
| Annex C (informative) Principles of test sample extraction..... | 23 |
| Annex D (informative) Exhaustive extraction of polymeric materials for biological evaluation..... | 26 |
| Bibliography..... | 28 |