# 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 Termsanddefinitions ..... 1

4 General requirements ..... 3

5 Reference materials (RMs) ..... 4
5.1 General ..... 4
5.2 CertificationofRMsforbiologicalsafetytesting ..... 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 Extractionconditionsforhazardidentificationandriskestimationintheexaggerated-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)Exhaustiveextractionofpolymericmaterialsforbiologicalevaluation ..... 17

Bibliography ..... 19