

Contents

Page

Foreword..... iv

Introduction vi

1 Scope 1

2 Normative references 1

3 Terms and definitions..... 1

4 General requirements..... 3

5 Reference materials..... 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..... 8

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

Bibliography 17