DIN EN ISO 11607-1:2017-10 (E)

Packaging for terminally sterilized medical devices - Part 1: Requiremen ts for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006 + Amd 1.:2014)

Contents

Page

European foreword 3

Annex ZA (informative) Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered 5

Annex ZB (informative) Relationship between this European Standard and the essential requirements of Directive 90/385/EEC [OJ L 189] aimed to be covered 7

Annex ZC (informative) Relationship between this European Standard and the essential requirements of Directive 98/79/EC [OJ L 331] aimed to be covered 8

Introduction 10

1 Scope 11

2 Normative references 11

3 Terms and definitions 11

4 General requirements 15
4.1 General 15
4.2 Quality systems 15
4.3 Sampling 16
4.4 Test methods 16
4.5 Documentation 16

5 Materials and preformed sterile barrier systems 17
5.1 General requirements 17
5.2 Microbial barrier properties 19
5.3 Compatibility with the sterilization process 20
5.4 Compatibility with the labelling system 20
5.5 Storage and transport 20

6 Design and development requirements for packaging systems 21
6.1 General 21
6.2 Design 21
6.3 Packaging-system performance testing 22
6.4 Stability testing 22

7 Information to be provided 23

Annex A (informative) Guidance on medical packaging 24

A.1 Factors influencing the choice of the materials and design of the packaging system 24
A.2 Sterilization processes and considerations 24
A.3 Sterile barrier systems 24

Annex B (informative) Standardized test methods and procedures that may be used to demonstrate compliance with the requirements of this part of ISO 11607 27

B.1 General 27

Annex C (normative) Test method for resistance of impermeable materials to the passage of air 36

Bibliography 39