DIN EN ISO 11607-2:2017-10 (E)

Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2006 + 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 14
4.1 Quality systems 14
4.2 Sampling 14
4.3 Test methods 14
4.4 Documentation 15

5 Validation of packaging processes 15
5.1 General 15
5.2 Installation qualification (IQ) 16
5.3 Operational qualification (OQ) 16
5.4 Performance qualification (PQ) 17
5.5 Formal approval of the process validation 18
5.6 Process control and monitoring 18
5.7 Process changes and revalidation 18

6 Packaging system assembly 18

7 Use of reusable sterile barrier systems 19

8 Sterile fluid-path packaging 19

Annex A (informative) Process development 20

Bibliography 21