DIN EN ISO 11607-2:2006-07 (E)

Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2006)

Contents

Page

Foreword 2

Introduction 4

1 Scope 5

2 Normative references 5

3 Terms and definitions 5

4 General requirements 8
4.1 Quality systems 8
4.2 Sampling 8
4.3 Test methods 8
4.4 Documentation 9

5 Validation of packaging processes 9
5.1 General 9
5.2 Installation qualification (IQ) 10
5.3 Operational qualification (OQ) 10
5.4 Performance qualification (PQ) 11
5.5 Formal approval of the process validation 12
5.6 Process control and monitoring 12
5.7 Process changes and revalidation 12

6 Packaging system assembly 12

7 Use of reusable sterile barrier systems 13

8 Sterile fluid-path packaging 13

Annex A (informative) Process development 14

Bibliography 15

ANNEX ZA (informative) Relationship between this International Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices 16