DIN EN ISO 11607-2:2024-02 (E)

Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (I SO 11607-2:2019 + Amd 1:2023) (includes Amendment A1:2023)

Contents

Page

European foreword ... **3**

[A1] European foreword to Amendment A1 [A1] ... **4**

Annex ZA (informative) **[A1] Relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered [A1]** ... **5**

Annex ZB (informative) **[A1] Relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/746 aimed to be covered [A1]** ... **11**

Foreword ... **16**

[A1] Foreword to Amendment 1 [A1] ... **17**

Introduction ... **18**

1 Scope ... **19**

2 Normative references ... **19**

3 Terms and definitions ... **19**

4 General requirements ... **24**
4.1 Quality systems ... 24
4.2 Risk management ... 24
4.3 Sampling ... 24
4.4 Test methods ... 24
4.5 Documentation ... 25

5 Validation of packaging processes ... **25**
5.1 General ... 25
5.2 Installation qualification ... 26
5.3 Operational qualification ... 27
5.4 Performance qualification ... 27
5.5 Formal approval of the process validation ... 28
5.6 Process control and monitoring ... 28
5.7 Process changes and revalidation ... 28

6 Assembly ... **29**

7 Use of reusable sterile barrier systems ... **29**

8 Sterile fluid-path packaging ... **29**

Annex A (informative) **Process development** ... **30**

Annex B (normative) **[A1] Risk management [A1]** ... **31**

Bibliography ... **35**