

DIN EN ISO 11607-1:2024-02 (E)

Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607 -1:2019 + Amendment 1:2023) (includes Amendment A1:2023)

Contents	Page
European foreword	4
A1 European foreword to Amendment A1 A1	5
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	6
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	25
4.1 Quality systems	25
4.2 Risk management	25
4.3 Sampling	25
4.4 Test methods	25
4.5 Documentation	26
5 Materials, preformed sterile barrier systems and sterile barrier systems	26
5.1 General requirements	26
5.2 Microbial barrier properties	29
5.3 Compatibility with the sterilization process	30
5.4 Labelling system	30
5.5 Storage and transport of materials and preformed sterile barrier systems	30
6 Design and development for packaging systems	31
6.1 General	31
6.2 Design	31
7 Usability evaluation for aseptic presentation	32
8 Packaging system performance and stability	33
8.1 General	33
8.2 Packaging system performance testing	33
8.3 Stability testing	34
9 Packaging system validation and changes	34
10 Inspection immediately prior to aseptic presentation	35
11 Information to be provided	35

Annex A (informative) Guidance on medical packaging	36
Annex B (informative) Standardized test methods, guides and procedures that can be used to demonstrate conformity with the requirements of this document	39
Annex C (normative) Test method for resistance of impermeable materials to the passage of air	50
Annex D (informative) Environmental aspects	51
Annex E (informative) Draft guidance on ways to differentiate a sterile barrier system from protective packaging	52
Annex F (normative) ⌈A1⌋ Risk management ⌋A1⌋	57
Annex G (informative) ⌈A1⌋ Risk management for medical device packaging — Rationale for requirements ⌋A1⌋	61
Bibliography	71