

ISO 11607-1:2006-04 (E)

Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	General requirements	5
4.1	General	5
4.2	Quality systems	5
4.3	Sampling	6
4.4	Test methods	6
4.5	Documentation	6
5	Materials and preformed sterile barrier systems	7
5.1	General requirements	7
5.2	Microbial barrier properties	9
5.3	Compatibility with the sterilization process	10
5.4	Compatibility with the labelling system	10
5.5	Storage and transport	10
6	Design and development requirements for packaging systems	11
6.1	General	11
6.2	Design	11
6.3	Packaging-system performance testing	12
6.4	Stability testing	12
7	Information to be provided	13
Annex A (informative)	Guidance on medical packaging	14
Annex B (informative)	Standardized test methods and procedures that may be used to Annex C (normative) Test method for resistance of impermeable materials to the passage of air	21
Bibliography		22