

ISO/TS 16775:2021-11 (E)

Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2

Contents		Page
Foreword.....		vii
Introduction.....		viii
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Guidance on Clauses 1-4 of ISO 11607-1:2019 and ISO 11607-2:2019	2
4.1	Scope (ISO 11607-1:2019, Clause 1 and ISO 11607-2:2019, Clause 1).....	2
4.1.1	Intent.....	2
4.1.2	Guidance.....	2
4.2	Normative references (ISO 11607-1:2019, Clause 2 and ISO 11607-2:2019, Clause 2).....	3
4.2.1	Intent.....	3
4.2.2	Guidance.....	3
4.3	Terms and definitions (ISO 11607-1:2019, Clause 3 and ISO 11607-2:2019, Clause 3).....	4
4.3.1	Intent.....	4
4.3.2	Guidance.....	4
4.4	Quality and risk management (ISO 11607-1:2019, 4.1, 4.2 and ISO 11607-2:2019, 4.1, 4.2).....	4
4.4.1	Intent.....	4
4.4.2	Guidance.....	4
4.5	Sampling (ISO 11607-1:2019, 4.3 and ISO 11607-2:2019, 4.3).....	6
4.5.1	Intent.....	6
4.5.2	Guidance.....	6
4.6	Test methods (ISO 11607-1:2019, 4.4 and ISO 11607-2:2019, 4.4).....	7
4.6.1	Intent.....	7
4.6.2	Guidance.....	7
4.7	Documentation (ISO 11607-1:2019, 4.5 and ISO 11607-2:2019, 4.5).....	9
4.7.1	Intent.....	9
4.7.2	Guidance.....	9
5	Guidance on Clauses 5-11 of ISO 11607-1:2019	10
5.1	General requirements for materials, preformed sterile barrier systems and sterile barrier systems (ISO 11607-1:2019, 5.1.1 and 5.1.2).....	10
5.1.1	Intent.....	10
5.1.2	Guidance.....	10
5.2	Conditions for production and handling (ISO 11607-1:2019, 5.1.3 and 5.1.4).....	10
5.2.1	Intent.....	10
5.2.2	Guidance.....	10
5.3	Source, history and traceability of materials (ISO 11607-1:2019, 5.1.5).....	11
5.3.1	Intent.....	11
5.3.2	Guidance.....	11
5.4	Properties to be evaluated (ISO 11607-1:2019, 5.1.6).....	12
5.4.1	Intent.....	12
5.4.2	Guidance.....	12
5.5	General performance requirements for materials (ISO 11607-1:2019, 5.1.7 and 5.1.8).....	12
5.5.1	Intent.....	12
5.5.2	Guidance.....	13
5.6	Additional requirements for sterile barrier systems and preformed sterile barrier systems (ISO 11607-1:2019, 5.1.9).....	16

5.6.1	Intent	16
5.6.2	Guidance	16
5.7	Reusable sterile barrier systems (ISO 11607-1:2019, 5.1.10, 5.1.11 and 5.1.12)	17
5.7.1	Intent	17
5.7.2	Guidance	17
5.8	Microbial barrier properties (ISO 11607-1:2019, 5.2)	17
5.8.1	Intent	17
5.8.2	Guidance	17
5.9	Compatibility with the sterilization process (ISO 11607-1:2019, 5.3)	18
5.9.1	Intent	18
5.9.2	Guidance	18
5.10	Labelling system (ISO 11607-1:2019, 5.4)	19
5.10.1	Intent	19
5.10.2	Guidance	19
5.11	Storage and transport of materials and preformed sterile barrier systems (ISO 11607-1:2019, 5.5)	21
5.11.1	Intent	21
5.11.2	Guidance	21
5.12	Design and development (ISO 11607-1:2019, 6.1.1)	22
5.12.1	Intent	22
5.12.2	Guidance	22
5.13	Aseptic presentation (ISO 11607-1:2019, 6.1.2)	23
5.13.1	Intent	23
5.13.2	Guidance	23
5.14	Physical protection (ISO 11607-1:2019, 6.1.3 and 6.1.4)	24
5.14.1	Intent	24
5.14.2	Guidance	24
5.15	Sterilization compatibility (ISO 11607-1:2019, 6.1.5)	25
5.15.1	Intent	25
5.15.2	Guidance	25
5.16	Maintenance of Sterility (ISO 11607-1:2019, 6.1.6 and 6.1.7)	25
5.16.1	Intent	25
5.16.2	Guidance	25
5.17	Requirements for multi-layer packaging (ISO 11607-1:2019, 6.1.8)	26
5.17.1	Intent	26
5.17.2	Guidance	26
5.18	Packaging families (ISO 11607-1:2019, 6.1.9)	27
5.18.1	Intent	27
5.18.2	Guidance	27
5.19	Design process (ISO 11607-1:2019, 6.2.1)	28
5.19.1	Intent	28
5.19.2	Guidance	29
5.20	Design inputs (ISO 11607-1:2019, 6.2.2 and 6.2.3)	29
5.20.1	Intent	29
5.20.2	Guidance	29
5.21	Sterile fluid path (ISO 11607-1:2019, 6.2.4, 6.2.5)	31
5.21.1	Intent	31
5.21.2	Guidance	31
5.22	Usability evaluation for aseptic presentation (ISO 11607-1:2019, 7.1, 7.2 and 7.3)	32
5.22.1	Intent	32
5.22.2	Guidance	32
5.23	Leveraging usability evaluations (ISO 11607-1:2019, 7.4)	33
5.23.1	Intent	33
5.23.2	Guidance	33
5.24	Usability evaluation failures (ISO 11607-1:2019, 7.5)	33
5.24.1	Intent	33
5.24.2	Guidance	33
5.24.3	Guidance on formative and summative studies	34
5.25	Packaging system performance and stability (ISO 11607-1:2019, 8.1)	35
5.25.1	Intent	35
5.25.2	Guidance	35
5.26	Packaging system performance testing (ISO 11607-1:2019, 8.2)	37

5.26.1	Intent	37
5.26.2	Guidance	37
5.27	Stability testing (ISO 11607-1:2019, 8.3)	38
5.27.1	Intent	38
5.27.2	Guidance	38
5.28	Packaging system validation and changes (ISO 11607-1:2019, 9.1)	40
5.28.1	Intent	40
5.28.2	Guidance	40
5.29	Change control (ISO 11607-1:2019, 9.2)	40
5.29.1	Intent	40
5.29.2	Guidance	40
5.30	Revalidations (ISO 11607-1:2019, 9.3, 9.4, and 9.5)	40
5.30.1	Intent	40
5.30.2	Guidance	40
5.31	Inspection immediately prior to aseptic presentation (ISO 11607-1:2019, Clause 10)	41
5.31.1	Intent	41
5.31.2	Guidance	41
5.32	Information to be provided (ISO 11607-1:2019, Clause 11)	41
5.32.1	Intent	41
5.32.2	Guidance	41
6	Guidance on Clauses 5-8 of ISO 11607-2:2019	42
6.1	General Clauses 1-4 of ISO 11607-2:2019	42
6.2	Validation of packaging processes – general requirements (ISO 11607-2:2019, 5.1.1 and 5.1.2)	42
6.2.1	Intent	42
6.2.2	Guidance	42
6.3	Process specification (ISO 11607-2:2019, 5.1.3)	43
6.3.1	Intent	43
6.3.2	Guidance	43
6.4	Process validation of packaging families (ISO 11607-2:2019, 5.1.4)	43
6.4.1	Intent	43
6.4.2	Guidance	43
6.5	Installation qualification (ISO 11607-2:2019, 5.2)	44
6.5.1	Intent	44
6.5.2	Guidance	45
6.6	Operational qualification (ISO 11607-2:2019, 5.3)	45
6.6.1	Intent	45
6.6.2	Guidance	46
6.7	Performance qualification (ISO 11607-2:2019, 5.4)	46
6.7.1	Intent	46
6.7.2	Guidance	46
6.8	Formal approval of the process validation (ISO 11607-2:2019, 5.5)	47
6.8.1	Intent	47
6.8.2	Guidance	47
6.9	Process control and monitoring (ISO 11607-2:2019, 5.6)	48
6.9.1	Intent	48
6.9.2	Guidance	48
6.10	Process changes and revalidation (ISO 11607-2:2019, 5.7)	48
6.10.1	Intent	48
6.10.2	Guidance	48
6.11	Assembly (ISO 11607-2:2019, Clause 6)	49
6.11.1	Intent	49
6.11.2	Guidance	49
6.12	Use of reusable sterile barrier systems (ISO 11607-2:2019, Clause 7)	51
6.12.1	Intent	51
6.12.2	Guidance	51
6.13	Sterile fluid path packaging (ISO 11607-2:2019, Clause 8)	51
6.13.1	Intent	51

6.13.2 Guidance	51
Annex A (informative) Design and development for packaging systems – guidance for industry	52
Annex B (informative) Guidance on the application of the ISO 11607 series in healthcare facilities	60
Annex C (informative) Risk analysis tools — Guidance for industry and healthcare facilities	91
Annex D (informative) Considerations for sampling plans – Guidance for healthcare facilities	93
Annex E (informative) Guidance on establishing process parameters – guidance for industry	95
Annex F (informative) Sterilization considerations – Guidance for industry and healthcare facilities	101
Annex G (informative) Use of contract packagers – Guidance for industry and healthcare facilities	108
Annex H (informative) Example of a handling, distribution and storage checklist – Guidance for healthcare facilities for selecting a sterile barrier system	109
Annex I (informative) Investigating failure – Guidance for industry and healthcare facilities	112
Annex J (informative) Validation summary – Guidance for healthcare facilities	116
Annex K (informative) Validation for wrapping process — Guidance for healthcare facilities	118
Annex L (informative) Validation for reusable container process – Guidance for healthcare facilities	124
Annex M (informative) Validation for heat sealing process for preformed sterile barrier systems (PSBS) – Guidance for healthcare facilities	130
Annex N (informative) Evaluation of sterile packaging by end users — Guidance for healthcare facilities	138
Bibliography	139