

---

---

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

*Emballages des dispositifs médicaux stérilisés au stade terminal —  
Lignes directrices relatives à l'application de l'ISO 11607-1 et l'ISO  
11607-2*

**ITeH Standards**  
**(<https://standards.iteh.ai>)**  
**Document Preview**

[ISO/TS 16775:2021](https://standards.iteh.ai/catalog/standards/iso/4ce5f436-6800-498d-9814-b69030350c7c/iso-ts-16775-2021)

<https://standards.iteh.ai/catalog/standards/iso/4ce5f436-6800-498d-9814-b69030350c7c/iso-ts-16775-2021>



**iTeh Standards**  
**(<https://standards.iteh.ai>)**  
**Document Preview**

[ISO/TS 16775:2021](https://standards.iteh.ai/catalog/standards/iso/4ce5f436-6800-498d-9814-b69030350c7c/iso-ts-16775-2021)

<https://standards.iteh.ai/catalog/standards/iso/4ce5f436-6800-498d-9814-b69030350c7c/iso-ts-16775-2021>



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
CP 401 • Ch. de Blandonnet 8  
CH-1214 Vernier, Geneva  
Phone: +41 22 749 01 11  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

Published in Switzerland

# Contents

	Page
<b>Foreword</b> .....	<b>vii</b>
<b>Introduction</b> .....	<b>viii</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 Guidance on Clauses 1-4 of ISO 11607-1:2019 and ISO 11607-2:2019</b> .....	<b>2</b>
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
<b>5 Guidance on Clauses 5-11 of ISO 11607-1:2019</b> .....	<b>10</b>
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
<b>6</b>	<b>Guidance on Clauses 5-8 of ISO 11607-2:2019</b>	<b>42</b>
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
<b>Annex A (informative) Design and development for packaging systems – guidance for industry.....</b>	<b>52</b>
<b>Annex B (informative) Guidance on the application of the ISO 11607 series in healthcare facilities.....</b>	<b>60</b>
<b>Annex C (informative) Risk analysis tools — Guidance for industry and healthcare facilities.....</b>	<b>91</b>
<b>Annex D (informative) Considerations for sampling plans – Guidance for healthcare facilities.....</b>	<b>93</b>
<b>Annex E (informative) Guidance on establishing process parameters – guidance for industry.....</b>	<b>95</b>
<b>Annex F (informative) Sterilization considerations – Guidance for industry and healthcare facilities.....</b>	<b>101</b>
<b>Annex G (informative) Use of contract packagers – Guidance for industry and healthcare facilities.....</b>	<b>108</b>
<b>Annex H (informative) Example of a handling, distribution and storage checklist – Guidance for healthcare facilities for selecting a sterile barrier system.....</b>	<b>109</b>
<b>Annex I (informative) Investigating failure – Guidance for industry and healthcare facilities.....</b>	<b>112</b>
<b>Annex J (informative) Validation summary – Guidance for healthcare facilities.....</b>	<b>116</b>
<b>Annex K (informative) Validation for wrapping process — Guidance for healthcare facilities.....</b>	<b>118</b>
<b>Annex L (informative) Validation for reusable container process – Guidance for healthcare facilities.....</b>	<b>124</b>
<b>Annex M (informative) Validation for heat sealing process for preformed sterile barrier systems (PSBS) – Guidance for healthcare facilities.....</b>	<b>130</b>
<b>Annex N (informative) Evaluation of sterile packaging by end users — Guidance for healthcare facilities.....</b>	<b>138</b>
<b>Bibliography.....</b>	<b>139</b>

ISO/TS 16775:2021  
<https://standards.iteh.ai/catalog/standards/iso/4ce5f436-6800-498d-9814-b69030350c7c/iso-ts-16775-2021>

## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 102, *Sterilizers and associated equipment for processing of medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO/TS 16775:2014), which has been technically revised.

The main changes compared to the previous edition are as follows:

- updates to reflect ISO 11607-1:2019 and ISO 11607-2:2019 editions;
- intent and guidance is provided for each clause of the standard to improve usability of this document.
- new annexes have been added;
- some annexes have been removed.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).