BS EN ISO 11607-2:2020+A1:2023

BSI Standards Publication

Packaging for terminally sterilized medical devices

Part 2: Validation requirements for forming, sealing and assembly processes

bsi.

National foreword

This British Standard is the UK implementation of EN ISO 11607-2:2020+A1:2023. It is identical to ISO 11607-2:2019, incorporating amendment 1:2023. It supersedes BS EN ISO 11607-2:2020+A11:2022, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by ⟩A1⟨.

The UK participation in its preparation was entrusted to Technical Committee CH/198, Sterilization and Associated Equipment and Processes.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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For the Great Britain market (England, Scotland and Wales), if UK Government has designated this publication for conformity with UKCA marking (or similar) legislation, it may contain an additional National Annex. Where such a National Annex exists, it shows the correlation between this publication and the relevant UK legislation. If there is no National Annex of this kind, the relevant Annex ZA or ZZ in the body of the European text will indicate the relationship to UK regulation applicable in Great Britain. References to EU legislation may need to be read in accordance with the UK designation and the applicable UK law. Further information on designated standards can be found at www.bsigroup.com/standardsandregulation.

For the Northern Ireland market, UK law will continue to implement relevant EU law subject to periodic confirmation. Therefore Annex ZA/ZZ in the European text, and references to EU legislation, are still valid for this market.

Published by BSI Standards Limited 2023

ISBN 978 0 539 14211 2

ICS 11.080.30

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 January 2020.

Amendments/corrigenda issued since publication

Date	Text affected
30 September 2022	Implementation of CEN amendment A11:2022: Annexes ZA, ZB and ZC added.
31 October 2023	Implementation of ISO amendment 1:2023 with CEN endorsement A1:2023

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11607-2:2020+A1

October 2023

ICS 11.080.30

Supersedes EN ISO 11607-2:2017

English Version

Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)

Emballages des dispositifs médicaux stérilisés au stade terminal - Partie 2: Exigences de validation pour les procédés de formage, scellage et assemblage (ISO 11607-2:2019)

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 2: Validierungsanforderungen an Prozesse der Formgebung, Siegelung und des Zusammenstellens (ISO 11607-2:2019)

This European Standard was approved by CEN on 4 December 2019.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 11607-2:2020+A11:2022: E

European foreword

This document (EN ISO 11607-2:2020) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 102 “Sterilizers and associated equipment for processing of medical devices” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 2020, and conflicting national standards shall be withdrawn at the latest by July 2020.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 11607-2:2017.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 11607-2:2019 has been approved by CEN as EN ISO 11607-2:2020 without any modification.

European foreword to amendment A11

This document (EN ISO 11607-2:2020/A11:2022) has been prepared by Technical Committee CEN/TC 102 “Sterilizers and associated equipment for processing of medical devices”, the secretariat of which is held by DIN.

This Amendment to the European Standard EN ISO 11607-1:2020 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2022, and conflicting national standards shall be withdrawn at the latest by December 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document amends EN ISO 11607-2:2020 with a revised European Foreword and European Annexes ZA, ZB and ZC.

This Amendment to the European Standard EN ISO 11607-2:2020 has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, ZB and ZC, which are an integral part of this document.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN websites.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard 'within the meaning of Annex ZA', the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO or IEC
ISO 11607-1	EN ISO 11607-1:2020	ISO 11607-1:2019

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Republic of North Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

European foreword to amendment A1

This document (EN ISO 11607-2:2020/A1:2023) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 102 "Sterilizers and associated equipment for processing of medical devices" the secretariat of which is held by DIN.

This Amendment to the European Standard EN ISO 11607-2:2020 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2024, and conflicting national standards shall be withdrawn at the latest by April 2024.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a Standardization Request given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s) / Regulation(s).

For relationship with EU Directive(s) / Regulation(s), see informative Annex ZA and Annex ZB, which are integral parts of this document.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 11607-2:2019/Amd 1:2023 has been approved by CEN as EN ISO 11607-2:2020/A1:2023 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up.

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZA.1 and application of the edition of the normatively referenced standards as given in Table ZA.2 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA Regulations.

Where a definition in this harmonised standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall indicated in the Annex Z. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this document can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region the standard can only support European regulatory requirements to the extent of the scope of the European Regulation for medical devices ((EU) 2017/745).

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/745. This means that risks have to be ‘reduced as far as possible’, ‘reduced to the lowest possible level’, ‘reduced as far as possible and appropriate’, ‘removed or reduced as far as possible’, ‘eliminated or reduced as far as possible’, ’removed or minimized as far as possible’, or ‘minimized’, according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer’s policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Annex I of Regulation (EU) 2017/745 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
1	4.2, Annex B 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 6.1, 6.2, 6.3, if applicable 7, 8	Partially covered: Covers this GSPR for the packaging of sterile medical devices through process development, validation of the sealing and assembly process, production control by applying risk management to all these phases. Does not cover the weighing against the benefits to the patient as this needs to consider the specific intended purpose of the medical device and cannot be covered by sterile packaging alone.
3	4.2, Annex B	Partially covered: Covered for sterile packaging by providing a framework for applying risk management to sterile packaging over the phases of design, process development, validation and production. Does not cover the benefits-risk ratio to the patient as this needs to consider the specific intended purpose of the medical device and cannot be covered by sterile packaging alone. Evaluation of production and post market surveillance information under GSPR 3 (e) against overall risk and benefit risk-ratio is not covered, not part of the scope of EN ISO 11607-2:2020/A1:2023. GSPR 3 (f) only covered (see B.2) for production phase and if post-production information is available, to determine if risks are controlled appropriately.
4	4.2, Annex B	Partially covered: Applying this principle for maintenance of sterility through rigorous performance and stability testing and by qualification of materials, design with systematic risk reduction, process development to minimize risk.
5		Not covered: Applicable only to EN ISO 11607-1:2020/A1:2023.
6		Not covered: Applicable only to EN ISO 11607-1:2020/A1:2023.

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
7	4.2, Annex B, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 6.1, 6.2, 6.3, if applicable: 7, 8	Partially covered for sterile packaging by validating the forming, assembly and sealing process.
10		Not covered.
11.1	4.2, Annex B 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 6.1, 6.2, 6.3, if applicable: 7, 8	Partially covered: GSPR 11.1 (b) and (d) are covered only in respect of the function of the sterile barrier system(s) to protect the sterility of the device from the point of sterilisation to the point of use and to allow for aseptic presentation and only if the requirements of EN ISO 11607-1:2020/A1:2023 are met as well. GSPR 11.1 (a), and 11.1 (c) are not covered. Clause 5 addresses the requirements of packaging processes and the way to validate. Subclause 5.7 addresses management of changes and revalidations to maintain the process in the state of control. SBS assembly requirements are listed in Clause 6. Specifics for reusable SBS are covered in Clause 7. Specifics for sterile fluid-path SBS are covered in Clause 8.
11.2		Not covered: Applicable only to reusable sterilization containers and reusable materials (EN ISO 11607-1:2020/A1:2023). No presumption of conformity.

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
11.4	4.2, Annex B, 4.3, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7 6.1, 6.2, 6.3, if applicable: 8	Partially covered: GSPR 11.4 is covered only in respect of the function of sterile barrier system(s) to protect the sterility of the device from the point of sterilisation to the point of use and to allow for aseptic presentation but only if the requirements of EN ISO 11607-1:2020/A1:2023 are met as well (requirements for materials, sterile barrier systems and packaging systems). In this respect damage to the "packaging which is intended to maintain their sterile condition" is taken to mean damage to or loss of integrity of the sterile barrier system only. Regarding the aspects of "clearly evident integrity of the packaging", this document includes considerations for seals and closure quality properties as supportive requirements for compliance. Clause 5 addresses the requirements of packaging processes and the way to validate. Subclause 5.7 addresses management of changes and revalidations to maintain the process in the state of control. SBS assembly requirements are listed in clauses 6. Specifics for sterile fluid-path SBS are covered in Clause 8.
11.5	4.2, Annex B, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7 6.1, 6.2, 6.3, If applicable: 8	Partially covered: GSPR 11.5 is covered only in respect of the validation of forming, sealing and assembling processes for packaging, assuming that the requirements of EN ISO 11607-1:2020/A1:2023 are met as well (requirements for materials, sterile barrier systems and packaging systems which includes compatibility between the packaging and the selected sterilisation processes, packaging system performance testing and sterile barrier system stability testing). Clause 5 addresses the requirements of packaging processes and the way to validate. Subclause 5.7 addresses management of changes and revalidations to maintain the process in the state of control. SBS assembly requirements are listed in clauses 6. Specifics for sterile fluid-path SBS are covered in Clause 8.
11.6, 11.7, 11.8		Not covered.

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
13		Not covered.
22.1	4.2, annex B, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7 6.1, 6.2, 6.3, If applicable: 8	Partially covered: No specific requirements for lay persons. User and environment of use are factors to include into the design (EN ISO 11607-1:2020/A1:2023) which includes defining the sealing and closure specifications. EN ISO 11607-2:2020/A1:2023 provides the framework for validation of the sealing processes to meet those requirements. The last sentence of GSPR 22.1 is not covered by EN ISO 11607-2:2020/A1:2023.
22.2	4.2, annex B 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 6.1, 6.2, 6.3, If applicable: 8	Partially covered: No specific requirements for lay persons. User and environment of use are factors to include into the design (EN ISO 11607-1:2020/A1:2023) which includes defining the sealing and closure specifications. EN ISO 11607-2:2020/A1:2023 provides the framework for validation of the sealing and assembly processes (manufacturing) to meet those requirements. Dashes 2 and 3 are not covered.
23.3		Not covered.
23.4		Not covered.

Table ZA.2 — Applicable Standards to confer presumption of conformity as described in this Annex ZA

Column 1 Reference in Clause 2	Column 2 International Standard Edition	Column 3 Title	Column 4 Corresponding European Standard Edition
ISO 11607-1	ISO 11607-1:20181 ISO 11607-1:2019/Amd1:2023	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes	EN ISO 11607-1:2020 EN ISO 11607-1:2020/A11:2022 EN ISO 11607-1:2020/A1:2023

The documents listed in the Column 1 of table ZA.2, in whole or in part, are normatively referenced in this document, i.e. are indispensable for its application. The achievement of the presumption of conformity is subject to the application of the edition of Standards as listed in Column 4 or, if no European Standard Edition exists, the International Standard Edition given in Column 2 of table ZA.2.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

Annex ZB
(informative)

Relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/746 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/746 of 5 April 2017 concerning in vitro diagnostic medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, performance studies, clinical evidence or post-market performance follow-up

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZB.1 and application of the edition of the normatively referenced standards as given in Table ZA.2 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA Regulations.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/746, the differences shall indicated in the Annex Z. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/746, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the In vitro Diagnostic Regulation (EU) 2017/746).

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/746. This means that risks have to be ‘reduced as far as possible’, ‘reduced to a level as low as reasonably practicable’, ‘reduced to the lowest possible level’, ‘reduced as far as possible and appropriate’, ‘removed or reduced as far as possible’, ‘eliminated or reduced as far as possible’, ‘prevented’ or ‘minimized’, according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer’s policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 10, 11, 13, 15, 16, 17, 18 and 19 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in Table ZB.1, it means that it is not addressed by this European Standard.

Table ZB.1 — Correspondence between this European Standard and Annex I of Regulation (EU) 2017/746 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up

General Safety and Performance Requirements of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
1	4.2, Annex B 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 6.1, 6.2, 6.3, if applicable 7, 8	Partially covered: Covers this GSPR for the packaging of sterile devices through process development, validation of the sealing and assembly process, production control by applying risk management to all these phases. Does not cover the weighing against the benefits to the patient as this needs to consider the specific intended purpose of the medical device and cannot be covered by sterile packaging alone.
3	4.2, Annex B	Partially covered: Covered for sterile packaging by providing a framework for applying risk management to sterile packaging over the phases of design, validation and production. Does not cover the benefits-risk ratio to the patient as this needs to consider the specific intended purpose of the medical device and cannot be covered by sterile packaging alone. Evaluation of production and post market surveillance information under GSPR 3 (e) against overall risk and benefit risk-ratio is not covered, not part of the scope of EN ISO 11607-2:2020/A1:2023. GSPR 3 (f) only covered (see B.2) for production phase and if post-production information is available, to determine if risks are controlled appropriately.
4	4.2, Annex B	Partially covered: Applying this principle for maintenance of sterility through rigorous performance and stability testing and by qualification of materials, design with systematic risk reduction, process development to minimize risk.
5		Not covered: Applicable only to EN ISO 11607-1:2020/A1:2023.
6		Not covered: Applicable only to EN ISO 11607-1:2020/A1:2023.

General Safety and Performance Requirements of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
7	4.2, Annex B, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 6.1, 6.2, 6.3, if applicable: 7, 8	Partially covered for sterile packaging by validating the forming, assembly and sealing process
10		Not covered.
11.1	4.2, Annex B 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 6.1, 6.2, 6.3, if applicable 7, 8	Partially covered: GSPR 11.1 (a) and (c) are covered only in respect of the function of the sterile barrier system(s) to protect the sterility of the device from the point of sterilisation to the point of use and to allow for aseptic presentation and only if the requirements of EN ISO 11607-1:2020/A1:2023 are met as well. GSPR 11.1 (b) are not covered. Clause 5 addresses the requirements of packaging processes and the way to validate. Subclause 5.7 addresses management of changes and revalidations to maintain the process in the state of control. SBS assembly requirements are listed in Clause 6. Specifics for reusable SBS are covered in Clause 7. Specifics for sterile fluid-path SBS are covered in Clause 8.
11.2	4.2, Annex B, 4.3, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7 6.1, 6.2, 6.3, if applicable: 8	Partially covered: GSPR 11.2 is covered only in respect of the function of the sterile barrier system(s) to protect the sterility of the device from the point of sterilisation to the point of use and to allow for aseptic presentation but only if the requirements of EN ISO 11607-1:2020/A1:2023 are met as well (requirements for materials, sterile barrier systems and packaging systems). In this respect damage to the "packaging which maintains their sterile condition" is taken to mean damage to or loss of integrity of the sterile barrier system only. Clause 5 addresses the requirements of packaging processes and the way to validate. Subclause 5.7 addresses management of

General Safety and Performance Requirements of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
		changes and revalidations to maintain the process in the state of control. SBS assembly requirements are listed in Clause 6. Specifics for sterile fluid-path SBS are covered in Clause 8.
11.3	4.2, Annex B, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7 6.1, 6.2, 6.3, if applicable: 8	Partially covered: GSPR 11.5 is covered only in respect of the validation of forming, sealing and assembling processes for packaging, assuming that the requirements of EN ISO 11607-1:2020/A1:2023 are met as well (requirements for materials, sterile barrier systems and packaging systems which includes compatibility between the packaging and the selected sterilisation processes, packaging system performance testing and sterile barrier system stability testing). Clause 5 addresses the requirements of packaging processes and the way to validate. Subclause 5.7 addresses management of changes and revalidations to maintain the process in the state of control. SBS assembly requirements are listed in Clause 6. Specifics for sterile fluid-path SBS are covered in Clause 8.
11.4.		Not covered.
11.5.		Not covered.
11.6.		Not covered.
12.		Not covered
19.1.	4.2, Annex B, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7 6.1, 6.2, 6.3, if applicable: 8	Partially covered. No specific requirements for lay persons. User and environment of use are factors to include into the design (EN ISO 11607-1:2020/A1:2023) which includes defining the sealing and closure specifications. EN ISO 11607-2:2020/A1:2023 provides the framework for validation of the sealing processes to meet those requirements.

General Safety and Performance Requirements of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
		The last two sentences are not covered by EN ISO 11607-2:2020/A1:2023.
19.2.	4.2, Annex B, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7 6.1, 6.2, 6.3, if applicable: 8	Partially covered. No specific requirements for lay persons. User and environment of use are factors to include into the design (EN ISO 11607-1:2020/A1:2023) which includes defining the sealing and closure specifications. EN ISO 11607-2:2020/A1:2023 provides the framework for validation of the sealing processes to meet those requirements. GSPR 19.2 (b) is not covered.
20.3		Not covered.
20.4		Not covered

The documents listed in the Column 1 of table ZA.2, in whole or in part, are normatively referenced in this document and are indispensable for its application. The achievement of the presumption of conformity is subject to the application of the edition of Standards as listed in Column 4 or, if no European Standard Edition exists, the International Standard Edition given in Column 2 of table ZA.2.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

Annex ZC
(informative)

Relationship between this European Standard and the essential requirements of Directive 98/79/EC [OJ L 331] aimed to be covered

This European Standard has been prepared under a Commission's standardization mandate M/252 section II.1(8), concerning the development of European Standards related to in vitro diagnostic medical devices to provide one voluntary means of conforming to essential requirements of Council Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices [OJ L 331].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZC.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 98/79/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements Part A: 1, 2 and 5; Part B: 1.2, 2, 3, 5, 6 and 7 of the Directive.

NOTE 3 This Annex ZC is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZC.1, it means that it is not addressed by this European Standard.

Table ZC.1 — Correspondence between this European Standard and requirements of Annex I of Directive 98/79/EC [OJ L 331]

Essential Requirements of Annex I of Directive 98/79/EC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
B.2.3	4.3, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 6.1, 6.2, 6.3, 8	Partially covered. E.R. B.2.3 is covered only in respect of the function of the sterile barrier system(s) to protect the sterility of the device from the point of sterilization to the point of use and to allow for aseptic presentation but only if the requirements of EN ISO 11607-1:2020 are met as well (requirements for materials, sterile barrier systems and packaging systems). In this respect damage to the "protective packaging" is taken to mean damage to or loss of integrity of the sterile barrier system only. Clause 5 addresses the requirements of packaging processes and the way to validate. Subclause 5.7 addresses management of changes and revalidations to maintain the process in the state of control. SBS assembly requirements are listed in subclauses 6. Specifics for sterile fluid-path SBS are covered in clause 8.
B.2.4	5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 6.1, 6.2, 6.3, 8	Partially covered. E.R. B.2.4 is covered only in respect of the validation of forming, sealing and assembling processes for packaging, assuming that the requirements of EN ISO 11607-1:2020 are met as well (requirements for materials, sterile barrier systems and packaging systems which includes compatibility between the packaging and the selected sterilisation processes, packaging system performance testing and sterile barrier system stability testing). See also row B.2.3 above for details on listed clauses and sub-clauses.

WARNING 1 Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 Other Union legislation may be applicable to the products falling within the scope of this standard.

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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).

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).

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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 11607-2:2006), which has been technically revised. It also incorporates the amendment ISO 11607-2:2006/Amd.1:2014.

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

— terms and definitions for “process variable”, “process parameter” and “monitoring of processes” have been added;

— various definitions have been aligned with the latest version of ISO 11139;

— the terminology of “critical” process parameters has been discontinued and the concept of a process specification has been introduced to include all elements required to manufacture a product that consistently meets specifications.

A list of all parts in the ISO 11607 series can be found on the ISO website.

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.

Introduction

Packaging for terminally sterilized medical devices should be designed and manufactured to ensure that the medical device can be sterilized and remain sterile under documented storage and transport conditions until the sterile barrier system is damaged or opened.

One of the most critical characteristics of a sterile barrier system and packaging system for sterile medical devices is the assurance of sterility maintenance. Medical devices delivered in a sterile state should have been manufactured, packed and sterilized by appropriate, validated methods. The development and validation of packaging processes are crucial to ensure that sterile barrier system integrity is attained and will remain so until opened by the users of sterile medical devices.

There should be a documented process validation programme demonstrating the efficacy and reproducibility of all packaging and sterilization processes. Along with the sterilization process, some of the packaging operations that can affect sterile barrier system integrity are sealing, capping or other closure systems, cutting, form/fill/seal, assembly processes and subsequent handling. This document provides the framework of activities and requirements to develop and validate the process used to make and assemble the packaging system. Guidance for ISO 11607 series can be found in ISO/TS 16775.

The term “sterile barrier system” was introduced in 2006 to describe the minimum packaging required to perform the unique functions required of medical packaging: to allow sterilization, to provide an acceptable microbial barrier, and to allow for aseptic presentation. “Protective packaging” protects the sterile barrier system, and together they form the packaging system. “Preformed sterile barrier systems” would include any partially assembled sterile barrier systems such as pouches, header bags or hospital packaging reels.

The sterile barrier system is essential to ensure the safety of terminally sterilized medical devices. Regulatory authorities recognize the critical nature of sterile barrier systems by considering them as an accessory or a component of a medical device. Preformed sterile barrier systems sold to health care facilities for use in internal sterilization are considered medical devices in many parts of the world.

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INTERNATIONAL STANDARD **ISO 11607-2:2019+A1:2023**

Packaging for terminally sterilized medical devices —

Part 2: Validation requirements for forming, sealing and assembly processes

1 Scope

This document specifies requirements for the development and validation of processes for packaging medical devices that are terminally sterilized. These processes include forming, sealing and assembly of preformed sterile barrier systems, sterile barrier systems and packaging systems.

〚A1〛 *Text deleted* 〚A1〛

It does not cover all requirements for packaging medical devices that are manufactured aseptically. Additional requirements can be necessary for drug/device combinations.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

〚A1〛 ISO 11607-1:2019 and ISO 11607-1:2019/Amd 1:2023 〚A1〛, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
aseptic presentation
transfer of sterile contents from its sterile barrier system using conditions and procedures that minimize the risk of microbial contamination

[SOURCE: ISO 11139:2018, 3.13]

3.2
closure
<packaging> means used to complete a sterile barrier system where no seal is formed

EXAMPLE By a reusable container gasket or sequential folding to construct a tortuous path.

[SOURCE: ISO 11139:2018, 3.51, modified — The example has been added.]

3.3
control
regulation of variables within specified limits

[SOURCE: ISO 11139:2018, 3.63]

3.4
expiry date
date by which product should be used

Note 1 to entry: For the purpose of this document and ISO 11607-1, expiry date refers to the medical device in a sterile barrier system. The term "use by date" is used to describe the shelf life of packaging materials and *preformed sterile barrier systems* (3.13) prior to assembly into a *sterile barrier system* (3.25).

[SOURCE: ISO 11139:2018, 3.110, modified — The Note 1 to entry has been added.]

3.5
installation qualification
IQ
process of establishing by objective evidence that all key aspects of the process equipment and ancillary system installation comply with the approved specification

[SOURCE: ISO 11139:2018, 3.220.2]

3.6
labelling
label, instructions for use and any other information that is related to identification, technical description, intended purpose and proper use of the health care product but excluding shipping documents

[SOURCE: ISO 13485:2016, 3.8, modified — The term "medical device" has been replaced by "health care product".]

3.7
medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease;

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

— investigation, replacement, modification, or support of the anatomy or of a physiological process;

— supporting or sustaining life;

— control of conception;

— disinfection of medical devices;

— providing information by means of *in vitro* examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means

Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions but not in others include:

— items specifically intended for cleaning or sterilization of medical devices;

— pouches, reel goods, sterilization wrap and reusable containers for packaging of medical devices for sterilization;

— disinfection substances;

— aids for persons with disabilities;

— devices incorporating animal and/or human tissues;

— devices for *in vitro* fertilization or assisted reproduction technologies.

[SOURCE: ISO 13485:2016, 3.11, modified — The first two list items in Note 1 to entry have been added.]

3.8
microbial barrier
property of a sterile barrier system to minimize the risk of ingress of microorganisms

[SOURCE: ISO 11139:2018, 3.169]

3.9
monitoring
continual checking, supervising, critically observing or determining the status in order to identify change from the performance level required or expected

[SOURCE: ISO Guide 73:2009, 3.8.2.1, modified — The note has been deleted.]

3.10
operational qualification
OQ
process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

[SOURCE: ISO 11139:2018, 3.220.3]

3.11
packaging system
combination of a *sterile barrier system* (3.25) and *protective packaging* (3.18)

[SOURCE: ISO 11139:2018, 3.192]

3.12
performance qualification
PQ
process of establishing by objective evidence that the process, under anticipated conditions, consistently produces a *product* (3.17) which meets all predetermined requirements

[SOURCE: ISO 11139:2018, 3.220.4]

3.13
preformed sterile barrier system
sterile barrier system (3.25) that is supplied partially assembled for filling and final closure or sealing

EXAMPLE Pouches, bags and open *reusable containers* (3.21).

[SOURCE: ISO 11139:2018, 3.201, modified — The example has been added.]

3.14
process parameter
specified value for a *process variable* (3.16)

Note 1 to entry: The specification for a process includes the process parameters and their tolerances.

[SOURCE: ISO 11139:2018, 3.211]

3.15
process specification
documented procedure that includes all equipment, process parameters, monitors and materials required to manufacture a product that consistently meets requirements

3.16
process variable
chemical or physical attribute within a cleaning, disinfection, packaging or sterilization process, changes in which can alter its effectiveness

EXAMPLE Time, temperature, pressure, concentration, humidity, wavelength.

[SOURCE: ISO 11139:2018, 3.213]

3.17
product
tangible result of a process

EXAMPLE Raw material(s), intermediate(s), sub-assembly(ies), healthcare product(s).

Note 1 to entry: For the purposes of this document and ISO 11607-1, products include *preformed sterile barrier systems* (3.13), *sterile barrier systems* (3.25) and contents within them.

[SOURCE: ISO 11139:2018, 3.217, modified — Note 1 to entry has been added.]

3.18
protective packaging
configuration of materials designed to prevent damage to the *sterile barrier system* (3.25) and its contents from the time of their assembly until the point of use

[SOURCE: ISO 11139:2018, 3.219]

3.19
repeatability
condition of measurement, out of a set of conditions that includes the same measurement procedure, same operators, same measuring system, same operating conditions and same location, and replicate measurements on the same or similar objects over a short period of time

[SOURCE: ISO/IEC Guide 99:2007, 2.20, modified — The term name has been simplified and the notes omitted.]

3.20
reproducibility
condition of measurement, out of a set of conditions that includes different locations, processors, measuring systems, and replicate measurements on the same or similar objects

Note 1 to entry: The different measuring systems may use different measurement procedures.

Note 2 to entry: A specification should give the conditions changed and unchanged to the extent practical.

[SOURCE: ISO/IEC Guide 99:2007, 2.24, modified — The term has been simplified.]

3.21
reusable container
rigid *sterile barrier system* (3.25) designed to be used repeatedly

[SOURCE: ISO 11139:2018, 3.235]

3.22
seal
<packaging> result of joining surfaces together by fusion to form a microbial barrier

Note 1 to entry: Surfaces can be joined together by, for example, adhesives or thermal fusion.

[SOURCE: ISO 11139:2018, 3.244 modified — The Note 1 to entry has been added.]

3.23
seal strength
mechanical capacity of the seal to withstand force

[SOURCE: ISO 11139:2018, 3.246]

3.24
sterile
free from viable microorganisms

[SOURCE: ISO 11139:2018, 3.271]

3.25
sterile barrier system
SBS
minimum package that minimizes the risk of ingress of microorganisms and allows aseptic presentation of the sterile contents at the point of use

[SOURCE: ISO 11139:2018, 3.272]

3.26
sterile fluid-path packaging
system of protective port covers and/or packaging designed to ensure sterility of the portion of the medical device intended for contact with fluids

EXAMPLE The interior of the tubing for administration of an intravenous fluid.

[SOURCE: ISO 11139:2018, 3.273]

3.27
terminally sterilized
condition of a product that has been exposed to a sterilization process in its sterile barrier system

[SOURCE: ISO 11139:2018, 3.296]

3.28
validation
confirmation process, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

Note 1 to entry: The objective evidence needed for a validation is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The word “validated” is used to designate the corresponding status.

Note 3 to entry: The use conditions for validation can be real or simulated.

[SOURCE: ISO 9000:2015, 3.8.13, modified — “process” has been added to the definition.]

〚A1〛 **3.29**
hazard
potential source of harm

[SOURCE: ISO/IEC Guide 63:2019, 3.2]

3.30
process
set of interrelated or interacting activities that use inputs to deliver an intended result

Note 1 to entry: Whether the "intended result" of a process is called output, product or service depends on the context of the reference. 〚A1〛

〈A1〉 Note 2 to entry: Inputs to a process are generally the outputs of other processes and outputs of a process are generally the inputs to other processes.

Note 3 to entry: Two or more interrelated and interacting processes in series can also be referred to as a process.

[SOURCE: ISO 9000:2015, 3.4.1, modified — Notes to entry 4, 5 and 6 were deleted.]

3.31
risk
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO/IEC Guide 63:2019, 3.10, modified — Note 1 to entry was deleted. 〈A1〉]

4 General requirements

4.1 Quality systems

The activities described within this document shall be carried out within a formal quality system.

NOTE ISO 9001, ISO 13485, and ANSI/AAMI ST90 contain requirements for suitable quality systems. Additional requirements can be specified by a country or region.

4.2 Risk management

〈A1〉 A risk management process conforming with the requirements of Annex B shall be implemented.

NOTE Annex B details requirements for the risk management process for forming, sealing and assembly of sterile barrier systems, which is a subset of risk management for medical devices. Additional requirements for risk management of medical devices including sterile packaging can be specified by some regulatory jurisdictions. ISO 14971 covers application of risk management to medical devices and guidance on the application of ISO 14971 can be found in ISO/TR 24971. 〈A1〉

4.3 Sampling

The sampling plans used for testing of materials, sterile barrier systems or packaging systems shall be applicable to materials, sterile barrier systems or packaging systems being evaluated. Sampling plans shall be based upon statistically valid rationale.

NOTE Common statistically based sampling plans as given, for example, in ISO 2859-1 or ISO 186 (with appropriate modifications if necessary) can be applied to materials, sterile barrier systems or packaging systems. Additional sampling plans can be specified by countries or regions. For further guidance, see ISO/TS 16775.

4.4 Test methods

4.4.1 A rationale for the selection of appropriate tests for the packaging system shall be established and recorded.

4.4.2 A rationale for acceptance criteria shall be established and recorded.

NOTE Pass/fail is a type of acceptance criterion.

4.4.3 All test methods used to show conformity to this document shall be validated and documented by the laboratory performing the test.

〈A1〉 NOTE ISO 11607-1:2019, Annex B contains a list of test methods. Publication of a method by a standards body does not make it validated by the user of the test method. 〈A1〉

4.4.4 The test method validation shall demonstrate the suitability of the method as used. The following elements shall be included:

— determination of test method repeatability;

— determination of test method reproducibility;

— establishment of test method sensitivity for integrity tests.

4.5 Documentation

4.5.1 Demonstration of conformity with the requirements of this document shall be recorded.

4.5.2 All records shall be retained for a specified period of time. The retention period shall consider factors such as applicable requirements, expiry date and traceability of the medical device or sterile barrier system.

4.5.3 Records of conformity with the requirements shall include, but is not limited to, performance data, specifications and test results from validated test methods as well as validation protocols, conclusions and any necessary actions.

4.5.4 Electronic records, electronic signatures and handwritten signatures executed to electronic records that contribute to validation, process control or other quality decision-making processes shall remain legible, readily identifiable and retrievable.

5 Validation of packaging processes

5.1 General

5.1.1 Preformed sterile barrier systems and sterile barrier system manufacturing processes shall be validated.

NOTE Examples of these processes include, but are not limited to, the following:

— pouch, reel, or bag forming and sealing;

— form/fill/seal automated processes;

— kit assembly and wrapping, including application of tape;

— assembly of sterile fluid-path products;

— tray/lid sealing;

— filling and closing of reusable containers;

— sterilization sheets folding and wrapping, including application of tape.

5.1.2 Process validation shall include, at a minimum, an installation qualification (IQ), an operational qualification (OQ), and a performance qualification (PQ), in this order.

5.1.3 A process specification shall be established for forming, assembly and sealing processes, including, but not limited to, the following elements:

— the required process output;

— the process variables and process (and/or product) attributes to be monitored in order to maintain the process in a state of control and capability;

— the process parameters for control to produce the specified process output.

NOTE 1 Process development, while not formally part of process validation, is considered an integral part of forming and sealing (see Annex A).

NOTE 2 Validation of existing products can rely on data from previous validations of existing products. That data can be used for determining the tolerances for process parameters.

5.1.4 When similar preformed sterile barrier systems and sterile barrier system manufacturing processes are validated, a rationale for establishing similarities and identifying the worst case configuration shall be documented. As a minimum, the worst case configuration shall be validated to determine conformity with this document.

NOTE For example, similarity can be established by different sizes of preformed sterile barrier systems made of the same or comparable raw materials.

5.2 Installation qualification

5.2.1 The IQ shall be performed including, as minimum, all elements to be listed in the process specification.

The following shall be considered:

— equipment design features;

— installation conditions, such as wiring, utilities, functionality, etc.;

— safety features;

— equipment operating within the stated design parameters;

— supplier documentation, prints, drawings and manuals;

— spare-parts lists;

— software and/or firmware validation;

— environmental conditions such as cleanliness, temperature, humidity, lighting;

— documented operator training;

— operating manual or procedure.

5.2.2 Tests shall be performed to confirm that process variables can be controlled as specified.

NOTE For further guidance, see Annex A.

5.2.3 Functions that allow process variable monitoring shall be checked or certified in place.

5.2.4 Alarms, warning systems or machine stops shall be challenged in the event that process variables exceed predetermined limits.

5.2.5 Specified instruments, sensors, displays, controllers, etc., shall be calibrated and have written calibration schedules.

5.2.6 There shall be written preventive maintenance and cleaning schedules.

5.2.7 The application of software systems shall be validated.

NOTE For software validation, see also ISO 13485:2016, 7.5.6 and Reference [14].

5.3 Operational qualification

5.3.1 Process variables shall be challenged to determine the upper and lower parameter limits that produce preformed sterile barrier systems and/or sterile barrier systems that meet all predetermined specifications.

NOTE See Annex A.

5.3.2 As a minimum, preformed sterile barrier systems and sterile barrier systems shall be produced at both the upper and lower process limits (see 5.3.1) and exhibit the properties that meet predefined specifications.

The following quality properties shall be considered.

a) For forming/assembly:

- sterile barrier system completely formed/assembled;
- product fits into the sterile barrier system;
- essential dimensions are met.

b) For sealing:

- seal strength;
- intact seal for a specified seal width;
- absence of channels or open seals;
- absence of punctures or tears;
- absence of material delamination for seals designed to be opened.

c) For other closure systems:

- continuous closure;
- absence of punctures or tears;
- absence of material delamination or separation.

5.4 Performance qualification

5.4.1 The PQ shall demonstrate that the process will consistently produce preformed sterile barrier systems and sterile barrier systems that meet predetermined requirements under anticipated operating conditions.

5.4.2 The PQ shall include the following:

- the actual or simulated contents, unless a rationale can be established that the contents are not required for process validation activities;
- nominal process parameters established in the OQ;
- verification of product/package requirements;
- assurance of process control and capability;
- process repeatability and reproducibility.

5.4.3 Challenges to the process shall include conditions anticipated to be encountered during manufacture.

NOTE These challenges can include, but are not limited to, machine set-up and change-over procedures; process start-up and restart procedures; power failure and variations; and multiple shifts, if applicable.

5.4.4 The PQ of the process shall include at least three production runs to assess variability within a run and reproducibility between different runs.

NOTE These process variations include, but are not limited to, machine warm up until equilibrium is reached, breaks and shift changes, normal starts and stops, and material lot-to-lot differences.

5.4.5 Documented procedures and/or process specifications for the forming, assembly, sealing or closing operations shall be established and incorporated into the PQ.

5.4.6 Specified process variables shall be monitored and recorded.

5.4.7 The process shall be under control and capable of consistently producing products according to predetermined requirements.

5.5 Formal approval of the process validation

5.5.1 Review and formal approval of the process validation shall be carried out and documented as a final step in the validation program.

5.5.2 The documentation shall summarize and reference all protocols and results, and state conclusions regarding the validation status of the process.

5.6 Process control and monitoring

5.6.1 Procedures shall be established, implemented and maintained to ensure that the packaging process is under control and within the established parameters during routine operation and consistently producing the specified process output.

5.6.2 Specified process variables shall be routinely monitored and records shall be maintained.

5.7 Process changes and revalidation

5.7.1 Processes concerning forming, assembly, sealing or closing shall be covered by a change-control procedure for documenting, verifying and authorizing change.

NOTE The change control procedure can include a check for the need to revalidate.

5.7.2 Processes shall be revalidated if changes are made to the equipment, contents, packaging materials or packaging process that compromise the original validation.

NOTE 1 The following list gives examples of changes that usually affect the status of a validated process:

— raw material changes that can impact the process variables;

— changes or exchanges to a main part of the equipment which can affect one or more of the established parameters;

— modification or refurbishment of equipment;

— transfer of processes and/or equipment from one facility or location to another, or relocation within the same facility;

— negative trends in quality or process control indicators.

NOTE 2 Installation of a new piece of equipment is not included in changes requiring revalidation but rather new process validation.

5.7.3 The need for revalidation shall be evaluated and documented. If the situation does not require that all aspects of the original validation be repeated, this revalidation does not have to be as extensive as the initial validation.

NOTE It is acceptable practice to keep design validation separate from process validation to allow for targeted root cause analysis in case of issues and to limit the effort of revalidation to only those aspects that are really affected.

5.7.4 Minor process changes shall be documented and can require review of the validation status.

NOTE Multiple minor changes are considered to be able to cumulatively affect the validation status of the packaging system.

6 Assembly

6.1 The sterile barrier system shall be assembled under appropriate environmental conditions to minimize the risk posed by contaminants to the medical device.

6.2 The packaging system assembly process shall follow controlled labelling and processing procedures to prevent mislabelling.

NOTE Additional guidance can be found in ISO/TS 16775, DIN 58953-7 and DIN 58953-8.

6.3 Packaging systems shall be assembled and filled according to the instructions based on a validated process that enables sterilization in a defined sterilization process. These instructions should include configuration of contents and organizing inserts, total weight, inner wrapping and absorbent materials.

7 Use of reusable sterile barrier systems

In addition to the requirements listed in Clause 6, instructions and restrictions for use as specified in [A1] ISO 11607-1:2019 [A1], 5.1.10 and 5.1.11 shall be followed (e.g. assembly, disassembly, maintenance, repair, storage).

NOTE For additional guidance on reusable containers, see EN 868-8, DIN 58953-9 and ANSI/AAMI ST77. For additional guidance on reusable fabrics, see EN 13795-1 and ANSI/AAMI ST65.

8 Sterile fluid-path packaging

Assembly of sterile fluid-path components and closures shall meet the requirements of Clauses 5 and 6.

Annex A
(informative)

Process development

Process development, while not a formal part of process validation, should be considered as an integral part of forming and sealing. Process development or process design requires an assessment to identify and evaluate

— the required process elements (e.g. sealers, conveyers, forming equipment, assembly tools, etc.),

— process variables and attributes to be monitored along with their thresholds, deviations or states that require action for producing the desired process output, and

— process variables to be controlled to meet established parameters (i.e. the operating ranges, settings and tolerances).

A process assessment is conducted to establish appropriate and necessary upper and lower processing limits, as well as the expected normal operating conditions to achieve a robust process capable of consistently producing the desired process output. These process limits should be sufficiently removed from failure or marginal conditions. One technique is the creation of seal-strength curves with accompanying visual examples of seal results that can aid in the selection of an optimal process window.

Potential failure modes and action levels having the greatest impact on the process should be identified and addressed (failure mode and effects analysis, cause and effect analysis).

Statistically valid techniques, such as screening experiments and statistically designed experiments to optimize the process, should be used.

Process variables that are evaluated can include, but are not limited to, the following:

— temperature;

— contact pressure;

— dwell time (line speed);

— vacuum;

— energy levels/frequency (radio frequency/ultrasonic);

— torque limits for lid/cap closure systems.

The specified process variables will be selected such that they will produce a process that is in control, and capable of yielding sterile barrier systems and packaging systems that meet predetermined design specifications.

A1 Annex B
(normative)

Risk management

B.1 General

An ongoing risk management process shall be established, implemented, documented and maintained to minimize the risk for the user and the patient. This process shall include:

a) identification of hazards and hazardous situations associated with the forming, sealing and assembly processes for packaging (see B.4);

b) estimation (see B.5) and evaluation (see B.6) of the associated risks;

c) risk control (see B.7);

d) monitoring the effectiveness of the risk control measures (see B.8).

NOTE ISO/TR 24971:2020, Annex B provides examples of techniques that support risk analysis. FMEA is an example of a risk analysis tool.

B.2 Application of the risk management process

This process shall apply throughout the phases of design and development, validation, production and post-production of the process for forming, sealing and assembly of sterile barrier systems. The following shall be included:

a) Design and development phase

— Forming, sealing and assembly process development (see 5.1).

NOTE 1 Process development includes defining required process elements (e.g. sealers, conveyers, forming equipment, assembly tools). See Annex A for information on process development.

NOTE 2 Packaging system design is addressed in ISO 11607-1.

b) Validation phase

— Process validation (see 5.2, 5.3, 5.4 and 5.5).

NOTE Performance testing, stability testing and usability evaluation are addressed in ISO 11607-1.

c) Production phase

— Process control and monitoring (see 5.6);

— Assembly (see Clause 6);

— Use of reusable sterile barrier systems (see Clause 7) if applicable;

— Process changes and revalidation (see 5.7).

NOTE Packaging system changes are addressed in ISO 11607-1.

d) Post-production phase

— If post-production information is available, which can be related to the performance of the process for forming, sealing and assembly of sterile barrier systems, it shall be analysed to determine if risks are controlled appropriately or if unidentified hazards or hazardous situations are present. Consequent corrective and preventive actions shall be implemented as needed.

NOTE 1 The corrective and preventive actions can include redesign, additional controls or revalidation.

NOTE 2 This document does not include requirements for collecting post-production information or for reporting adverse events and field safety corrective actions to authorities or other related activities. This is typically established based on the requirements of the quality management system.

NOTE 3 For guidance on risk management for medical device packaging see ISO 11607-1:2019/Amd1:2023, Annex G.

B.3 Risk management plan

B.3.1 General

A risk management plan shall be documented in accordance with the risk management process for each process for forming, sealing and assembly of sterile barrier systems including at least the following:

— the scope of the planned risk management activities;

— criteria for risk acceptability;

— activities for verification of the implementation and effectiveness of risk control measures.

Risk management plans and related records and documentation for forming, sealing and assembly of sterile barrier systems may be combined with those for the medical device.

B.3.2 Criteria for risk acceptability

Criteria for risk acceptability shall be developed based on the following principles**:**

— align with the device SBS specification or preformed SBS specification as applicable;

— differentiate between critical and essential requirements (e.g. integrity) and lesser impact requirements (e.g. dimensional variance);

— consider the hazards defined in Table B.1, taking into account generally acknowledged state-of-the-art acceptance criteria as applicable.

NOTE 1 Local regulatory requirements can provide mandatory criteria for risk acceptability or these criteria can be based on the generally accepted state of the art.

NOTE 2 The manufacturing of a preformed SBS will only need a preformed SBS specification.

Risk management plans for similar processes for forming, sealing and assembly of sterile barrier systems may be combined, in which case the rationale for these similarities shall be documented.

B.4 Specific hazards and hazardous situations to be addressed

For each of the following hazards, considering both normal and fault conditions, sequences of events shall be identified and the resulting hazardous situations from the process evaluated.

— microbial contamination;

— chemical contamination;

— adverse environmental and processing conditions;

— misleading information.

See Table B.1 for examples of hazards and contributing factors.

Table B.1 — Hazards and contributing factors

Hazard	Possible contributing factors
Microbial contamination	Airborne, surface or material microbial contamination
Chemical contamination	Process residuals (e.g. lubricants), cleaning agents
Adverse environmental and processing conditions	Exposure of packaging materials to incompatible temperature / pressure / humidity or moisture / UV lighting / shock / vibration
	Inadequate or uncontrolled manufacturing process including the work environment and human factors
Misleading information	Labelling / printing application inadequate
	Misallocation (e.g. incorrect label, information, data)

B.5 Risk estimation

For each identified hazardous situation, the associated risk(s) shall be estimated using available information or data.

Hazardous situations shall be assessed based on the probability of occurrence and the potential severity of related harm.

For hazardous situations for which the probability of the occurrence of harm cannot be estimated, the possible consequences shall be listed for use in risk evaluation and risk control.

The risk estimate may include detectability if the ability to detect the hazardous situation can be directly assessed.

B.6 Risk evaluation

Under risk evaluation, estimated risks shall be compared against criteria for risk acceptability defined in the risk management plan to determine if the risk is acceptable or not and to identify risks to be controlled.

B.7 Risk control

Risk shall be controlled by implementing appropriate measures such that they are reduced to, or maintained within, levels as defined by the criteria for risk acceptability.

Risk control in packaging system forming, assembly and sealing for terminally sterilized medical devices shall be based on the following principles in the priority order listed:

a) eliminate and reduce risk through process development as well as consideration of potential design modifications of packaging or contents, to make the process inherently safe;

b) take adequate measures to control the process (e.g. process monitors, in-process controls, alarms, alignment aids/fixtures);

c) provide information on potential failure modes to operators and inspect the output.

B.8 Monitoring effectiveness of risk control measures

The implementation of risk control measures shall be verified.

If both design and manufacturing process outputs meet the acceptance criteria established in process validation activities, the effectiveness of risk controls is then verified.

Any deviations from desired process performance shall be investigated and the risk analysis reviewed and adapted as required. A1

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