

<b>STN</b>	<b>Obaly na sterilizované zdravotnícke pomôcky Časť 2: Požiadavky validácie na procesy tvarovania, spájania a skladania Zmena A1: Uplatňovanie manažérstva rizika (ISO 11607-2: 2019/Amd 1: 2023)</b>	<b>STN EN ISO 11607-2/A1</b>  85 6543
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Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)

Táto norma obsahuje anglickú verziu európskej normy.  
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 12/23

Obsahuje: EN ISO 11607-2:2020/A1:2023, ISO 11607-2:2019/Amd 1:2023

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EUROPEAN STANDARD

EN ISO 11607-2:2020/A1

NORME EUROPÉENNE

EUROPÄISCHE NORM

October 2023

ICS 11.080.30

English Version

**Packaging for terminally sterilized medical devices - Part  
2: Validation requirements for forming, sealing and  
assembly processes - Amendment 1: Application of risk  
management (ISO 11607-2:2019/Amd 1:2023)**

Emballages des dispositifs médicaux stérilisés au stade  
terminal - Partie 2: Exigences de validation pour les  
procédés de formage, scellage et assemblage -  
Amendement 1: Application de la gestion des risques  
(ISO 11607-2:2019/Amd 1:2023)

Verpackungen für in der Endverpackung zu  
sterilisierende Medizinprodukte - Teil 2:  
Validierungsanforderungen an Prozesse der  
Formgebung, Siegelung und des Zusammenstellens -  
Änderung 1 (ISO 11607-2:2019/Amd 1:2023)

This amendment A1 modifies the European Standard EN ISO 11607-2:2020; it was approved by CEN on 12 September 2023.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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 amendment 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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EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

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**EN ISO 11607-2:2020/A1:2023 (E)**

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## **European foreword**

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.

**EN ISO 11607-2:2020/A1:2023 (E)****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 [O] 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 be 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.

## EN ISO 11607-2:2020/A1:2023 (E)

<b>General Safety and Performance Requirements of Regulation (EU) 2017/745</b>	<b>Clause(s) / sub-clause(s) of this EN</b>	<b>Remarks / Notes</b>
<b>7</b>	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.
<b>10</b>		Not covered.
<b>11.1</b>	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	<p>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.</p> <p>GSPR 11.1 (a), and 11.1 (c) are not covered.</p> <p>Clause 5 addresses the requirements of packaging processes and the way to validate.</p> <p>Subclause 5.7 addresses management of changes and revalidations to maintain the process in the state of control.</p> <p>SBS assembly requirements are listed in Clause 6.</p> <p>Specifics for reusable SBS are covered in Clause 7.</p> <p>Specifics for sterile fluid-path SBS are covered in Clause 8.</p>
<b>11.2</b>		<p>Not covered: Applicable only to reusable sterilization containers and reusable materials (EN ISO 11607-1:2020/A1:2023).</p> <p>No presumption of conformity.</p>

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	<p>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.</p> <p>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.</p> <p>Clause 5 addresses the requirements of packaging processes and the way to validate.</p> <p>Subclause 5.7 addresses management of changes and revalidations to maintain the process in the state of control.</p> <p>SBS assembly requirements are listed in clauses 6.</p> <p>Specifics for sterile fluid-path SBS are covered in Clause 8.</p>
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	<p>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).</p> <p>Clause 5 addresses the requirements of packaging processes and the way to validate.</p> <p>Subclause 5.7 addresses management of changes and revalidations to maintain the process in the state of control.</p> <p>SBS assembly requirements are listed in clauses 6.</p> <p>Specifics for sterile fluid-path SBS are covered in Clause 8.</p>
11.6, 11.7, 11.8		Not covered.



**EN ISO 11607-2:2020/A1:2023 (E)**

<b>General Safety and Performance Requirements of Regulation (EU) 2017/745</b>	<b>Clause(s) / sub-clause(s) of this EN</b>	<b>Remarks / Notes</b>
<b>13</b>		Not covered.
<b>22.1</b>	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.
<b>22.2</b>	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.
<b>23.3</b>		Not covered.
<b>23.4</b>		Not covered.

**koniec náhľadu – text ďalej pokračuje v platenej verzii STN**