# SLOVENSKI STANDARD
# SIST EN ISO 11607-2:2020/A11:2022

**01-september-2022**

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**Embalaža za končno sterilizirane medicinske pripomočke - 2. del: Zahteve za validacijo pri procesih oblikovanja, označevanja in sestavljanja - Dopolnilo A11 (ISO 11607-2:2019)**

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

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)



**Ta slovenski standard je istoveten z:** **EN ISO 11607-2:2020/A11:2022**

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**ICS:**

| | | |
|---|---|---|
| 11.080.30 | Sterilizirana embalaža | Sterilized packaging |

**SIST EN ISO 11607-2:2020/A11:2022** **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN ISO 11607-2:2020/A11

June 2022

ICS 11.080.30

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 amendment A11 modifies the European Standard EN ISO 11607-2:2020; it was approved by CEN on 13 April 2022.

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.

CEN members are the national standards bodies of 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 United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

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## European foreword

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 11607-2:2020 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by 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.