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

01-september-2022

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/A11:2020)

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**

ICS:

11.080.30	Sterilizirana embalaža	Sterilized packaging

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

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN ISO 11607-2:2020/A11

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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.

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

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Contents

Page

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.

Annex ZA
(informative)

Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] (as amended) aimed to be covered

This European Standard has been prepared under a Commission's standardization mandate BC/CEN/CENELEC/09/89 "*Standardization mandate jointly to CEN and CENELEC concerning the preparation of European standards relating to Horizontal aspects in the field of medical devices*" referred to in the mandate M/023, concerning the development of European Standards related to medical devices to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZA.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 93/42/EEC as amended by 2007/47/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 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA 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 ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and requirements of Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements of Annex I of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
8.1	4.3, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 6.1, 6.2, 6.3, 7, 8	Partially covered. E.R. 8.1 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 and only if the requirements of EN ISO 11607-1:2020 (Requirements for materials, sterile barrier systems

Essential Requirements of Annex I of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
		and packaging systems) are met as well. 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 reusable SBS are covered in clause 7. Specifics for sterile fluid-path SBS are covered in clause 8.
8.3	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. 8.3 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 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.
8.4	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. 8.4 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,

Essential Requirements of Annex I of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
		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 subclauses 6. Specifics for sterile fluid-path SBS are covered in clause 8.

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.

Annex ZB
(informative)

Relationship between this European Standard and the essential requirements of Directive 90/385/EEC [OJ L 189] (as amended) aimed to be covered

This European Standard has been prepared under a Commission's standardization mandate BC/CEN/CENELEC/09/89 of 19 December 1991 "*Standardization mandate jointly to CEN and CENELEC concerning the preparation of European standards relating to Horizontal aspects in the field of medical devices*" to provide one voluntary means of conforming to essential requirements of Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices [OJ L 189].

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 ZB.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 90/385/EEC as amended by 2007/47/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 1, 4, 5, 8, 9 and 10 of the Directive.

NOTE 3 This Annex ZB 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 ZB.1, it means that it is not addressed by this European Standard.