SLOVENSKI STANDARD

SIST EN ISO 11607-1:2009/A1:2014

01-oktober-2014

Embalaža za končno sterilizirane medicinske pripomočke - 1. del: Zahteve za materiale, sterilne pregradne sisteme in sisteme embalaže (ISO 11607-1:2009/Amd 1:2014)

Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2009/Amd 1:2014)

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 1: Anforderungen an Materialien, Sterilbarrieresysteme und Verpackungssysteme (ISO 11607-1:2009/Amd 1:2014)

Emballages des dispositifs médicaux stérilisés au stade terminal - Partie 1: Exigences relatives aux matériaux, aux systèmes de barrière stérile et aux systèmes d'emballage (ISO 11607-1:2009/Amd 1:2014)

Ta slovenski standard je istoveten z: EN ISO 11607-1:2009/A1:2014

ICS:

11.080.30	Sterilizirana embalaža	Sterilized packaging

SIST EN ISO 11607-1:2009/A1:2014 en

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11607-1:2009/A1

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English Version

Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2009/Amd 1:2014)

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This amendment A1 modifies the European Standard EN ISO 11607-1:2009; it was approved by CEN on 14 June 2014.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, 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: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 11607-1:2009/A1:2014 E

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Foreword

This document (EN ISO 11607-1:2009/A1:2014) has been prepared by Technical Committee ISO/TC 198 “Sterilization of health care products” in collaboration with Technical Committee CEN/TC 102 “Sterilizers for medical purposes” the secretariat of which is held by DIN.

This Amendment to the European Standard EN ISO 11607-1:2009 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2015, and conflicting national standards shall be withdrawn at the latest by January 2015.

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 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, which is an integral part of this document.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 11607-1:2006/Amd 1:2014 has been approved by CEN as EN ISO 11607-1:2009/A1:2014 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

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 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.

Table ZA.1 — Correspondence between this International Standard and Directive 93/42/EEC on medical devices

Clause(s)/subclause(s) of this International standard	Essential Requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/notes
5.1.3, 5.1.4, 5.1.5, 5.5	7.2	
5.1.6 e), 5.1.7 a), 5.1.7 d), 5.1.7 f), 5.1.7 g), 5.1.9 a), 5.3.1, 6.1.3, 6.2.3,	7.3, 1st part	
5.1.7 a), 5.1.7 g), 5.1.9 a), 5.4 c)	7.5, 1st paragraph	
5.1.7 g)	7.5, 2nd paragraph	Partly addressed. Only toxics are dealt with.
5.1.6 a), 5.1.10 b) 5.1.10 c), 5.2, 6.1.1, 6.1.2, 6.1.4	7.6	Partly addressed. To fully address the ER, validation requirements for forming, sealing and assembling processes need to be addressed (ISO 11607-2).
5.1.6 a), 5.1.10 b), 5.1.10 c), 5.2, 6.1.1, 6.1.2, 6.1.4, 6.2.2, 6.3.5	8.1	Partly addressed. To fully address the ER, validation requirements for forming, sealing and assembling processes need to be addressed (ISO 11607-2).
5.1.10 a), 5.1.10 b), 5.1.10 c), 6.1.1, 6.1.2, 6.1.4, 6.2.2, 6.3.1, 6.3.5, 6.4.1, 7.1	8.3	Partly addressed. To fully address the ER, validation requirements for forming, sealing and assembling processes need to be addressed (ISO 11607-2).
5.1.3, 5.1.4, 5.1.5, 5.1.7 d)	8.5	

5.1.3, 5.1.4, 5.1.5, 7.1, 5.1.6 e), 5.1.7 f), 5.1.7 g), 5.1.9 a), 5.3, 6.1.3	8.6	
5.3.6, 7.1	9.1	Partly addressed. To fully address the ER, validation requirements for forming, sealing and assembling processes need to be addressed (ISO 11607-2).
6.2.3 h), 6.2.3 j), 7.1	9.2, 2nd dash	Partly addressed. Standard does not mention or define values and/or limits.
7	13.1	Partly addressed. Training and knowledge of the potential users is not dealt with.
7	13.3 a), b), d), e), f), i), j), m)	
5.1.10 d), 5.1.11 b), 5.1.12	13.6 h)	Partly addressed. Standard requires this information only for reusable SBS.

INTERNATIONAL STANDARD

ISO 11607-1

First edition
2006-04-15

AMENDMENT 1
2014-07-15

Packaging for terminally sterilized medical devices —

Part 1: Requirements for materials, sterile barrier systems and packaging systems

AMENDMENT 1

Emballages des dispositifs médicaux stérilisés au stade terminal —

Partie 1: Exigences relatives aux matériaux, aux systèmes de barrière stérile et aux systèmes d'emballage

AMENDEMENT 1

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ISO 11607-1:2006/Amd.1:2014(E)

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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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

The committee responsible for this document is ISO/TC 198, *Sterilization of health care products*.

ISO 11607 consists of the following parts, under the general title Packaging for terminally sterilized medical devices:

— *Part 1: Requirements for materials, sterile barrier systems and packaging systems*

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