ICS 11.080.30

ČSN
EN ISO 11607-2
OPRAVA 1
85 5280

Duben 2018

ČESKÁ TECHNICKÁ NORMA

Obaly pro závěrečně sterilizované zdravotnické prostředky – Část 2: Validace požadavků na proces tvarování, utěsnění a sestavení

Upozornění

ČSN EN ISO 11607-2 (85 5280) Obaly pro závěrečně sterilizované zdravotnické prostředky – Část 2: Validace požadavků na proces tvarování, utěsnění a sestavení z března 2018 se na základě Correction Notice vydaného CEN dne 2017-11-22 opravuje takto:

Nahrazuje se titulní strana evropské normy a evropská předmluva a doplňuje se změna ISO 11607-2:2006/Amd.1:2014.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11607-2

July 2017

ICS 11.080.30

Supersedes EN ISO 11607-2:2006

English Version

Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2006, including Amd 1:2014)

Emballages des dispositifs médicaux stérilisés au stade terminal - Partie 2: Exigences de validation pour les procédés de formage, scellage et assemblage (ISO 11607-2:2006, y compris Amd 1:2014)

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 2: Validierungsanforderungen an Prozesse der Formgebung, Siegelung und des Zusammenstellens (ISO 11607-2:2006, einschließlich Amd 1:2014)

This European Standard was approved by CEN on 18 July 2017.

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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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 11607-2:2017 E

European foreword

The text of ISO 11607-2:2006, including Amd 1:2014 has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 11607-2:2017 by 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 January 2018, and conflicting national standards shall be withdrawn at the latest by January 2018.

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 standard replaces EN ISO 11607-2:2006.

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).

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

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 11607-1:2009/A1: 2014	

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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 11607-2:2006, including Amd 1:2014 has been approved by CEN as EN ISO 11607-2:2017 without any modification.

INTERNATIONAL STANDARD

ISO 11607-2

First edition
2006-04-15

AMENDMENT 1
2014-07-15

Packaging for terminally sterilized medical devices —

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

AMENDMENT 1

Emballages des dispositifs médicaux stérilisés au stade terminal —

Partie 2: Exigences de validation pour les procédés de formage, scellage et assemblage

AMENDEMENT 1

Reference number
ISO 11607-2:2006/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*

Packaging for terminally sterilized medical devices —

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

AMENDMENT 1

Page 2, definition 3.9

Update the date of publication of the reference to read '[ISO 9000:2005]'.

Page 4, 4.1.2

Replace 'It is not necessary' with 'It shall not be necessary'.

Page 4, 4.1.3

Replace 'Health care facilities may use' with 'Health care facilities shall consider using'.

Page 7, 5.3.2 b), Note

Replace 'See EN 868-5: 1999, 4.3.2' with 'See EN 868-5: 2009, 4.3.2'

Page 11, Bibliography

Replace reference [2] with ISO 2859-1:1999 (including Corrigendum 1:2001 + Amendment 1:2011), *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

Replace reference [3] with ISO 9001:2008 (including Corrigendum 1:2009), *Quality management systems — Requirements*

Replace reference [5] with ISO 13485:2003 (including Corrigendum 1:2009), Medical devices — Quality management systems — Requirements for regulatory purposes

Replace reference [6] with ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary*

Replace reference [7] with EN 868-5:2009, *Packaging for terminally sterilized medical devices — Part 5: Sealable pouches and reels of porous materials and plastic film construction — Requirements and test methods*

Replace reference [8] with EN 868-6:2009, *Packaging for terminally sterilized medical devices — Part 6: Paper for low temperature sterilization processes — Requirements and test methods*

Replace reference [9] with EN 868-8:2009, *Packaging for terminally sterilized medical devices — Part 8: Re-usable sterilization containers for steam sterilizers conforming to* EN 285 — *Requirements and test methods*

Replace reference [10] with EN 13795-1+A1:2009, *Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment — Part 1: General requirements for manufacturers, processors and products*

Delete reference [11].

Replace reference [12] with AAMI/ANSI ST 65:2008, *Processing of reusable surgical textiles for use in health care facilities*

Replace reference [13] with DIN 58953-7:2010, *Sterilization — Sterile supply — Part 7: Use of sterilization paper, nonwoven wrapping material, textile materials, paper bags and sealable pouches and reels*

Replace reference [14] with DIN 58953-8:2010, *Sterilization — Sterile supply — Part 8: Logistics of sterile medical devices*

Replace reference [15] with DIN 58953-9:2010, *Sterilization — Sterile supply — Part 9: Use of sterilization container*

Renumber the Bibliography.

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Price based on 2 pages

U p o z o r n ě n í : Oznámení o změnách, opravách a nově vydaných normách jsou uveřejňována ve Věstníku Úřadu pro technickou normalizaci, metrologii a státní zkušebnictví.

Vaše názory, podněty a připomínky týkající se technických norem a zájmu o možnou účast v procesech technické normalizace lze zaslat na e-mailovou adresu info@agentura-cas.cz.

ČSN EN ISO 11607-2 OPRAVA 1

ČESKÁ AGENTURA PRO STANDARDIZACI

504801

Vydala Česká agentura pro standardizaci na základě ustanovení § 5 odst. 2 zákona č. 22/1997 Sb.
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