SLOVENSKI STANDARD
SIST EN ISO 11607-2:2006/oprA1:2013

01-maj-2013

Embalaža za končno sterilizirane medicinske pripomočke - 2. del: Zahteve validacije za proces oblikovanja, označevanja in sestavljanja - Dopolnilo 1 (ISO 11607-2:2006/DAM 1:2013)

Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes - Amendment 1 (ISO 11607-2:2006/DAM 1:2013)

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 2: Validierungsanforderungen an Prozesse der Formgebung, Siegelung und des Zusammenstellens - Änderung 1 (ISO 11607-2:2006/DAM 1:2013)

Emballages des dispositifs médicaux stérilisés au stade terminal - Partie 2: Exigences de validation pour les procédés de formage, scellage et assemblage - Amendement 1 (ISO 11607-2:2006/DAM 1:2013)

Ta slovenski standard je istoveten z: **EN ISO 11607-2:2006/prA1**

ICS:

11.080.30	Sterilizirana embalaža	Sterilized packaging

SIST EN ISO 11607-2:2006/oprA1:2013 **en**

EUROPEAN STANDARD

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Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 2: Validierungsanforderungen an Prozesse der Formgebung, Siegelung und des Zusammenstellens - Änderung 1 (ISO 11607-2:2006/DAM 1:2013)

This draft amendment is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 102.

This draft amendment A1, if approved, will modify the European Standard EN ISO 11607-2:2006. If this draft becomes an amendment, 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.

This draft amendment was established by CEN 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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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

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Foreword

This document (EN ISO 11607-2:2006/prA1:2013) 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 document is currently submitted to the parallel Enquiry.

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).

Endorsement notice

The text of ISO 11607-2:2006/DAM 1:2013 has been approved by CEN as EN ISO 11607-2:2006/prA1:2013 without any modification.

DRAFT AMENDMENT ISO 11607-2:2006/DAM 1

ISO/TC **198** Secretariat: **ANSI**

Voting begins on **2013-03-14** Voting terminates on **2013-08-14**

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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

ICS 11.080.30

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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