SLOVENSKI STANDARD
kSIST prEN ISO 11607-1:2009

Embalaǵa za konḷ no sterilizirane medicinske pripomoḷ ke - 1. del: Zahteve za materiale, sterilne pregradne sisteme in sisteme embalaǵe (ISO 11607-1:2006)

Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 1: Anforderungen an Materialien, Sterilbarrieresysteme und Verpackungssysteme (ISO 11607-1:2006)

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 11607-1:2006)

Ta slovenski standard je istoveten z: **prEN ISO 11607-1**

ICS:

11.080.30	Sterilizirana embalaža	Sterilized packaging

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2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

FINAL DRAFT
prEN ISO 11607-1

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ICS 11.080.30

Will supersede EN ISO 11607-1:2006

English Version

Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)

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Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 1: Anforderungen an Materialien, Sterilbarrieresysteme und Verpackungssysteme (ISO 11607-1:2006)

This draft European Standard is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 102.

If this draft becomes a European Standard, 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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

The text of ISO 11607-1:2006 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 prEN ISO 11607-1:2009 by Technical Committee CEN/TC 102 “Sterilizers for medical purposes” the secretariat of which is held by DIN.

This document is currently submitted to the Unique Acceptance Procedure.

This document will supersede EN ISO 11607-1:2006.

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 EC Directive.

For relationship with EC Directive, see informative Annex ZA, which is an integral part of this document.

Endorsement notice

The text of ISO 11607-1:2006 has been approved by CEN as a prEN ISO 11607-1:2009 without any modification.

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Annex ZA
(informative)

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

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 Communities 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 European Standard and Directive 93/42/EEC

Clause(s)/Sub-clause(s) of this International Standard	Essential Requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
4.1, 4.2	1, 2	
4.3, 4.4, 4.5	3, 4, 5, 6	
5.1.1 to 5.1.11 (except 5.1.10)	7.1, 7.3, 7.5, 7.6, 8.5	
5.1.9	9.1, 9.2	
5.2	8.1	
5.3	8.3, 8.6	
5.4	8.6	
5.5	5, 8.3	
6.1	1,2, 6	
6.2	3, 7.1, 7.3, 7.5, 7.6, 8.3, 8.6, 13.1, 13.5	
6.3	8.1, 8.6	
6.4	5	
7	13	The applicable parts of the Essential Requirement 13 are partly addressed
	13.3 a)	This relevant Essential Requirement is not addressed in this European Standard
	13.3 f)	This relevant Essential Requirement is not addressed in this European Standard
	13.6 h)	This relevant Essential Requirement is not addressed in this European Standard
	13.6 (q)	This relevant Essential Requirement is not addressed in this European Standard

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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INTERNATIONAL STANDARD

ISO 11607-1

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