# SLOVENSKI STANDARD
# SIST EN ISO 11137-1:2006/oprA1:2012

**01-julij-2012**

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**Sterilizacija izdelkov za zdravstveno nego - Sevanje - 1. del: Zahteve za razvoj, validacijo in rutinsko kontrolo sterilizacijskih postopkov za medicinske pripomočke (ISO 11137-1:2006/Amd.1:2012)**

Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006/Amd.1:2012)

Sterilisation von Produkten für die Gesundheitsfürsorge - Strahlen - Teil 1: Anforderungen an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte (ISO 11137-1:2006/Amd.1:2012)

Stérilisation des produits de santé - Irradiation - Partie 1: Exigences relatives à la mise au point, à la validation et au contrôle de routine d'un procédé de stérilisation pour les dispositifs médicaux (ISO 11137-1:2006/Amd.1:2012)

**Ta slovenski standard je istoveten z:** **EN ISO 11137-1:2006/prA1**

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**ICS:**

| | | |
|---|---|---|
| 11.080.01 | Sterilizacija in dezinfekcija na splošno | Sterilization and disinfection in general |

**SIST EN ISO 11137-1:2006/oprA1:2012** **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# DRAFT
# EN ISO 11137-1:2006

## prA1

May 2012

ICS 11.080.99

English Version

# Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006/Amd.1:2012)

Stérilisation des produits de santé - Irradiation - Partie 1: Exigences relatives à la mise au point, à la validation et au contrôle de routine d'un procédé de stérilisation pour les dispositifs médicaux (ISO 11137-1:2006/Amd.1:2012)

Sterilisation von Produkten für die Gesundheitsfürsorge - Strahlen - Teil 1: Anforderungen an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte (ISO 11137-1:2006/Amd.1:2012)

This draft amendment is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 204.

This draft amendment A1, if approved, will modify the European Standard EN ISO 11137-1:2006. 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.

**Warning** : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

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

**Management Centre: Avenue Marnix 17, B-1000 Brussels**

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# Foreword

This document (EN ISO 11137-1:2006/prA1:2012) has been prepared by Technical Committee ISO/TC 198 “Sterilization of health care products” in collaboration with Technical Committee CEN/TC 204 “Sterilization of medical devices” the secretariat of which is held by BSI.

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.

**Endorsement notice**

The text of ISO 11137-1:2006/DAM 1:2012 has been approved by CEN as a EN ISO 11137-1:2006/prA1:2012 without any modification.

**DRAFT AMENDMENT** ISO 11137-1:2006/DAM 1

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

Voting begins on **2012-05-03** Voting terminates on **2012-10-03**

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

# Sterilization of health care products — Radiation —

## Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

## AMENDMENT 1

*Stérilisation des produits de santé — Irradiation —*

*Partie 1: Exigences relatives à la mise au point, à la validation et au contrôle de routine d'un procédé de stérilisation pour les dispositifs médicaux*

*AMENDEMENT 1*

ICS 11.080.01

## ISO/CEN PARALLEL PROCESSING

This draft has been developed within the European Committee for Standardization (CEN), and processed under the **CEN-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 r eceived 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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