



SLOVENSKI STANDARD
SIST EN ISO 11137-1:2015/oprA2:2017
01-november-2017

Sterilizacija izdelkov za zdravstveno nego - Sevanje - 1. del: Zahteve za razvoj, validacijo in rutinsko kontrolo sterilizacijskih postopkov za medicinske pripomočke - Dopolnilo A2 (ISO 11137-1:2006/DAM 2:2017)

Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices - Amendment 2 (ISO 11137-1:2006/DAM 2:2017)

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/DAM 2:2017)

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 2 (ISO 11137-1:2006/DAM 2:2017)

Ta slovenski standard je istoveten z: EN ISO 11137-1:2015/prA2

ICS:

11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general
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DRAFT AMENDMENT

ISO 11137-1:2006/DAM 2

ISO/TC 198

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Sterilization of health care products — Radiation —

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

AMENDMENT 2: .

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 2: .

ICS: 11.080.01

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ISO/CEN PARALLEL PROCESSING



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This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

A list of all parts in the ISO 11137- series can be found on the ISO website.

Sterilization of health care products — Radiation —

Part 1:

Requirements for development, validation and routine control of a sterilization process for medical devices

AMENDMENT 2: .

AMENDMENT 2: Revision to 11.2

Page 17, 11.2

Replace the second sentence with the following:

The procedure(s) shall define the requirements (see 9.4.3 or 9.4.4 as appropriate) for designating a sterilization process as conforming.