

SVENSK STANDARD

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Sterilisering av sjukvårdsprodukter – Strålning – Del 3: Riktlinjer för dosimetriska aspekter av utveckling, validering och rutinkontroll (ISO 11137-3:2017)

Sterilization of health care products – Radiation – Part 3: Guidance on dosimetric aspects of development, validation and routine control (ISO 11137-3:2017)

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Denna standard ersätter SS-EN ISO 11137-3:2006, utgåva 1.

The European Standard EN ISO 11137-3:2017 has the status of a Swedish Standard. This document contains the official version of EN ISO 11137-3:2017.

This standard supersedes the Swedish Standard SS-EN ISO 11137-3:2006, edition 1.

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EUROPEAN STANDARD

EN ISO 11137-3

NORME EUROPÉENNE

EUROPÄISCHE NORM

July 2017

ICS 11.080.01

Supersedes EN ISO 11137-3:2006

English Version

**Sterilization of health care products - Radiation - Part 3:
Guidance on dosimetric aspects of development, validation
and routine control (ISO 11137-3:2017)**

Stérilisation des produits de santé - Irradiation - Partie
3: Directives relatives aux aspects dosimétriques de
développement, la validation et le contrôle de routine
(ISO 11137-3:2017)

Sterilisation von Produkten für die
Gesundheitsfürsorge - Strahlen - Teil 3: Anleitung zu
dosimetrischen Aspekten der Entwicklung, Validierung
und Lenkung der Anwendung (ISO 11137-3:2017)

This European Standard was approved by CEN on 15 March 2017.

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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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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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European foreword

This document (EN ISO 11137-3:2017) 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 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 document supersedes EN ISO 11137-3:2006.

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 11137-3:2017 has been approved by CEN as EN ISO 11137-3:2017 without any modification.

SS-EN ISO 11137-3:2017 (E)

Introduction

An integral part of radiation sterilization is the ability to measure dose. Dose is measured during all stages of development, validation and routine monitoring of the sterilization process. It has to be demonstrated that dose measurement is traceable to a national or an International Standard, that the uncertainty of measurement is known, and that the influence of temperature, humidity and other environmental considerations on dosimeter response is known and taken into account. Process parameters are established and applied based on dose measurements. This document provides guidance on the use of dose measurements (dosimetry) during all stages in the development, validation and routine control of the radiation sterilization process.

Requirements in regard to dosimetry are given in ISO 11137-1 and ISO 11137-2 and ISO/TS 13004. This document gives guidance to these requirements. The guidance given is not normative and is not provided as a checklist for auditors. The guidance provides explanations and methods that are regarded as being suitable means for complying with the requirements. Methods other than those given in the guidance may be used, if they are effective in achieving compliance with the requirements of ISO 11137-1, ISO 11137-2 and ISO/TS 13004.

Sterilization of health care products — Radiation —

Part 3:

Guidance on dosimetric aspects of development, validation and routine control

1 Scope

This document gives guidance on meeting the requirements in ISO 11137-1 and ISO 11137-2 and in ISO/TS 13004 relating to dosimetry and its use in development, validation and routine control of a radiation sterilization process.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

ISO/TS 13004, *Sterilization of health care products — Radiation — Substantiation of a selected sterilization dose: Method VD_{max}^{SD}*

ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

3 Terms, definitions and symbols

For the purposes of this document, the terms and definitions given in ISO 11137-1 and ISO 11137-2 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

3.1 General

3.1.1

absorbed dose dose

quantity of ionizing radiation energy imparted per unit mass of a specified material

[SOURCE: ISO 11137-1:2006, 3.1, modified]

Note 1 to entry: For the purposes of this document, the term “dose” is used to mean “absorbed dose”.