

<b>STN P</b>	<b>Sterilizácia výrobkov zdravotnej starostlivosti žiarením Časť 4: Pokyny na kontrolu procesu (ISO/TS 11137-4: 2020)</b>	<b>STN P CEN ISO/TS 11137-4</b>  85 5012
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Sterilization of health care products - Radiation - Part 4: Guidance on process control (ISO/TS 11137-4:2020)

Táto norma obsahuje anglickú verziu európskej normy.  
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 08/23

Táto predbežná slovenská technická norma je určená na overenie. Prípadné pripomienky pošlite do júna 2025 Úradu pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky.

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**CEN ISO/TS 11137-4**

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English Version

**Sterilization of health care products - Radiation - Part 4:  
Guidance on process control (ISO/TS 11137-4:2020)**

Stérilisation des produits de santé - Irradiation - Partie  
4: Recommandations sur le contrôle de processus  
(ISO/TS 11137-4:2020)

Sterilisation von Produkten für die  
Gesundheitsfürsorge - Strahlen - Teil 4: Leitfaden zur  
Verfahrenssteuerung (ISO/TS 11137-4:2020)

This Technical Specification (CEN/TS) was approved by CEN on 28 May 2023 for provisional application.

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**CEN ISO/TS 11137-4:2023 (E)**

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## **European foreword**

The text of ISO/TS 11137-4:2020 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 CEN ISO/TS 11137-4:2023 by Technical Committee CEN/TC 204 "Sterilization of medical devices" the secretariat of which is held by BSI.

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## **Endorsement notice**

The text of ISO/TS 11137-4:2020 has been approved by CEN as CEN ISO/TS 11137-4:2023 without any modification.



# TECHNICAL SPECIFICATION

# ISO/TS 11137-4

First edition  
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## **Sterilization of health care products — Radiation —**

### **Part 4: Guidance on process control**

*Stérilisation des produits de santé — Irradiation —*

*Partie 4: Recommandations sur le contrôle de processus*



Reference number  
ISO/TS 11137-4:2020(E)

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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

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.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

## ISO/TS 11137-4:2020(E)

### Introduction

ISO 11137-1 describes the requirements for the development, validation and routine control of a radiation sterilization process, and ISO 11137-3 gives guidance on dosimetric requirements in all stages of this development, validation and control. The purpose of ISO/TS 11137-4 is to provide additional guidance on the establishment and control of the irradiation process, including setting process target doses and verifying that the process is in a state of control.

This document addresses the establishment of methods to set process target doses and verify the process is in a state of control. Dosimetry is used during the validation of a radiation sterilization process to measure doses, and the interpretation of dosimetry results from operational and performance qualification studies is critical in establishing a process that will meet the requirements specified for minimum and maximum dose as outlined in ISO 11137-1, ISO 11137-2 and ISO/TS 13004.

Routine dosimetry is used to monitor that the process is in a state of control and dose specifications have been met. One purpose of this technical specification is to provide guidance on the application of a dose measurement as a tool used for monitoring an irradiation process using statistical techniques.

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 achieving conformity with the minimum and maximum dose specifications. Methods other than those given in the guidance may be used, if they are effective in achieving conformity with the requirements of ISO 11137-1, ISO 11137-2 and ISO/TS 13004.

# Sterilization of health care products — Radiation —

## Part 4: Guidance on process control

### 1 Scope

This document provides additional guidance to that given in ISO 11137-3 on meeting the requirements specified in ISO 11137-1, ISO 11137-2 and ISO/TS 13004 for the establishment and control of a radiation sterilization process using gamma, electron beam, and X-irradiation.

### 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 11137-1:2006, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

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

**koniec náhľadu – text ďalej pokračuje v platenej verzii STN**