



BSI Standards Publication

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

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

## National foreword

This British Standard is the UK implementation of EN ISO 11137-1:2015+A2:2019. It is identical to ISO 11137-1:2006, incorporating amendments 1:2013 and 2:2018. It supersedes BS EN ISO 11137-1:2015, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by A1 A1.

The UK participation in its preparation was entrusted to Technical Committee CH/198, Sterilization and Associated Equipment and Processes.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2019  
Published by BSI Standards Limited 2019

ISBN 978 0 580 99289 6

ICS 11.080.01

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 August 2006.

### Amendments/corrigenda issued since publication

Date	Text affected
31 August 2013	Implementation of ISO amendment 1:2013 with CEN endorsement A1:2013: Annex ZA updated; Annex ZB and Annex ZC inserted
31 July 2015	CEN have reissued this document with the updated identifier EN ISO 11137-1:2015, which has been reflected in the BSI adoption of this standard
30 November 2019	Implementation of ISO amendment 2:2018 with CEN endorsement A2:2019

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, including Amd 1:2013)**

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, y compris Amd 1:2013)

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, einschließlich Amd 1:2013)

This European Standard was approved by CEN on 20 May 2015.

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. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

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COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

## European foreword

The text of ISO 11137-1:2006, including Amd 1:2013 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 EN ISO 11137-1:2015 by 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 December 2015, and conflicting national standards shall be withdrawn at the latest by December 2015.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 11137-1:2006.

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 EU Directives.

For relationship with EU Directives, see informative [Annexes ZA, ZB, ZC](#), which are an integral part of this document.

The following referenced documents are indispensable for the application of this document. For undated references, the edition of the referenced document (including any amendments) listed below applies. For dated references, only the edition cited applies. However, for any use of this standard within the meaning of [Annex ZA, ZB or ZC](#), the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this should be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

**Table — Correlation between normative references and dated EN and ISO standards**

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO
ISO 10012-1	EN ISO 10012:2003	ISO 10012:2003
ISO 11137-2	EN ISO 11137-2:2013	ISO 11137-2:2013
ISO 11737-1	EN ISO 11737-1:2006 + AC:2009	ISO 11737-1:2006 + Cor 1:2007
ISO 11737-2	EN ISO 11737-2:2009	ISO 11737-2:2009
ISO 13485	EN ISO 13485:2012	ISO 13485:2003

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### Endorsement notice

The text of ISO 11137-1:2006, including Amd 1:2013 has been approved by CEN as EN ISO 11137-1:2015 without any modification.

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## Foreword to amendment A1

This document ISO 11137-1:2006/A1:2013 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 Amendment to the European Standard EN ISO 11137:2006 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2014, and conflicting national standards shall be withdrawn at the latest by January 2014.

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### Endorsement notice

The text of ISO 11137-1:2006/Amd1:2013 has been approved by CEN as EN ISO 11137-1:2015/A1:2013 without any modification.

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## Foreword to amendment A2

This document (EN ISO 11137-1:2015/A2:2019) 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 Amendment to the European Standard EN ISO 11137-1:2015 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2020, and conflicting national standards shall be withdrawn at the latest by May 2020.

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This document modifies EN ISO 11137-1:2006/Amd 1:2013 with a revised European Foreword and European [Annexes ZA, ZB](#) and [ZC](#), and additional European [Annexes ZD](#) and [ZE](#).

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(s).

For relationship with EU Directive(s) and Regulation(s), see informative [Annex ZA, ZB, ZC, ZD](#) and [ZE](#), which are an integral part of this document.

The following referenced documents are indispensable for the application of this document. For undated references, the edition of the referenced document (including any amendments) listed below applies.

For dated references, only the edition cited applies. However, for any use of this standard within the meaning of [Annex ZA](#), [ZB](#), [ZC](#), [ZD](#) or [ZE](#), the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this should be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

**Table — Correlation between normative references and dated EN and ISO standards**

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO
ISO 10012-1	EN ISO 10012:2003	ISO 10012:2003
ISO 11137-2	EN ISO 11137-2:2015	ISO 11137-2:2013
ISO 11737-1	EN ISO 11737-1:2006	ISO 11737-1:2006
ISO 11737-2:2009	EN ISO 11737-2:2009	ISO 11737-2:2009
ISO 13485:2003	EN ISO 13485:2016	ISO 13485:2016

NOTE Some standards normatively referred to by EN ISO 11137-1/Amd 2:2019 are undated. These referred standards also include normative references to other dated and undated standards. For undated normative references, it should always be assumed that the latest edition applies.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

**Endorsement notice**

The text of ISO 11137-1:2006/Amd 2:2018 has been approved by CEN as EN ISO 11137-1:2015/A2:2019 without any modification.

# Contents

Page

<b>Foreword</b> .....	<b>xvii</b>
<b>Introduction</b> .....	<b>xviii</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>2</b>
<b>3 Terms and definitions</b> .....	<b>2</b>
<b>4 Quality management system elements</b> .....	<b>8</b>
4.1 Documentation.....	8
4.2 Management responsibility.....	8
4.3 Product realization.....	8
4.4 Measurement, analysis and improvement — Control of nonconforming product.....	9
<b>5 Sterilizing agent characterization</b> .....	<b>9</b>
5.1 Sterilizing agent.....	9
5.2 Microbicidal effectiveness.....	9
5.3 Material effects.....	9
5.4 Environmental considerations.....	9
<b>6 Process and equipment characterization</b> .....	<b>9</b>
6.1 Process.....	9
6.2 Equipment.....	10
<b>7 Product definition</b> .....	<b>11</b>
<b>8 Process definition</b> .....	<b>12</b>
8.1 Establishing the maximum acceptable dose.....	12
8.2 Establishing the sterilization dose.....	12
8.3 Specifying the maximum acceptable dose and the sterilization dose.....	12
8.4 Transference of maximum acceptable, verification or sterilization dose between radiation sources.....	13
8.4.1 Transference of maximum acceptable dose.....	13
8.4.2 Transference of verification dose or sterilization dose.....	13
<b>9 Validation</b> .....	<b>13</b>
9.1 Installation qualification.....	13
9.2 Operational qualification.....	14
9.3 Performance qualification.....	15
9.4 Review and approval of validation.....	15
<b>10 Routine monitoring and control</b> .....	<b>16</b>
<b>11 Product release from sterilization</b> .....	<b>17</b>
<b>12 Maintaining process effectiveness</b> .....	<b>17</b>
12.1 Demonstration of continued effectiveness.....	17
12.1.1 General.....	17
12.1.2 Frequency of determinations of bioburden.....	18
12.1.3 Frequency of sterilization dose audits.....	19
12.2 Recalibration.....	20
12.3 Maintenance of equipment.....	20
12.4 Requalification of equipment.....	20
12.5 Assessment of change.....	21
<b>Annex A (informative) Guidance</b> .....	<b>22</b>
<b>Bibliography</b> .....	<b>37</b>



## 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 11137-1 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care product*.

This first edition, together with ISO 11137-2 and ISO 11137-3, cancels and replaces ISO 11137:1995.

ISO 11137 consists of the following parts, under the general title *Sterilization of health care products — Radiation*:

- *Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*
- *Part 2: Establishing the sterilization dose*
- *Part 3: Guidance on dosimetric aspects*



## Introduction

A sterile medical device is one that is free of viable microorganisms. International Standards, which specify requirements for validation and routine control of sterilization processes, require, when it is necessary to supply a sterile medical device, that adventitious microbiological contamination of a medical device prior to sterilization be minimized. Even so, medical devices produced under standard manufacturing conditions in accordance with the requirements for quality management systems (see, for example, ISO 13485) may, prior to sterilization, have microorganisms on them, albeit in low numbers. Such medical devices are non-sterile. The purpose of sterilization is to inactivate the microbiological contaminants and thereby transform the non-sterile medical devices into sterile ones.

The kinetics of inactivation of a pure culture of microorganisms by physical and/or chemical agents used to sterilize medical devices can generally best be described by an exponential relationship between the numbers of microorganisms surviving and the extent of treatment with the sterilizing agent; inevitably this means that there is always a finite probability that a microorganism may survive regardless of the extent of treatment applied. For a given treatment, the probability of survival is determined by the number and resistance of microorganisms and by the environment in which the organisms exist during treatment. It follows that the sterility of any one medical device in a population subjected to sterilization processing cannot be guaranteed and the sterility of a processed population is defined in terms of the probability of there being a viable microorganism present on a medical device.

This part of ISO 11137 describes requirements that, if met, will provide a radiation sterilization process intended to sterilize medical devices, that has appropriate microbicidal activity. Furthermore, compliance with the requirements ensures that this activity is both reliable and reproducible so that predictions can be made, with reasonable confidence, that there is a low level of probability of there being a viable microorganism present on product after sterilization. Specification of this probability is a matter for regulatory authorities and may vary from country to country (see, for example, EN 556-1 and ANSI/AAMI ST67).

Generic requirements of the quality management system for design and development, production, installation and servicing are given in ISO 9001 and particular requirements for quality management systems for medical device production are given in ISO 13485. The standards for quality management systems recognise that, for certain processes used in manufacturing, the effectiveness of the process cannot be fully verified by subsequent inspection and testing of the product. Sterilization is an example of such a process. For this reason, sterilization processes are validated for use, the performance of the sterilization process is monitored routinely and the equipment is maintained.

Exposure to a properly validated, accurately controlled sterilization process is not the only factor associated with the provision of reliable assurance that the products are sterile and, in this regard, suitable for its intended use. Attention is therefore given to a number of considerations including:

- a) the microbiological status of incoming raw materials and/or components;
- b) the validation and routine control of any cleaning and disinfection procedures used on the product;
- c) the control of the environment in which the product is manufactured, assembled and packaged;
- d) the control of equipment and processes;
- e) the control of personnel and their hygiene;
- f) the manner and materials in which the product is packaged;
- g) the conditions under which product is stored.

This part of ISO 11137 describes the requirements for ensuring that the activities associated with the process of radiation sterilization are performed properly. These activities are described in documented work programmes designed to demonstrate that the radiation process will consistently yield sterile products on treatment with doses falling within the predetermined limits.

The requirements are the normative parts of this part of ISO 11137 with which compliance is claimed. The guidance given in the informative annexes is not normative and is not provided as a checklist for auditors. The guidance provides explanations and methods that are regarded as being a 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 this part of ISO 11137.

The development, validation and routine control of a sterilization process comprise a number of discrete but interrelated activities; e.g. calibration, maintenance, product definition, process definition, installation qualification, operational qualification and performance qualification. While the activities required by this part of ISO 11137 have been grouped together and are presented in a particular order, this part of ISO 11137 does not require that the activities be performed in the order that they are presented. The activities required are not necessarily sequential, as the programme of development and validation may be iterative. It is possible that performing these different activities will involve a number of separate individuals and/or organizations, each of whom undertake one or more of these activities. This part of ISO 11137 does not specify the particular individuals or organizations to carry out the activities.



# Sterilization of health care products — Radiation —

## Part 1:

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

## 1 Scope

**1.1** This part of ISO 11137 specifies requirements for the development, validation and routine control of a radiation sterilization process for medical devices.

**NOTE** Although the scope of this part of ISO 11137 is limited to medical devices, it specifies requirements and provides guidance that may be applicable to other products and equipment.

This part of ISO 11137 covers radiation processes employing irradiators using,

- a) the radionuclide  $^{60}\text{Co}$  or  $^{137}\text{Cs}$ ,
- b) a beam from an electron generator
- or
- c) a beam from an X-ray generator.

**1.2** This part of ISO 11137 does not specify requirements for development, validation and routine control of a process for inactivating the causative agents of spongiform encephalopathies such as scrapie, bovine spongiform encephalopathy and Creutzfeld-Jakob disease. Specific recommendations have been produced in particular countries for the processing of materials potentially contaminated with these agents.

**NOTE** See, for example, ISO 22442-1, ISO 22442-2 and ISO 22442-3.

**1.2.1** This part of ISO 11137 does not detail specified requirements for designating a medical device as sterile.

**NOTE** Attention is drawn to regional and national requirements for designating medical devices as “sterile.” See, for example, EN 556-1 or ANSI/AAMI ST67.

**1.2.2** This part of ISO 11137 does not specify a quality management system for the control of all stages of production of medical devices.

**NOTE** It is not a requirement of this part of ISO 11137 to have a complete quality management system during manufacture, but the elements of a quality management system that are the minimum necessary to control the sterilization process are normatively referenced at appropriate places in the text (see, in particular, [Clause 4](#)). Attention is drawn to the standards for quality management systems (see ISO 13485) that control all stages of production of medical devices, including the sterilization process. Regional and national regulations for the provision of medical devices might require implementation of a complete quality management system and the assessment of that system by a third party.

**1.2.3** This part of ISO 11137 does not require that biological indicators be used for validation or monitoring of radiation sterilization, nor does it require that a pharmacopoeial test for sterility be carried out for product release.