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**Sterilization of health care products –
Radiation –
Part 2: Establishing the sterilization dose (ISO 11137-2:2013);
English version EN ISO 11137-2:2015,
English translation of DIN EN ISO 11137-2:2015-11**

Sterilisation von Produkten für die Gesundheitsfürsorge –
Strahlen –
Teil 2: Festlegung der Sterilisationsdosis (ISO 11137-2:2013);
Englische Fassung EN ISO 11137-2:2015,
Englische Übersetzung von DIN EN ISO 11137-2:2015-11

Stérilisation des produits de santé –
Irradiation –
Partie 2: Établissement de la dose stérilisante (ISO 11137-2:2013);
Version anglaise EN ISO 11137-2:2015,
Traduction anglaise de DIN EN ISO 11137-2:2015-11

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Translation by DIN-Sprachendienst.
In case of doubt, the German-language original shall be considered authoritative.

A comma is used as the decimal marker.

National foreword

This document (EN ISO 11137-2:2015) has been prepared by Technical Committee ISO/TC 198 “Sterilization of health care products” in collaboration with Technical Committee CEN/TC 204 “Sterilizers for medical purposes” (Secretariat: BSI, United Kingdom).

The responsible German body involved in its preparation was *DIN-Normenausschuss Medizin* (DIN Standards Committee Medical), Working Committee NA 063-01-07 AA *Sterilisation von Medizinprodukten*.

According to Resolution CEN/BT C52/2015 Annexes ZA, ZB and ZC and the European Foreword have been updated and published in June 2015 as a new edition of EN ISO 11137-2:2015. Thus, this new edition of DIN EN ISO 11137-2 has also been published. This document contains ISO 11137-2:2013, unchanged.

DIN EN 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*

The DIN Standards corresponding to the International Standards referred to in this document are as follows:

ISO 11137-1	DIN EN ISO 11137-1
ISO 11137-3	DIN EN ISO 11137-3
ISO 11737-1	DIN EN ISO 11737-1
ISO 11737-2	DIN EN ISO 11737-2
ISO 13485	DIN EN ISO 13485
ISO 14971	DIN EN ISO 14971

Amendments

This standard differs from DIN EN ISO 11137-2:2013-09 as follows:

- a) the European foreword has been updated;
- b) Annex ZA (informative) “Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on active implantable medical devices” has been updated;
- c) Annex ZB (informative) “Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices” has been updated;
- d) Annex ZC (informative) “Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EEC on *in vitro* diagnostic medical devices” has been updated.

Previous editions

DIN EN 552: 1994-11, 2001-02

DIN EN 552 Corrigendum 1: 1999-07

DIN EN ISO 11137-2: 2006-07, 2007-09, 2012-07, 2013-09

DIN EN ISO 11137-2 Corrigendum 1: 2009-09

National Annex NA
(informative)

Bibliography

DIN EN 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*

DIN EN ISO 11137-3, *Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects*

DIN EN ISO 11737-1, *Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products*

DIN EN ISO 11737-2, *Sterilization of medical devices — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*

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

DIN EN ISO 14971, *Medical devices — Application of risk management to medical devices*

English Version

**Sterilization of health care products - Radiation -
Part 2: Establishing the sterilization dose
(ISO 11137-2:2013)**

Stérilisation des produits de santé - Irradiation - Partie 2:
Établissement de la dose stérilisante (ISO 11137-2:2013)

Sterilisation von Produkten für die Gesundheitsfürsorge -
Strahlen - Teil 2: Festlegung der Sterilisationsdosis
(ISO 11137-2:2013)

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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Foreword

The text of ISO 11137-2:2013 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 11137-2:2015 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 11137-2:2013.

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 and ZC, which are integral parts 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 11137	EN ISO 11137-1:2006/A1:2013	ISO 11137-1:2006/A1:2013
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

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, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 11137-2:2013 has been approved by CEN as EN ISO 11137-2:2015 without any modification.

Introduction

This part of ISO 11137 describes methods that can be used to establish the sterilization dose in accordance with one of the two approaches specified in 8.2 of ISO 11137-1:2006. The methods used in these approaches are:

- dose setting to obtain a product-specific dose;
- dose substantiation to verify a preselected dose of 25 kGy or 15 kGy.

The basis of the dose setting methods described in this part of ISO 11137 (Methods 1 and 2) owe much to the ideas first propounded by Tallentire^{[19][20][21]}. Subsequently, standardized protocols were developed^{[10][11]}, which formed the basis of the dose setting methods detailed in the AAMI Recommended Practice for Sterilization by Gamma Radiation^{[6][8]}.

Methods 1 and 2 and the associated sterilization dose audit procedures use data derived from the inactivation of the microbial population in its natural state on product. The methods are based on a probability model for the inactivation of microbial populations. The probability model, as applied to bioburden made up of a mixture of various microbial species, assumes that each such species has its own unique D_{10} value. In the model, the probability that an item will possess a surviving microorganism after exposure to a given dose of radiation is defined in terms of the initial number of microorganisms on the item prior to irradiation and the D_{10} values of the microorganisms. The methods involve performance of tests of sterility on product items that have received doses of radiation lower than the sterilization dose. The outcome of these tests is used to predict the dose needed to achieve a predetermined sterility assurance level (SAL).

Methods 1 and 2 can also be used to substantiate 25 kGy if, on performing a dose setting exercise, the derived sterilization dose for an SAL of 10^{-6} is less than or equal to 25 kGy. The basis of the method devised specifically for substantiation of 25 kGy, Method VD_{max} , was put forward by Kowalski and Tallentire^[16]. Subsequent evaluations involving computational techniques demonstrated that the underlying principles were soundly based^[15] and field trials confirmed that Method VD_{max} is effective in substantiating 25 kGy for a wide variety of medical devices manufactured and assembled in different ways^[18].

A standardized procedure for the use of VD_{max} for substantiation of a sterilization dose of 25 kGy has been published in the AAMI Technical Information Report *Sterilization of health care products — Radiation sterilization — Substantiation of 25 kGy as a sterilization dose — Method VD_{max}* ^[7], a text on which the method described herein is largely based. Method VD_{max} is founded on dose setting Method 1 and, as such, it possesses the high level of conservativeness characteristic of Method 1. In a similar manner to the dose setting methods, it involves performance of tests of sterility on product items that have received a dose of radiation lower than the sterilization dose. The outcomes of these tests are used to substantiate that 25 kGy achieves an SAL of 10^{-6} .

To link the use of VD_{max} for the substantiation of a particular preselected sterilization dose, the numerical value of the latter, expressed in kilograys, is included as a superscript to the VD_{max} symbol. Thus, for substantiation of a sterilization dose of 25 kGy, the method is designated Method VD_{max}^{25} .

Method VD_{max}^{15} is based on the same principles as Method VD_{max}^{25} . The test procedure is similar to that of Method VD_{max}^{25} , but Method VD_{max}^{15} is limited to product with an average bioburden less than or equal to 1,5. The outcomes of the associated tests of sterility are used to substantiate that 15 kGy achieves a sterility assurance level of 10^{-6} .

This part of ISO 11137 also describes methods that can be used to carry out sterilization dose audits in accordance with ISO 11137-1:2006, Clause 12. Following establishment of the sterilization dose, sterilization dose audits are performed routinely to confirm that the sterilization dose continues to achieve the desired SAL.

1 Scope

This part of ISO 11137 specifies methods for determining the minimum dose needed to achieve a specified requirement for sterility and methods to substantiate the use of 25 kGy or 15 kGy as the sterilization dose to achieve a sterility assurance level, SAL, of 10^{-6} . This part of ISO 11137 also specifies methods of sterilization dose audit used to demonstrate the continued effectiveness of the sterilization dose.

This part of ISO 11137 defines product families for sterilization dose establishment and sterilization dose audit.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 the development, validation and routine control of a sterilization process for medical devices*

ISO 11737-1, *Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products*

ISO 11737-2, *Sterilization of medical devices — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*

3 Terms, definitions, and abbreviated terms

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

3.1 Terms and definitions

3.1.1

batch

defined quantity of product, intended or purported to be uniform in character and quality, which has been produced during a defined cycle of manufacture

[ISO/TS 11139:2006, definition 2.1]

3.1.2

bioburden

population of viable microorganisms on or in product and/or sterile barrier system

[ISO/TS 11139:2006, definition 2.2]