SLOVENSKI STANDARD
kSIST-TS FprCEN ISO/TS 13004:2014

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Sterilizacija izdelkov za zdravstveno nego - Sevanje - Utemeljitev izbranega odmerka sterilizacije: metoda VDmaxSD (ISO/TS 13004:2013)

Sterilization of health care products - Radiation - Substantiation of selected sterilization dose: Method VDmaxSD (ISO/TS 13004:2013)

Stérilisation des produits de santé - Irradiation - Justification de la dose de stérilisation choisie: méthode VDmaxSD (ISO/TS 13004:2013)

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TECHNICAL SPECIFICATION

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ICS

English Version

Sterilization of health care products - Radiation - Substantiation of selected sterilization dose: Method VDmaxSD (ISO/TS 13004:2013)

Stérilisation des produits de santé - Irradiation - Justification de la dose de stérilisation choisie: méthode VDmaxSD (ISO/TS 13004:2013)

Sterilisation von Produkten für die Gesundheitsfürsorge - Strahlen - Bestätigung der gewählten Sterilisationsdosis: Methode VDmaxSD (ISO/TS 13004:2013)

This draft Technical Specification is submitted to CEN members for formal vote. It has been drawn up by the Technical Committee CEN/TC 204.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

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Foreword

The text of ISO/TS 13004:2013 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 FprCEN ISO/TS 13004:2014 by Technical Committee CEN/TC 204 “Sterilization of medical devices” the secretariat of which is held by BSI.

This document is currently submitted to the Formal Vote.

Endorsement notice

The text of ISO/TS 13004:2013 has been approved by CEN as FprCEN/TS ISO 13004:2014 without any modification.

TECHNICAL SPECIFICATION

ISO/TS 13004

First edition
2013-05-01

Sterilization of health care products — Radiation — Substantiation of selected sterilization dose: Method VD_{max}^{SD}

Stérilisation des produits de santé — Irradiation — Justification de la dose de stérilisation choisie: méthode VD_{max}^{SD}

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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.

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.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

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— an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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/TS 13004 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products.*

Introduction

This Technical Specification is intended to be used in conjunction with 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*. One of the activities encompassed within process definition in ISO 11137-1 is the option to select and substantiate a sterilization dose to be applied to health care products.

ISO 11137-2 includes Method VD_{max} for the substantiation of 25 kGy as a sterilization dose (termed Method VD_{max}^{25}) for product with an average bioburden less than or equal to 1 000 and Method VD_{max}^{15} for the substantiation of 15 kGy as a sterilization dose for product with an average bioburden less than or equal to 1,5.

This Technical Specification extends the methods of selection and substantiation of a sterilization dose specified in ISO 11137-2. It provides a methodology for the substantiation of selected sterilization doses of 17,5, 20, 22,5, 27,5, 30, 32,5 and 35 kGy, each of which is valid only for a specified upper limit of average bioburden.

NOTE Selected sterilization doses of 25 kGy and 15 kGy are not included in this Technical Specification. The seven methods in this Technical Specification follow the same technical steps as the methods given in ISO 11137-2 for selection and substantiation of sterilization doses of 25 kGy and 15 kGy. However, the descriptive text in this Technical Specification has been modified to better communicate the methods and hence the text occasionally differs from that in ISO 11137-2.

The method described in this Technical Specification is for substantiation of a selected sterilization dose to achieve a sterility assurance level (SAL) of 10^{-6} or less at that dose, (e.g. Method VD_{max}^{20} for a selected sterilization dose of 20 kGy). The application of the method is not limited by production batch size or production frequency, and the number of product items irradiated in the verification dose experiment remains constant. The method is founded on and embodies the following three principles:

— existence of a direct link between the outcome of the verification dose experiment and the attainment of an SAL of 10^{-6} at the selected sterilization dose;

— possession of a level of conservativeness at least equal to that of the standard distribution of resistances (SDR);

— for a given bioburden, use of a maximal verification dose (VD_{max}) corresponding to substantiation of a selected sterilization dose.

This approach to sterilization dose substantiation was first outlined by Kowalski and Tallentire[6] and, from subsequent evaluations involving computational techniques (Kowalski, Aoshuang and Tallentire[7]) and field evaluations (Kowalski et al[8]), it was concluded that the method is soundly based. An overview of the method and aspects of putting it into practice are provided in Kowalski and Tallentire.[9][10] Application of the Method VD_{max} approach to doses other than 25 kGy is discussed in Kowalski and Tallentire.[11][12]

The method described here and designated Method VD_{max}^{SD} procedurally comprises elements that closely parallel those of dose setting Method 1 described in ISO 11137-2. One key area of difference is the number of product items used in the verification dose experiment. In the computer evaluations referred to above, changing the verification SAL value had little effect on the substantiation outcome and this finding led to a sample size of 10 product items being chosen for subsequent field evaluations and, ultimately, for inclusion in this document.

Manufacturers of health care products who intend to use this specification are reminded that the requirements contained in ISO 11137 apply to the manufacture and control of production batches destined for radiation sterilization. In particular, one requirement states that products have to be manufactured in circumstances such that the bioburden is controlled. Compliance with the requirements for controlling the quality of raw materials, the manufacturing environment, the health, hygiene and attire of personnel and for establishing the basic properties of packaging material is essential.

Sterilization of health care products — Radiation — Substantiation of selected sterilization dose: Method VD_{max}^{SD}

1 Scope

1.1 Inclusions

This Technical Specification describes a method for substantiating a selected sterilization dose of 17,5, 20, 22,5, 27,5, 30, 32,5 or 35 kGy that achieves a sterility assurance level (SAL) of 10^{-6} or less for radiation sterilization of health care products. This Technical Specification also specifies a method of sterilization dose audit used to demonstrate the continued effectiveness of the substantiated sterilization dose.

NOTE Selection and substantiation of the sterilization dose is used to meet the requirements for establishing the sterilization dose within process definition in ISO 11137-1.

1.2 Exclusions

This method is for the substantiation of a selected sterilization dose of 17,5, 20, 22,5, 27,5, 30, 32,5, or 35 kGy only and is not used to substantiate other sterilization doses. The method is not used for the substantiation of a selected sterilization dose if the average bioburden of the entire product item exceeds the limit specified for the selected sterilization dose (see Table 3).

NOTE The methods for substantiation of selected sterilization doses of 25 kGy and 15 kGy are not included in this Technical Specification; they are described in ISO 11137-2.

1.3 Application

If the decision is made to use this method of sterilization dose establishment, the method is to be followed according to the requirements (shall) and guidance (should) stipulated herein.

2 Normative references

The following referenced documents are indispensable for the application 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 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 and definitions

For the purposes of this document, the following abbreviations, terms and definitions apply.

3.1
batch
defined quantity of product, intended or purported to be uniform in character and quality, that has been produced during a defined cycle of manufacture

[SOURCE: ISO/TS 11139:2006, 2.1]

3.2
bioburden
population of viable microorganisms on or in product and/or sterile barrier system

[SOURCE: ISO/TS 11139:2006, 2.2]

3.3
correction
action to eliminate a detected nonconformity

Note 1 to entry: A correction can be made in conjunction with corrective action (3.4).

[SOURCE: ISO 9000:2005, 3.6.6, modified]

3.4
corrective action
action to eliminate the cause of a detected nonconformity or other undesirable situation

Note 1 to entry: There can be more than one cause for a nonconformity.

Note 2 to entry: Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

Note 3 to entry: There is a distinction between correction and corrective action.

[SOURCE: ISO 9000:2005, 3.6.5]

3.5
dose
absorbed dose
quantity of ionizing radiation energy imparted per unit mass of specified material

Note 1 to entry: The unit of absorbed dose is the gray (Gy), where 1 Gy is equivalent to the absorption of 1 J/kg.

Note 2 to entry: For the purposes of this document, the term dose is used to mean absorbed dose.

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

3.6
dose mapping
measurement of dose distribution and variability in material irradiated under defined conditions

[SOURCE: ISO 11137-1:2006, 3.10]

3.7
false positive
test result interpreted as growth arising from product, or portion thereof, tested when either growth resulted from extraneous microbial contamination or turbidity occurred from interaction between the product, or portion thereof, and the test medium

[SOURCE: ISO 11137-2:2012, 3.1.3]

3.8
health care product(s)
medical device(s), including in vitro diagnostic medical device(s), or medicinal product(s), including biopharmaceutical(s)

[SOURCE: ISO/TS 11139:2006, 2.20]

3.9
medical device
instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material, or other related article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

— diagnosis, prevention, monitoring, treatment, or alleviation of disease;

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

— investigation, replacement, modification, or support of the anatomy or of a physiological process;

— supporting or sustaining life;

— control of conception;

— disinfection of medical devices;

— providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body;

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

Note 1 to entry: This definition from ISO 13485 has been developed by the Global Harmonization Task Force (GHTF 2002)

[SOURCE: ISO 13485:2003, 3.7, modified]

3.10
Method VD_{max}
procedure for sterilization dose substantiation that uses the maximal verification dose for a given bioburden, consistent with the attainment of a SAL of 10^{-6} at a selected sterilization dose

Note 1 to entry: The substantiation method is generally referred to as Method VD_{max}^{SD}, where SD takes the value of the selected sterilization dose.

3.11
microorganism
entity of microscopic size, encompassing bacteria, fungi, protozoa and viruses

Note 1 to entry: A specific standard might not require demonstration of the effectiveness of the sterilization process in inactivating all types of microorganisms, identified in the definition above, for validation and/or routine control of the sterilization process.

[SOURCE: ISO/TS 11139:2006, 2.26]

3.12
packaging system
combination of the sterile barrier system and protective packaging

[SOURCE: ISO/TS 11139:2006, 2.28]