PD CEN ISO/TS 13004:2014

BSI Standards Publication

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

urrently in preview, click buy full vers

bsi.

...making excellence a habit.™

National foreword

This Published Document is the UK implementation of CEN ISO/TS 13004:2014. It is identical to ISO/TS 13004:2013. It supersedes PD ISO/TS 13004:2013, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/198, Sterilization of medical devices.

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 2014.
Published by BSI Standards Limited 2014

ISBN 978 0 580 85152 0

ICS 11.080.01

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 28 February 2014.

Amendments/corrigenda issued since publication

Date	Text affected
31 July 2014	This corrigendum renumbers PD ISO/TS 13004:2013 as PD CEN ISO/TS 13004:2014

urrently in preview, click buy full versi

TECHNICAL SPECIFICATION

SPÉCIFICATION TECHNIQUE

TECHNISCHE SPEZIFIKATION

CEN ISO/TS 13004

May 2014

ICS 11.080.01

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 Technical Specification (CEN/TS) was approved by CEN on 27 May 2014 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

CEN members are required to announce the existence of this CEN/TS in the same way as for an EN and to make the CEN/TS available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the CEN/TS) until the final decision about the possible conversion of the CEN/TS into an EN is reached.

CEN members are the national standards bodies of 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 United Kingdom.

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

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

© 2014 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members.

Ref. No. CEN ISO/TS 13004:2014 E

Currently in preview, click buy full version

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

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.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this Technical Specification: 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/TS 13004:2013 has been approved by CEN as CEN ISO/TS 13004:2014 without any modification.

urrently in preview, click buy full versi

© ISO 2013 – All rights reserved

Contents

Page

Foreword ..... **iv**

Introduction ..... **v**

1 Scope **1**
1.1 Inclusions 1
1.2 Exclusions 1
1.3 Application 1

2 Normative references **1**

3 Terms and definitions **1**

4 Definition and maintenance of product families for sterilization dose substantiation and sterilization dose auditing **5**
4.1 General 5
4.2 Defining product families 5
4.3 Designation of product to represent a product family 6
4.4 Maintaining product families 7
4.5 Consequence of failure of sterilization dose substantiation or sterilization dose audit 8

5 Selection and testing of product for substantiating and auditing a selected sterilization dose **8**
5.1 Nature of product 8
5.2 Sample item portion (SIP) 9
5.3 Manner of sampling 10
5.4 Microbiological testing 11
5.5 Irradiation 11

6 Method VD_{max}^{SD} — Substantiation of a selected sterilization dose of 17,5, 20, 22,5, 27,5, 30, 32,5, or 35 kGy **11**
6.1 Rationale 11
6.2 Procedure for Method VD_{max}^{SD} for multiple production batches 12
6.3 Procedure for Method VD_{max}^{SD} for a single production batch 17

7 Maintaining process effectiveness **21**
7.1 General 21
7.2 Determination of bioburden 22
7.3 Sterilization dose audit 22

8 Tables of values for SIP equal to 1,0 VD_{max}^{SD}, SIP dose reduction factor and augmentation dose corresponding to applicable values of average bioburden for selected sterilization doses of 17,5, 20, 22,5, 27,5, 30, 32,5 and 35 kGy **27**

9 Worked examples **53**
9.1 Substantiation of a selected sterilization dose of 17,5 kGy (SIP less than 1,0) 53
9.2 Substantiation of a selected sterilization dose of 30 kGy (SIP equal to 1,0) 54
9.3 Sterilization dose audit for a sterilization dose substantiated using Method $VD_{max}^{22,5}$, the findings from which necessitated augmentation of the sterilization dose 55

Bibliography **57**

Currently in preview, click buy full version

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:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;

— 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.*

urrently in preview, click buy full versi

 © ISO 2013 – All rights reserved

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.

Currently in preview, click buy full version

© ISO 2013 – All rights reserved

urrently in preview, click buy full versi

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.

Currently in preview, click buy full version

© ISO 2013 – All rights reserved