Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the validation of a sterilization process

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EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 11737-2:2000 sisaldab Euroopa standardi EN ISO 11737-2:2000 ingliskeelset teksti. Käesolev dokument on jõustatud 08.08.2000 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 11737-2:2000 consists of the English text of the European standard EN ISO 11737-2:2000. This document is endorsed on 08.08.2000 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This Part of the Standard specifies the general criteria for tests of sterility on medical devices which have been exposed to a treatment with the sterilizing agent that is a fraction of the specified sterilization process.	**Scope:** This Part of the Standard specifies the general criteria for tests of sterility on medical devices which have been exposed to a treatment with the sterilizing agent that is a fraction of the specified sterilization process.

ICS 07.100.10, 11.080

Võtmesõnad:

EUROPEAN STANDARD
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English version

Sterilization of medical devices – Microbiological methods

Part 2: Tests of sterility performed in the validation of a sterilization process (ISO 11737-2 : 1998)

Stérilisation des dispositifs médicaux – Méthodes microbiologiques – Partie 2: Essais de stérilité pratiqués en cours de validation d'un procédé de stérilisation (ISO 11737-2 : 1998)

Sterilisation von Medizinprodukten – Mikrobiologische Verfahren – Teil 2: Sterilitätsprüfungen bei der Validierung eines Sterilisationsverfahrens (ISO 11737-2 : 1998)

This European Standard was approved by CEN on 1999-12-17.

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 Central Secretariat or to any CEN member.

The European Standards exist in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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CEN

European Committee for Standardization
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Europäisches Komitee für Normung

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Foreword

International Standard

ISO 11737-2 : 1998 Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process,

which was prepared by ISO/TC 198 'Sterilization of health care products' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 204 'Sterilization of medical devices', the Secretariat of which is held by BSI, as a European Standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by August 2000 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 11737-2 : 1998 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to international publications are listed in Annex ZA (normative).

Contents

Introduction

A sterile product item is one which is free of viable microorganisms. The International Standards for sterilization of medical devices require, when it is necessary to supply a sterile product item, that adventitious microbiological contamination of a medical device from all sources be minimized by all practical means. Even so, product items produced under standard manufacturing conditions in accordance with the requirements for quality systems for medical devices may, prior to sterilization, have microorganisms on them, albeit in low numbers. Such product items are non-sterile. The purpose of sterilization processing is to inactivate the microbiological contaminants and thereby transform the non-sterile items into sterile ones.

The inactivation of a pure culture of microorganisms by physical and/or chemical agents used to sterilize medical devices often approximates an exponential relationship; 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 item in a population of items subjected to sterilization processing cannot be guaranteed, and the sterility of the processed population of items has to be defined in terms of the probability of the existence of a non-sterile item in that population.

Requirements for the quality system for the design/development, production, installation and servicing of medical devices are given in ISO 9001 and ISO 9002 in conjunction with ISO 13485 and ISO 13488, respectively.

The ISO 9000 series of standards designates certain processes used in manufacture as 'special' if the results cannot be fully verified by subsequent inspection and testing of the product. Sterilization is an example of a special process because process efficacy cannot be verified by inspection and testing of the product. For this reason, sterilization processes have to be validated before use, the performance of the process monitored routinely and the equipment maintained.

International Standards specifying procedures for the validation and routine control of the processes used for sterilization of medical devices have been prepared (see ISO 11134, 11135 and 11137). An element of this validation may consist of exposing medical devices to the sterilizing agent when the extent of treatment has been reduced relative to that which will be used in routine processing in order to provide a knowledge of the resistance to the agent of the microbial contamination as it occurs naturally on medical devices. Subsequent to this exposure, medical devices are subjected individually to tests of sterility as described in this part of ISO 11737. An example of the use of such a test is in establishing a sterilizing dose for sterilization by radiation and for demonstrating the continued validity of this sterilization dose (see ISO 11137, Annex B).

Annex A of this part of ISO 11737 gives guidance on the techniques used and on practical aspects of the requirements.

1 Scope

1.1 This part of ISO 11737 specifies the general criteria for tests of sterility on medical devices which have been exposed to a treatment with the sterilizing agent that is a fraction of the specified sterilization process. These tests are intended to be performed when validating a sterilization process.

1.2 This part of ISO 11737 is not applicable to:

a) sterility testing for routine release of product that has been subjected to a sterilization process;

b) performance of a pharmacopoeial test for sterility; or

NOTE 1 The performance of a) or b) above is not a requirement of ISO 11134, 11135 or 11137.

c) culturing of biological indicators, including inoculated products.

NOTE 2 Methods of culturing biological indicators are described in ISO 11138.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 11737. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 11737 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 9001:1994, *Quality Systems — Model for quality assurance in design, development, production, installation and servicing.*

ISO 9002:1994, *Quality systems — Model for quality assurance in production, installation and servicing.*

3 Terms and definitions

For the purposes of this part of ISO 11737, the following terms and definitions apply.

3.1
aerobic organism
microorganisms that utilize oxygen as the final electron acceptor during metabolism and which will only grow in the presence of oxygen