Meditsiiniseadmete steriliseerimine. Niiske kuumusega steriliseerimise valideerimine ja rutiinkontroll

Sterilization of medical devices - Validation and routine control of sterilization by moist heat

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 554:2003 sisaldab Euroopa standardi EN 554:1994 ingliskeelset teksti.	This Estonian standard EVS-EN 554:2003 consists of the English text of the European standard EN 554:1994.
Standard on kinnitatud Eesti Standardikeskuse 23.11.1999 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 23.11.1999 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
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English version

Sterilization of medical devices

Validation and routine control of sterilization by moist heat

Stérilisation de dispositifs médicaux; validation et contrôle de routine de la stérilisation à la vapeur d'eau

Sterilisation von Medizinprodukten; Validierung und Routineüberwachung für die Sterilisation mit feuchter Hitze

This European Standard was approved by CEN on 1994-06-27.

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.

This European Standard exists 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.

CEN members are the national standards bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Contents

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 204 'Sterilization of medical devices', the Secretariat of which is held by BSI.

This European Standard has been prepared under a mandate given to CEN by the Commission of the European Communities and the European Free Trade Association and supports essential requirements of the relevant EC Directives.

This European Standard has been considered by CEN/TC 204 as one of a series of European Standards dealing with three common sterilization processes and their control. These standards are:

EN 550 Sterilization of medical devices; validation and routine control of ethylene oxide sterilization

EN 552 Sterilization of medical devices; validation and routine control of sterilization by irradiation

EN 554 Sterilization of medical devices; validation and routine control of sterilization by moist heat

EN 556 Sterilization of medical devices; requirements for medical devices to be labelled 'STERILE'

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 December 1994 at the latest.

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

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

Introduction

A *sterile* product item is one which is free of viable micro-organisms. The European standards for *medical devices* require, when it is necessary to supply a *sterile* product item, that adventitious microbiological contamination of a *medical device* from all sources is 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* (see EN 46001 or EN 46002) may, prior to sterilization, have micro-organisms 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 micro-organisms by physical and chemical agents used to sterilize *medical devices* often approximates to an exponential relationship; inevitably this means that there is always a finite probability that a micro-organism 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 micro-organisms 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. The value taken by this probability is specified elsewhere (see EN 556). However, the principles specified in this standard are applicable irrespective of the stated probability.

Requirements for the quality system for the design/development, production, installation and servicing of *medical devices* are given in EN 46001 and EN 46002 which supplement the EN 29000 series of European Standards.

The EN 29000 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.

It is important to be aware that exposure to a properly validated and accurately controlled sterilization process is not the only factor associated with the provision of reliable assurance that the product is *sterile* and, in this respect, suitable for its intended use. Attention has also to be given to a number of factors including the microbiological status (*bioburden*) of incoming raw materials and/or components, their subsequent storage and to the control of the environment in which the product is manufactured, assembled and packaged.

The object of this European Standard is standardization in the field of *validation* and routine monitoring of moist heat sterilization processes and procedures that are carried out by those who sterilize *medical devices*. The *validation* of sterilization procedures presupposes that the sterilizer complies with appropriate specifications.

This standard contains requirements for the *validation* and routine monitoring of sterilization by moist heat; guidance on the application of this standard is offered in informative annex A.

NOTE: The requirements are the obligatory parts of this standard in that these are to be observed if compliance is to be achieved. The guidance given in annex A, which includes methods accepted as being suitable for achieving compliance with the requirements, is not obligatory and it is not provided as a check list for auditors.

1 Scope

1.1 This European Standard specifies requirements for the process development, *validation*, process control and monitoring of the sterilization of *medical devices* using *moist heat*.

1.2 The method is based on the monitoring of the physical factors that cause the product to become sterile and presupposes that prior to *validation* the sterilizer and its installation comply with an appropriate specification.

NOTE: Specifications for sterilizers are being prepared by CEN/TC 102.

1.3 This European Standard does not describe a quality assurance system for the control of all stages of manufacture.

NOTE: Attention is drawn to the standards for quality systems (see EN 46001 or EN 46002) which control all stages of manufacture including the sterilization process. It is not a requirement of this standard to have a complete quality system during manufacture but certain elements of such a system are required and these are normatively referenced at appropriate places in the text.

1.4 This European Standard does not address the routine testing of samples (sterility testing) or the use of *biological indicators* as, except in a limited number of special applications, these practices are of limited value in *moist heat* sterilization. In such special applications, they should be regarded as additional to the measurement of physical parameters.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 556[1)]	Sterilization of medical devices - Requirements for medical devices to be labelled 'STERILE'
EN 1174-1[1)]	Sterilization of medical devices - Estimation of the population of micro-organisms on product Part 1: Requirements
EN 29001 : 1987	Quality systems - Model for quality assurance in design/development, production, installation and servicing
EN 29002 : 1987	Quality systems - Model for quality assurance in production and installation
EN 46001 : 1993	Particular requirements for the application of EN 29001 for medical devices
EN 46002 : 1993	Particular requirements for the application of EN 29002 for medical devices

3 Definitions

For the purposes of this standard the following definitions apply.

3.1 bioburden: Population of viable micro-organisms on a product and/or a package.

3.2 biological indicator: *Inoculated carrier* contained within its primary pack.

3.3 chamber temperature: Lowest temperature prevailing in the *sterilizer chamber*.

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1) In preparation.