SLOVENSKI STANDARD
SIST EN 554:2000

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Sterilizacija medicinskih pripomoļ kov - Validacija in redni nadzor sterilizacije z vlaģno toploto

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

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

Stérilisation de dispositifs médicaux - Validation et contrôle de routine pour la stérilisation a la vapeur d'eau

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

Stérilisation de dispositifs médicaux - Validation et contrôle de routine pour la stérilisation à la vapeur d'eau

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

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CEN

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

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Contents

Foreword

This European Standard has been prepared by the 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 European Commission and the European Free Trade Association, and supports essential requirements of EC Directive(s).

This standard has been considered by CEN/TC 204 as one of a sequence of European standards concerned 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"

In this European Standard the terms defined in clauses 3 are in italic type.

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of an identical text or by endorsement, at the latest by December 1994, and conflicting national standards shall be withdrawn at the latest by December 1994.

According to 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, 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.

3.4 **commissioning**: Obtaining and documenting evidence that equipment has been provided and installed in accordance with its specifications and that it functions within pre-determined limits when operated in accordance with operational instructions.

3.5 **equilibration time**: Period which elapses between the attainment of the *sterilization temperature* in the *sterilizer chamber* and the attainment of the *sterilization temperature* at all points within the load.

3.6 **holding time**: Period for which the temperature of all points within the *sterilizer load* is held within the *sterilization temperature band*.

NOTE: The *holding time* follows immediately after the *equilibration time*. The extent of the *holding time* is related to the *sterilization temperature*.

3.7 **inoculated carrier**: Piece of supporting material on which a defined number of specified micro-organisms has been deposited.

3.8 **installation qualification**: See *commissioning* (3.4).

3.9 **installation test**: Series of checks and tests performed after installation of the sterilizer in the place of use.

3.10 **medical device**: (The definition given in EN 46001 applies.)

3.11 **moist heat**: Heat that is derived from water, either as a liquid or as steam under pressure.

3.12 **national standard**: Standard recognized by an official national decision as the basis for fixing the value(s), in a country, of all other standards of the quantity concerned.

NOTE: The *national standard* in a country is often a *primary standard*.

3.13 **parametric release**: Declaring product as "sterile" based on physical process data rather than on the basis of sample testing or *biological indicator* results.

3.14 **performance qualification**: Obtaining and documenting evidence that the equipment as commissioned will produce acceptable product when operated in accordance with the process specification.

3.15 **performance requalification**: Procedure to confirm data recorded during *performance qualification*.

3.16 **primary standard**: Standard that is designated or widely acknowledged as having the highest metrological qualities and whose values are accepted without reference to other standards.

3.17 product compatibility: Ability of the *sterilization cycle* to achieve the intended results without detrimental effect on the product.

3.18 recommissioning: Procedure to confirm that the sterilizer functions in accordance with its specification and that data established during *commissioning* remain valid.

3.19 reference load: Specified load made up to represent the most difficult combination of products to be sterilized.

3.20 saturated steam: Water vapour at a temperature corresponding to the boiling point of the source liquid.

3.21 sensor: Element of a measuring instrument or measuring chain which is directly applied to the variable to be measured.

3.22 sterile: Condition of a *medical device* that is free from viable micro-organisms. (See EN 556.)

3.23 sterilization cycle: Automatic sequence of operating stages performed in a sterilizer for the purpose of sterilization.

3.24 sterilization temperature: Minimum temperature of the *sterilization temperature band*.

3.25 sterilization temperature band: Range of temperatures, expressed as the *sterilization temperature* and the maximum allowable temperature, which may prevail throughout the load during the *holding time*.

NOTE: These temperatures are usually stated in whole degrees celsius.

3.26 sterilized load: Goods that have been sterilized simultaneously in the same *sterilizer chamber*.

3.27 sterilizer chamber: That part of the sterilizer which receives the *sterilizer load*.

3.28 sterilizer load: Goods that are to be sterilized simultaneously in the same *sterilizer chamber*.

3.29 validation: Documented procedure for obtaining, recording and interpreting data required to show that a process will consistently comply with predetermined specifications.

NOTE: For moist heat sterilization, *validation* is considered as a total programme which consists of *commissioning* and *performance qualification*.

4 General

Medical devices to be sterilized shall be manufactured under conditions that ensure that their *bioburden* is consistently low (see EN 556). Employing a quality system complying with EN 46001 or EN 46002 meets this requirement.

The documented procedures and instructions specified in this standard shall be provided and implemented effectively. Documentation and records shall be reviewed and approved by designated personnel (see **4.1**).

4.1 Personnel

Responsibility for the installation and maintenance of *moist heat* sterilizers, for the *validation* and routine control of *moist heat* sterilization, and for release of sterilized product shall be assigned to qualified personnel as specified in **4.1.2.2** and **4.18** of EN 29001 : 1987 or in **4.1.2.2** and **4.17** of EN 29002 : 1987.

4.2 Product compatibility

4.2.1 Product shall be designed to be compatible with environmental changes occurring in the *sterilizer chamber* during the *sterilization cycle*.

4.2.2 Materials and procedures for packaging shall be specified in documented form and validated.

4.3 Product storage

After sterilization and prior to product release, conditions for product storage and handling shall not compromise the qualities of the product.

4.4 Equipment (sterilizer)

4.4.1 The specification for the sterilizer, including its installation, service requirements and *installation tests*, shall be documented.

4.4.2 The specification for the sterilizer shall include the requirement that the sterilization conditions are reproducibly and uniformly achieved throughout the *sterilizer chamber*. The variables of time, temperature, pressure and degree of saturation of steam shall be specified for the *sterilization cycle*.

These requirements are deemed to be met if:

a) the temperature and pressure in all parts of the *sterilizer chamber* throughout the *sterilization cycle* follow a predetermined profile;

b) throughout the *holding time* the temperatures measured in the *sterilizer chamber*:

1) are within the specified *sterilization temperature band* with the upper limit as the *sterilization temperature* plus 3 K;

2) do not fluctuate by more than 1 K;

3) do not differ from each other by more than 2 K;

c) on *medical devices* when a *saturated steam* environment is required in the *sterilizer chamber*:

1) the steam is at a temperature within the *sterilization temperature band* and at a temperature corresponding to its vapour pressure;

2) the interval of time between the attainment of the *sterilization temperature* in the hottest and coldest parts of the *sterilizer chamber* does not exceed 15 s for *sterilizer chambers* of not more than 800 l and not exceed 30 s for larger *sterilizer chambers*.

4.4.3 Documentary evidence shall be provided to demonstrate that the sterilizer complies with its specification.

4.4.4 The specification for the area in which the sterilizer is installed shall be documented.

4.4.5 The purity of the environment in contact with the *medical devices* shall not impair the safety of the product.

4.4.6 Documentation supplied with the sterilizer shall be written in a language agreed with the purchaser.

4.5 Process

4.5.1 During the *holding time*, the process cycle shall reproducibly cause a sterilizing environment to be present on all surfaces that are required to be *sterile* on the *medical device*.

4.5.2 Physical conditions occurring during the *sterilization cycle* shall not compromise the performance qualities of the *medical device* or its packaging.

4.6 Instrumentation

4.6.1 An effective system shall be established, documented and maintained for the calibration of all controlling, indicating and recording instruments used for *validation* and routine control of the *sterilization cycle*. This system shall comply with 4.11 of EN 29001 : 1987 or with 4.10 of EN 29002 : 1987.