

Meditsiiniseadmete steriliseerimine. Madala temperatuuriga aur ja formaldehüüd. Nõuded meditsiiniseadmete steriliseerimise protsessi väljatöötamiseks, usaldusväärse kontrollimiseks ja rutiinseks kontrollimiseks (ISO 25424:2009)

Sterilization of medical devices - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 25424:2009)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 25424:2011 sisaldab Euroopa standardi EN ISO 25424:2011 ingliskeelset teksti. Standard on kinnitatud Eesti Standardikeskuse 29.07.2011 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas. Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 22.06.2011. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 25424:2011 consists of the English text of the European standard EN ISO 25424:2011. This standard is ratified with the order of Estonian Centre for Standardisation dated 29.07.2011 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation. Date of Availability of the European standard text 22.06.2011. The standard is available from Estonian standardisation organisation.
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English Version

Sterilization of medical devices - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 25424:2009)

Stérilisation des dispositifs médicaux - Formaldéhyde et vapeur à faible température - Exigences pour le développement, la validation et le contrôle de routine d'un procédé de stérilisation pour dispositifs médicaux (ISO 25424:2009)

Sterilisation von Medizinprodukten - Niedertemperatur-Dampf- Formaldehyd - Anforderungen an die Entwicklung, Validierung und Routineüberwachung von Sterilisationsverfahren für Medizinprodukte (ISO 25424:2009)

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COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

The text of ISO 25424:2009 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 EN ISO 25424:2011 by Technical Committee CEN/TC 204 “Sterilization of medical devices” the secretariat of which is held by BSI.

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 2011, and conflicting national standards shall be withdrawn at the latest by December 2011.

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.

This document supersedes EN 15424:2007.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directives.

For relationship with EU Directives, see informative Annex ZA, ZB and ZC, which are integral parts of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 25424:2009 has been approved by CEN as a EN ISO 25424:2011 without any modification.

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on Active Implantable Medical Devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 90/385/EEC on active implantable medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 90/385/EEC

Clauses of this EN	Essential Requirements (ERs) of Directive 90/385/EEC	Qualifying remarks/Notes
4,5,6,7,8,9,10,11,12	7	This relevant Essential Requirement is only partly addressed in this European Standard

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this Standard.

Annex ZB (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZB.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZB.1 — Correspondence between this European Standard and Directive 93/42/EEC

Clauses of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4,5,6,7,8,9,10,11,12	8.3	This relevant Essential Requirement is only partly addressed in this European Standard
4,5,6,7,8,9,10,11,12	8.4	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this Standard.

Annex ZC (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC on *in vitro* diagnostic medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 98/79/EC on *in vitro* diagnostic medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZC.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZC.1 — Correspondence between this European Standard and Directive 98/79/EC

Clauses of this EN	Essential Requirements (ERs) of Directive 98/79/EC	Qualifying remarks/Notes
4,5,6,7,8,9,10,11,12	B.2.3	This relevant Essential Requirement is only partly addressed in this European Standard
4,5,6,7,8,9,10,11,12	B.2.4	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this Standard.

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Introduction

A sterile medical device is one which is free of viable microorganisms. European Standards, which specify requirements for validation and routine control of a sterilization process require, when it is necessary to supply a sterile medical device, that adventitious microbiological contamination of a medical device prior to sterilization be minimized. Even so, medical devices produced under standard manufacturing conditions in accordance with the requirements for quality management systems (see EN ISO 13485) or which have been subjected to a cleaning process as part of their reprocessing in a health care establishment may, prior to sterilization, have microorganisms on them, albeit in low numbers. Such products are non-sterile. The purpose of sterilization is to inactivate the microbiological contaminants and thereby transform the non-sterile products into sterile ones.

The kinetics of inactivation of a pure culture of microorganisms by physical and/or chemical agents used to sterilize medical devices can generally best be described by an exponential relationship between the numbers of microorganisms surviving and the extent of treatment with the sterilizing agent; 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 product in a population subjected to sterilization cannot be guaranteed and the sterility of a processed population is defined in terms of the probability of there being a viable microorganism present on a product item.

This standard describes requirements which will enable the demonstration that a low temperature steam and formaldehyde sterilization process intended to sterilize medical devices has appropriate microbicidal activity, and that this activity is both reliable and reproducible, such that the relationship for the inactivation of microorganisms can be extrapolated with reasonable confidence to low levels of probability of there being a viable microorganism present on a product after sterilization. This standard does not specify the maximal value to be taken by this probability; specification of this probability is given in EN 556-1.

Requirements of the quality management system for medical device design/development, production, installation and servicing are given in EN ISO 13485. The standard for quality management systems recognizes that, for certain processes used in manufacturing or reprocessing, the effectiveness cannot be fully verified by subsequent inspection and testing of the product. Sterilization is an example of such a process. For this reason, sterilization processes are validated for use, the performance of the sterilization process monitored routinely and the equipment maintained.

Exposure to a properly validated, accurately controlled sterilization process is not the only factor associated with the provision of reliable assurance that the product is sterile and, in this regard, suitable for its intended use. Attention is therefore given to a number of factors including:

- a) the microbiological status of incoming raw materials and/or components,
- b) the validation and routine control of any cleaning and disinfection procedures used on the product,
- c) the control of the environment in which the product is manufactured, assembled and packaged,
- d) the control of equipment and processes,
- e) the control of personnel and their hygiene,
- f) the manner and materials in which the product is packaged, and,
- g) the conditions under which the product is transported and stored.

The type of contamination on a product to be sterilized varies and this impacts upon the effectiveness of a sterilization process. Products that have been used in a health care setting and are being presented for re-sterilization in accordance with the manufacturer's instructions (see EN ISO 17664) should be regarded as a special case. There is the potential for such products to possess a wide range of contaminating microorganisms and residual inorganic and/or organic contamination in spite of the application of a cleaning process. Hence, particular attention has to be given to the validation and control of the cleaning and disinfection processes used during reprocessing.

The requirements are the normative parts of this standard with which compliance is claimed. The guidance given in the informative annexes is not normative and is not provided as a checklist for auditors. The guidance provides explanations as well as methods that are accepted as being suitable means for complying with the requirements. Approaches other than those given in the guidance may be used, if they are effective in achieving compliance with the requirements of this European Standard.

The development, validation and routine control of a sterilization process comprise a number of discrete but interrelated activities, for example calibration, maintenance, product definition, process definition, installation qualification, operational qualification, and performance qualification. While the activities required by this standard have been grouped together and are presented in a particular order, this European Standard does not require that the activities be performed in the order that they are presented. The activities required are not necessarily sequential, as the programs of development and validation may be iterative. It is possible that performing these different activities will involve a number of separate individuals and/or organizations, each of whom undertake one or more of these activities. This European Standard does not specify the particular individuals or organizations to carry out the activities.

Activities required by this standard might also give rise to an environmental burden that should be considered and minimized, e.g. by utilizing flexibility in planning. Environmental aspects are addressed in Annex D of this standard.

Sterilization of medical devices — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices

1 Scope

1.1 Inclusions

1.1.1 This European Standard specifies requirements for the development, validation and routine control of a Low Temperature Steam and Formaldehyde (LTSF) sterilization process for medical devices.

NOTE Although the scope of this standard is limited to medical devices, it specifies requirements and provides guidance that may be applicable to other products and equipment.

1.1.2 This European Standard is intended to be applied by process developers, manufacturers of sterilization equipment, manufacturers of medical devices to be sterilized and the organizations with responsibility for sterilizing medical devices. (See EN ISO 14937:2000, Table E.1)

1.1.3 This European Standard covers sterilization processes which use a mixture of low temperature steam and formaldehyde as sterilant, and which are working below ambient pressure only.

1.2 Exclusions

1.2.1 Sterilization processes validated and controlled in accordance with the requirements of this standard should not be assumed to be effective in inactivating the causative agents of spongiform encephalopathies such as scrapie, bovine spongiform encephalopathy and Creutzfeld-Jakob disease. Specific recommendations have been produced in particular countries for the processing of materials potentially contaminated with these agents.

1.2.2 This standard does not specify requirements for designating a medical device as “STERILE”. Such requirements are given in EN 556-1.

1.2.3 This standard does not specify a quality management system for the control of all stages of production of medical devices.

NOTE It is not a requirement of this standard to have a complete quality management system during manufacture or reprocessing, but those elements of such a system that are required are normatively referenced at appropriate places in the text. Attention is drawn to the standards for quality management systems (see EN ISO 13485) that control all stages of production or reprocessing of medical devices including the sterilization process. Further guidance is given in E.2 of EN ISO 14937:2000.

1.2.4 This standard does not specify requirements for occupational safety associated with the design and operation of LTSF sterilization facilities.

NOTE 1 Safety requirements for sterilizers are specified in EN 61010-2-040.

NOTE 2 Attention is also drawn to the existence in some countries of regulations stipulating safety requirements.

1.2.5 This European Standard does not cover analytical methods for determining levels or residues of formaldehyde and/or its reaction products.

NOTE 1 Attention is drawn to EN 14180.

NOTE 2 Attention is drawn to the possible existence in some countries of statutory regulation specifying limits for the level of formaldehyde residues on medical devices and products.

1.2.6 This European Standard does not cover preparatory measures that may be necessary before sterilization such as cleaning, disinfection and packing.

NOTE For re-sterilizable medical devices, the manufacturer(s) of these devices should supply information on the preparatory measures (see EN ISO 17664).

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.

EN 14180:2003, *Sterilizers for medical purposes — Low temperature steam and formaldehyde sterilizers — Requirements and testing*

EN ISO 11138-1, *Sterilization of health care products — Biological indicators — Part 1: General requirements (ISO 11138-1:2006)*

EN ISO 11138-5:2006, *Sterilization of health care products — Biological indicators — Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes (ISO 11138-5:2006)*

EN ISO 11140, *Sterilization of health care products — Chemical indicators* (Parts as appropriate)

EN ISO 11737-1, *Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006)*

EN ISO 11737-2, *Sterilization of medical devices — Microbiological methods — Part 2: Tests of sterility performed in the validation of a sterilization process (ISO 11737-2:1998)*

EN ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2003)*

3 Terms and definitions

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

3.1

adjustment

correction of a measurement device or system to indicate the value as established by calibration

3.2

aeration

part or parts of the sterilization process in which defined conditions are used such that formaldehyde and its reaction products are desorbed from the medical device, and which can be performed within the sterilizer, within a separate room or chamber, or by a combination of the two

[3.3 of EN 14180:2003]