

# **SLOVENSKI STANDARD**

## **SIST EN ISO 25424:2011**

**01-oktober-2011**

**Nadomešča:**  
**SIST EN 15424:2007**

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**Sterilizacija medicinskih pripomočkov - Para nizke temperature in formaldehid -  
Zahteve za razvoj, validacijo in rutinsko kontrolo sterilizacijskih postopkov za  
medicinske pripomočke (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)

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

**Ta slovenski standard je istoveten z: EN ISO 25424:2011**

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**ICS:**

11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general
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**SIST EN ISO 25424:2011**

**en**

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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

EN ISO 25424

June 2011

ICS 11.080.01

Supersedes EN 15424:2007

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)

This European Standard was approved by CEN on 3 June 2011.

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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

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COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

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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	

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## 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	

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# INTERNATIONAL STANDARD

**ISO**  
**25424**

First edition  
2009-09-01

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

*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*

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Reference number  
ISO 25424:2009(E)

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## 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.

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 25424 was prepared by CEN (as EN 15424:2007) and is submitted for approval under a special “fast-track procedure”, by Technical Committee ISO/TC 198, *Sterilization of health care products*, in parallel with its approval by the ISO member bodies.

For the purposes of this International Standard, the CEN annex regarding the fulfilment of European Council Directives has been removed.

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**ISO 25424:2009(E)****Foreword**

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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.

## iTeh STANDARD PREVIEW

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.