SLOVENSKI STANDARD
SIST EN 61010-2-043:1999

01-julij-1999

Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 2-043: Particular requirements for dry heat sterilizers using either hot air or hot inert gas for the treatment of medical materials, and for laboratory processes (IEC 61010-2-043:1997)

Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 2-043: Particular requirements for dry heat sterilizers using either hot air or hot inert gas for the treatment of medical materials, and for laboratory processes

Sicherheitsbestimmungen für elektrische Meß-, Steuer-, Regel- und Laborgeräte -- Teil 2 -043: Besondere Anforderungen an Sterilisatoren bei Verwendung trockener Hitze durch heiße Luft oder heiße inerte Gase zur Behandlung medizinischer Materialien und für Laboranwendungen

Règles de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire -- Partie 2-043: Prescriptions particulières pour les stérilisateurs utilisant de l'air chaud ou un gaz inerte chaud pour le traitement des matériels à usage médical et durant les procédés de traitement de laboratoire

Ta slovenski standard je istoveten z: **EN 61010-2-043:1997**

ICS:

11.080.10	Sterilizacijska oprema	Sterilizing equipment
19.080	Električno in elektronsko preskušanje	Electrical and electronic testing
71.040.10	Kemijski laboratoriji. Laboratorijska oprema	Chemical laboratories. Laboratory equipment

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61010-2-043

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ICS 11.080

Descriptors: Safety, electrical equipment, sterilizers, air or inert gas, treatment of medical materials, laboratory process

English version

Safety requirements for electrical equipment for measurement, control, and laboratory use
Part 2-043: Particular requirements for dry heat sterilizers using either hot air or hot inert gas for the treatment of medical materials, and for laboratory processes
(IEC 61010-2-043:1997)

Règles de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire
Partie 2-043: Prescriptions particulières pour les stérilisateurs utilisant de l'air chaud ou un gaz inerte chaud pour le traitement des matériels à usage médical et durant les procédés de traitement de laboratoire
(CEI 61010-2-043:1997)

Sicherheitsbestimmungen für elektrische Meß-, Steuer-, Regel- und Laborgeräte
Teil 2-043: Besondere Anforderungen an Sterilisatoren bei Verwendung trockener Hitze durch heiße Luft oder heiße inerte Gase zur Behandlung medizinischer Materialien und für Laboranwendungen
(IEC 61010-2-043:1997)

This European Standard was approved by CENELEC on 1997-07-01. CENELEC 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 CENELEC 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 CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

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

CENELEC

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of document 66/159/FDIS, future edition 1 of IEC 61010-2-043, prepared by IEC TC 66, Safety of measuring, control, and laboratory equipment, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 61010-2-43 on 1997-07-01.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1998-04-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1998-04-01

For products which have complied with the relevant national standard before 1998-04-01, as shown by the manufacturer or by a certification body, this previous standard may continue to apply for production until 2003-04-01.

This part 2 is to be used in conjunction with EN 61010-1:1993. Consideration may be given to future editions of, or amendments to, EN 61010-1.

This part 2 supplements or modifies the corresponding clauses of EN 61010-1.
Where a particular clause or subclause of part 1 is not mentioned in this part 2, that clause or subclause applies as far as is reasonable. Where this part 2 states "addition", "modification" or "replacement", the relevant text of part 1 is to be adapted accordingly.

Subclauses which are additional to those in part 1 are numbered starting from 101.

Endorsement notice

The text of the International Standard IEC 61010-2-043:1997 was approved by CENELEC as a European Standard without any modification.

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI IEC 61010-2-043

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GROUP SAFETY PUBLICATION

Règles de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire

Partie 2-043: Prescriptions particulières pour les stérilisateurs à chaleur utilisant de l'air chaud ou un gaz inerte chaud pour le traitement des matériels à usage médical et durant les procédés de traitement de laboratoire

Safety requirements for electrical equipment for measurement, control, and laboratory use

Part 2-043: Particular requirements for dry heat sterilizers using either hot air or hot inert gas for the treatment of medical materials, and for laboratory processes

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE

Part 2-043: Particular requirements for dry heat sterilizers using either hot air or hot inert gas for the treatment of medical materials, and for laboratory processes

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.
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6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 61010-2-043 has been prepared by IEC technical committee 66: Safety of measuring, control, and laboratory equipment.

It has the status of a group safety publication in accordance with IEC Guide 104.

The text of this standard is based on the following documents:

FDIS	Report on voting
66/159/FDIS	66/163/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This part 2 is intended to be used in conjunction with IEC 61010-1. It was established on the basis of the first edition (1990), its amendment 1 (1992) and its amendment 2 (1995). Consideration may be given to future editions of, or amendments to, IEC 61010-1.

This part 2 supplements or modifies the corresponding clauses in IEC 61010-1 so as to convert that publication into the IEC standard: *Safety requirements for* STERILIZERS *using either hot air or hot inert gas for the treatment of medical materials, and for laboratory processes.*

Where a particular subclause of part 1 is not mentioned in this part 2, that subclause applies as far as is reasonable. Where this part states "addition", "modification" or "replacement", the relevant requirement, test specification or note in part 1 should be adapted accordingly.

In this standard:

1) the following print types are used:
   - requirements: in roman type;
   - NOTES: in small roman type;
   - *conformity: in italic type*;
   - terms used throughout this standard which have been defined in clause 3: SMALL ROMAN CAPITALS;
2) subclauses or figures which are additional to those in part 1 are numbered starting from 101.

The word "*Conformity*" is used throughout this standard instead of "*Compliance*" in accordance with the requirements of ISO/IEC Guide 2: 1991, and all references in part 1 to "*Compliance*" should therefore be read as "*Conformity*". Part 1 will be changed to reflect "*Conformity*" when its next edition is published.

INTRODUCTION

Sterilizing equipment utilizing hot air or hot inert gas at atmospheric pressure has many potentially hazardous parts in its construction which require additional safety requirements to those given in part 1.

Other existing national and international standards and regulations should also be considered, since they may supplement this standard.

SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE

Part 2-043: Particular requirements for dry heat sterilizers using either hot air or hot inert gas for the treatment of medical materials, and for laboratory processes

1 Scope and object

This clause of part 1 is applicable except as follows:

1.1 *Scope*

Replacement:

This standard applies to STERILIZERS, including those having an automatic loading and unloading system, with one or more CHAMBERS operating at approximately atmospheric pressure and using hot air or hot inert gas intended for the treatment of medical materials, and for laboratory processes.

NOTES

1 Regulations and codes, national or other, may apply for the safety of automatic loading and unloading systems.

2 It is generally recommended that automatic control is provided for equipment using high temperatures because a manual control system could present serious hazards to the OPERATOR.

1.1.2 *Equipment excluded from scope*

Addition:

Add two new dashes and the note as follows:

– laboratory equipment for the heating of materials, other than for sterilization (see IEC 61010-2-010);

– environmental cabinets.

NOTE – This standard does not specify requirements for protection against high-risk microbiological hazards associated with the LOAD, or requirements for the design of the CHAMBER itself.

1.4 *Environmental conditions*

Replacement:

Replace the first dash by the following:

– indoor use, and outdoor use if specified by the manufacturer (see 11.6 of IEC 61010-1);

2 Normative references

This clause of IEC 61010-1: 1990 (including amendment 1: 1992 and amendment 2: 1995) is applicable, except as follows:

Addition:

2.2 *ISO standards*

3746: 1995, *Acoustics – Determination of sound power levels of noise sources using sound pressure – Survey method using an enveloping measurement surface over a reflecting plane*

3 Definitions

This clause of part 1 is applicable, except as follows:

Additions:

3.1 *Equipment and states of equipment*

Additional definition:

3.1.101 OPERATING CYCLE: The complete set of stages of the process that is carried out in a specified sequence.

3.2 *Parts and accessories*

Additional definitions:

3.2.101 CHAMBER: Part of a STERILIZER which receives the LOAD and in which the process takes place.

3.2.102 LOAD: Equipment and materials put into a STERILIZER to be processed through an OPERATING CYCLE.

3.2.103 STERILIZER: An apparatus designed to render a LOAD free from viable micro-organisms to a specified extent.

NOTE – In practice, no absolute condition can be achieved, therefore sterility is expressed in terms of probability.

4 Tests

This clause of part 1 is applicable, except as follows:

4.3.5 *Covers and removable parts*

Replacement:

Replace the second sentence by the following:

Covers which do not require the use of a TOOL for removal need not be removed if they have interlocks which automatically de-activate parts which would otherwise present a hazard (see 1.2) when the cover is opened.