SLOVENSKI STANDARD
SIST EN 61010-2-042:1999

01-julij-1999

Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 2-042: Particular requirements for autoclaves and sterilizers using toxic gas for the treatment of medical materials, and for laboratory processes (IEC 61010-2-042:1997)

Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 2-042: Particular requirements for autoclaves and sterilizers using toxic gas for the treatment of medical materials, and for laboratory processes

Sicherheitsbestimmungen für elektrische Meß-, Steuer-, Regel und Laborgeräte -- Teil 2-042: Besondere Anforderungen an Autoklaven und Sterilisatoren bei Verwendung toxischer Gase zur Behandlung medizinischer Materialien und für Laboranwendungen

Règles de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire -- Partie 2-042: Prescriptions particulières pour autoclaves et stérilisateurs utilisant des gaz toxiques pour le traitement des matériels à usage médical et durant les procédés de traitement de laboratoire

Ta slovenski standard je istoveten z: **EN 61010-2-042:1997**

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

SIST EN 61010-2-042:1999 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 61010-2-042

May 1997

ICS 11.080

Descriptors: Safety, electrical equipment, autoclaves, sterilizers, toxic gas, treatment of medical materials, laboratory process

English version

Safety requirements for electrical equipment for measurement, control, and laboratory use
Part 2-042: Particular requirements for autoclaves and sterilizers using toxic gas for the treatment of medical materials, and for laboratory processes
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This European Standard was approved by CENELEC on 1997-03-11. 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

Ref. No. EN 61010-2-042:1997 E

Foreword

The text of document 66/154/FDIS, future edition 1 of IEC 61010-2-042, 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 61010-2-042 on 1997-03-11.

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) 1998-01-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1998-01-01

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

This part 2 supplements or modifies the corresponding clauses of EN 61010-1:1993. 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.

Annexes designated "normative" are part of the body of the standard.
In this standard, annex ZA is normative.
Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 61010-2-042:1997 was approved by CENELEC as a European Standard without any modification.

In the official version, for annex L, Bibliography, the following note has to be added for the standard indicated:

IEC 60073	NOTE: Harmonized as EN 60073:1993, which is superseded by EN 60073:1996 (not modified).

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

Addition:

Publication	Year	Title	EN/HD	Year
IEC 79	series	Electrical apparatus for explosive gas atmospheres	EN 50014 & related ENs EN 60079	series
ISO 6718	1991	Bursting discs and bursting disc devices	-	-

NORME INTERNATIONALE
INTERNATIONAL STANDARD

CEI
IEC
61010-2-042

Première édition
First edition
1997-04

PUBLICATION GROUPÉE DE SÉCURITÉ
GROUP SAFETY PUBLICATION

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

Partie 2-042: Prescriptions particulières pour autoclaves et stérilisateurs utilisant des gaz toxiques 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 2-042: Particular requirements for autoclaves and sterilizers using toxic gas for the treatment of medical materials, and for laboratory processes

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

CODE PRIX
PRICE CODE U

Pour prix, voir catalogue en vigueur
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

Part 2-042: Particular requirements for autoclaves and sterilizers using toxic 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.

2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.

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.

4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.

5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.

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 61010-2-042 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
66/154/FDIS	66/162/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 autoclaves and sterilizers using toxic 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 toxic gas, above or below atmospheric pressure, has many potentially hazardous parts in its construction which require additional safety requirements to those given in IEC 61010-1. These particularly include protection of the OPERATOR and surroundings against the unintentional escape of toxic gas.

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

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

Part 2-042: Particular requirements for autoclaves and sterilizers using toxic 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 AUTOCLAVES and STERILIZERS, including those with an automatic loading and unloading system, which incorporate a CHAMBER using toxic gas intended for the treatment of medical materials, and for laboratory processes, for example for sterilization.

NOTES

1 National and other regulations or codes apply for the safety of automatic loading and unloading systems.

2 In general it is considered that automatic control of the sterilization cycle is essential for the safe operation of equipment using toxic gases because a manual control system might present serious hazards (see 1.2) to the OPERATOR.

3 The principal sterilant gases in use are ethylene oxide and formaldehyde.

4 For some applications, the CHAMBER may be operated at a pressure above or below atmospheric pressure.

5 All pressures are specified in absolute terms. Atmospheric pressure (1 bar) ≥100 kPa.

6 The word AUTOCLAVES includes STERILIZERS unless specifically stated otherwise.

Where an AUTOCLAVE incorporates a steam generator having its own PRESSURE VESSEL within the same enclosure for the purpose of humidifying the LOAD, the applicable safety requirements specified in this standard apply also to the steam generator.

1.1.2 *Equipment excluded from the scope*

Modification:

Add the following text at the end of the last dash:

except for an atmosphere created by the AUTOCLAVE itself (see 13.2.103.1).

Addition:

Add the following new dash and notes:

– environmental cabinets.