SLOVENSKI STANDARD
SIST EN 61010-2-040:2016

01-april-2016

Nadomešča:
SIST EN 61010-2-040:2006

Varnostne zahteve za električno opremo za meritve, nadzor in laboratorijsko uporabo - 2-040. del: Posebne zahteve za sterilizatorje in pralnike-dezinfektorje, ki se uporabljajo za obdelavo medicinskih materialov (IEC 61010-2-040:2015)

Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040 Particular requirements for sterilizers and washer-disinfectors used to treat medical materials (IEC 61010-2-040:2015)

Sicherheitsbestimmungen für elektrische Mess-, Steuer-, Regel- und Laborgeräte - Teil 2 -040: Besondere Anforderungen an Sterilisatoren und Reinigungs-Desinfektionsgeräte für die Behandlung medizinischen Materials (IEC 61010-2-040:2015)

Règles de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire - Partie 2-040: Exigences particulières pour stérilisateurs et laveurs désinfecteurs utilisés pour traiter le matériel médical (IEC 61010-2-040:2015)

Ta slovenski standard je istoveten z: **EN 61010-2-040:2015**

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 61010-2-040:2016 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61010-2-040

September 2015

ICS 19.080; 71.040.10

Supersedes EN 61010-2-040:2005

English Version

Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040 Particular requirements for sterilizers and washer-disinfectors used to treat medical materials (IEC 61010-2-040:2015)

Règles de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire - Partie 2-040: Exigences particulières pour stérilisateurs et laveurs désinfecteurs utilisés pour traiter le matériel médical (IEC 61010-2-040:2015)

Sicherheitsbestimmungen für elektrische Mess-, Steuer-, Regel- und Laborgeräte - Teil 2-040: Besondere Anforderungen an Sterilisatoren und Reinigungs-Desinfektionsgeräte für die Behandlung medizinischen Materials (IEC 61010-2-040:2015)

This European Standard was approved by CENELEC on 2015-08-11. 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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

CENELEC

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 61010-2-040:2015 E

European foreword

The text of document 66/570/FDIS, future edition 2 of IEC 61010-2-040, prepared by IEC/TC 66 "Safety of measuring, control and laboratory equipment" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 61010-2-040:2015.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2016-05-11
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-08-11

This document supersedes EN 61010-2-040:2005.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

Endorsement notice

The text of the International Standard IEC 61010-2-040:2015 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60079	NOTE	Harmonized in EN 60079 series.
IEC 60335-2-4	NOTE	Harmonized as EN 60335-2-4.
IEC 60335-2-5	NOTE	Harmonized as EN 60335-2-5.
IEC 60335-2-7	NOTE	Harmonized as EN 60335-2-7.
IEC 60335-2-11	NOTE	Harmonized as EN 60335-2-11.
IEC 60335-2-58	NOTE	Harmonized as EN 60335-2-58.
IEC 60601-1	NOTE	Harmonized as EN 60601-1.
IEC 60825-1	NOTE	Harmonized as EN 60825-1.
IEC 61010-2-010	NOTE	Harmonized as EN 61010-2-010.
IEC 61058	NOTE	Harmonized in EN 61058 series.
IEC 61672-1	NOTE	Harmonized as EN 61672-1.

IEC 61672-2	NOTE	Harmonized as EN 61672-2.
IEC 62061	NOTE	Harmonized as EN 62061.
IEC 62304	NOTE	Harmonized as EN 62304.
ISO 10472	NOTE	Harmonized in EN ISO 10472 series.
ISO 12100:2010	NOTE	Harmonized as EN ISO 12100:2010.
ISO 13849-2	NOTE	Harmonized as EN ISO 13849-2.
ISO 14971	NOTE	Harmonized as EN ISO 14971.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Publication	Year	Title	EN/HD	Year
***Addition** to Annex ZA of EN 61010-1:2010:*				
IEC 61770	-	Electric appliances connected to the water mains - Avoidance of backsiphonage and failure of hose-sets	EN 61770	-
IEC 62471	-	Photobiological safety of lamps and lamp systems	EN 62471	-
IEC/TR 62471-2	-	Photobiological safety of lamps and lamp systems - Part 2: Guidance on manufacturing requirements relating to non-laser optical radiation safety	-	-
ISO 3585	-	Borosilicate glass 3.3 - Properties	-	-
ISO 4126-1	-	Safety devices for protection against excessive pressure - Part 1: Safety valves	EN ISO 4126-1	-
ISO 4126-2	-	Safety devices for protection against excessive pressure - Part 2: Bursting disc safety devices	EN ISO 4126-2	-

IEC 61010-2-040

Edition 2.0 2015-07

INTERNATIONAL STANDARD

NORME INTERNATIONALE

GROUP SAFETY PUBLICATION
PUBLICATION GROUPÉE DE SÉCURITÉ

Safety requirements for electrical equipment for measurement, control, and laboratory use –
Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials

Règles de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire –
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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 19.080; 71.040.10

ISBN 978-2-8322-2776-3

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of 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, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). 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. 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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International Standard IEC 61010-2-040 has been prepared by IEC technical committee 66: Safety of measuring, control and laboratory equipment.

It has the status of a group safety publication, as specified in IEC Guide 104.

This second edition cancels and replaces the first edition published in 2005. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) A new clause (4.3.2.101) has been added for non-electrical supplies and services.
b) Additional requirements for marking and documentation (Clause 5) have been added.

c) Additional requirements for protection against mechanical hazards (Clause 7) have been included.

d) Additional requirements for protection against radiation, including laser sources, and against sonic and ultrasonic pressure (Clause 12) have been included.

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

FDIS	Report on voting
66/570/FDIS	66/576/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 publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

A list of all parts in the IEC 61010 series, published under the general title *Safety requirements for electrical equipment for measurement, control, and laboratory use,* can be found on the IEC website.

This Part 2-040 is intended to be used in conjunction with IEC 61010-1. It was established on the basis of the third edition (2010). Consideration may be given to future editions of, or amendments to, IEC 61010-1.

Where a particular subclause of Part 1 is not mentioned in this Part 2-040, that subclause applies as far as is reasonable. Where this part states “addition”, “modification”, “replacement”, or “deletion”, 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 and tests: *in italic type*;
   - terms used throughout this standard which have been defined in Clause 3: SMALL ROMAN CAPITALS.
2) subclauses, figures, and tables which are additional to those in Part 1 are numbered starting from 101; additional annexes are lettered starting from AA and additional list items are lettered from aa).

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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

Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials

1 Scope and object

This clause of Part 1 is applicable except as follows:

1.1.1 Equipment included in scope

Replacement:

Replace the existing text with the following:

This part of IEC 61010 specifies safety requirements for electrical equipment intended for sterilization, washing, and disinfection of medical materials in the medical, veterinary, pharmaceutical and laboratory fields, when used under the environmental conditions of 1.4.

Examples of such equipment include the following:

a) sterilizers and disinfectors using steam, and/or hot water as the sterilant;

b) sterilizers and disinfectors using toxic gas, toxic aerosol or toxic vapour as the sterilant;

c) sterilizers and disinfectors using hot air or hot inert gas as the sterilant; and

d) washer disinfectors.

1.1.2 Equipment excluded from scope

Addition:

Add the following note to item f):

NOTE IEC 60601-1 defines medical electrical equipment as follows:

Electrical equipment, provided with not more than one connection to a particular supply MAINS and intended by its manufacturer to be used in the diagnosis, treatment, or monitoring of a patient; and that makes physical or electrical contact with the patient or transfers energy to or from the patient or detects such energy transfer to or from the patient.

Addition:

Add the following new second paragraph:

This part of IEC 61010 does not apply to the following types of equipment:

aa) equipment for use in hazardous atmospheres (see IEC 60079) but does apply to an atmosphere created inside equipment by a flammable sterilizing agent (see 13.0);

bb) laboratory equipment for the heating of materials for other purposes than sterilization or disinfection (see IEC 61010-2-010);

cc) laundry equipment (see IEC 60335-2-4, IEC 60335-2-7, IEC 60335-2-11, and ISO 10472), unless designed for disinfecting medical materials;

dd) dishwashers (see IEC 60335-2-5 and IEC 60335-2-58).

1.2.1 Aspects included in scope

Replacement:

Replace item g) with the following new text:

g) liberated gases (including the non-intentional escape of toxic gas), pathogenic substances, explosion and implosion (see Clause 13).

1.2.2 Aspects excluded from scope

Addition:

Add the following two new items:

aa) special requirements for protection against chemical and high-risk micro-biological HAZARDS associated with the LOAD;
bb) general requirements for the design of calorifiers, shell boilers and PRESSURE VESSELS.

NOTE National and other regulations or codes apply for the safety of calorifiers, shell boilers and PRESSURE VESSELS (see 14.101).

2 Normative references

This clause of Part 1 is applicable except as follows:

Addition:

Add the following new references:

IEC 61770, *Electric appliances connected to the water mains — Avoidance of back-siphonage and failure of hose-sets*

IEC 62471, *Photobiological safety of lamps and lamp systems*

IEC TR 62471-2, *Photobiological safety of lamps and lamp systems – Part 2: Guidance on manufacturing requirements relating to non-laser optical radiation safety*

ISO 3585, *Borosilicate glass 3.3 — Properties*

ISO 4126-1, *Safety devices for protection against excessive pressure — Part 1: Safety valves*

ISO 4126-2, *Safety devices for protection against excessive pressure – Part 2: Bursting disc safety devices*

3 Terms and definitions

This clause of Part 1 is applicable except as follows:

3.5.2
HAZARD

Addition:

Add the following new note:

Note 1 to entry: In the context of this standard, the term HAZARD relates only to potential sources of harm to the OPERATOR and surroundings (see 1.2.1), and does not include potential sources of harm related to the efficacy of the process.

3.5.11
OPERATOR

Addition:

Add the following note:

Note 1 to entry: An OPERATOR includes persons installing, operating, adjusting, maintaining, cleaning, repairing or moving equipment.

Addition:

Add the following new terms and definitions:

3.2.101
CHAMBER
part of the equipment which receives the LOAD

3.2.102
LOAD
equipment or materials put into a CHAMBER to be processed through an OPERATING CYCLE

3.2.103
STERILIZER
equipment designed to achieve sterilization which comprises a series of actions or operations needed to achieve the specified requirements for sterility

3.2.104
PRESSURE VESSEL
assembly comprising the CHAMBER, the jacket (if fitted), doors, and all other components in permanent open connection with the CHAMBER

Note 1 to entry: The PRESSURE VESSEL does not include parts from which it can be isolated, such as steam generators, pipework, and fittings.

3.2.105
OPERATING CYCLE
complete set of stages of the process that is carried out, in a specified sequence

Note 1 to entry: Loading and unloading are not part of the OPERATING CYCLE.

3.2.106
WASHER-DISINFECTOR
equipment intended to clean and disinfect medical devices and other articles used in the context for example of medical, dental, pharmaceutical and veterinary practice

4 Tests

This clause of Part 1 is applicable except as follows:

4.3.2.4 Covers and removable parts

Addition:

Add the following new second paragraph: