SLOVENSKI STANDARD
SIST EN 61010-2-040:2006

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Nadomešča:
SIST EN 61010-2-041:1999
SIST EN 61010-2-042:1999
SIST EN 61010-2-043:1999
SIST EN 61010-2-045:2002

Varnostne zahteve za električno opremo za merjenje, nadzor in laboratorijsko uporabo - 2-040. del: Posebne zahteve za sterilizatorje in dezinfektorje pralnikov, ki se uporabljajo za obdelavo medicinskih materialov (IEC 61010-2-040:2005)

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

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

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

Ta slovenski standard je istoveten z: **EN 61010-2-040:2005**

ICS:

11.080.10	Sterilizacijska oprema	Sterilizing equipment
19.080	Električno in elektronsko preskušanje	Electrical and electronic testing

SIST EN 61010-2-040:2006 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN 61010-2-040

July 2005

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Supersedes EN 61010-2-041:1996 & EN 61010-2-042:1997 & EN 61010-2-043:1997 & EN 61010-2-045:2000

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 61010-2-040:2005)

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
(CEI 61010-2-040:2005)

Sicherheitsbestimmungen für elektrische Mess-, Steuer-, Regel- und Laborgeräte
Teil 2-040: Besondere Anforderungen an Sterilisatoren und Reinigungs-Desinfektionsgeräte für die Behandlung medizinischen Materials
(IEC 61010-2-040:2005)

This European Standard was approved by CENELEC on 2005-06-01. 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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, 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 61010-2-040:2005 E

Foreword

The text of document 66/353/FDIS, future edition 1 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 was approved by CENELEC as EN 61010-2-040 on 2005-06-01.

This European Standard supersedes EN 61010-2-041:1996 + corrigendum September 1996, EN 61010-2-042:1997, EN 61010-2-043:1997 and EN 61010-2-045:2000.

This Part 2-040 is to be used in conjunction with EN 61010-1:2001, Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements. Consideration may be given to future editions of, or amendments to, EN 61010-1.

This Part 2-040 supplements or modifies the corresponding clauses of EN 61010-1:2001 so as to convert it into the European Standard "Safety requirements for sterilizers and washer-disinfectors used to treat medical materials".

Where a particular clause or subclause of Part 1 is not mentioned in this Part 2-040, that clause or subclause applies as far as is reasonable. Where this part states "addition", "modification", "replacement" or "deletion", the relevant text of Part 1 is to 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: italic type;*
   - terms used throughout this standard which have been defined in Clause 3: SMALL ROMAN CAPITALS;

2) subclauses, figures, tables and notes which are additional to those in Part 1 are numbered starting from 101.

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)	2006-03-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2008-06-01

Annex ZA has been added by CENELEC.

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Endorsement notice

The text of the International Standard IEC 61010-2-040:2005 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 60335-2-4	NOTE	Harmonized as EN 60335-2-4:2002 (not modified).
IEC 60335-2-5	NOTE	Harmonized as EN 60335-2-5:2003 (modified).
IEC 60335-2-7	NOTE	Harmonized as EN 60335-2-7:2003 (modified).
IEC 60335-2-11	NOTE	Harmonized as EN 60335-2-11:2003 (modified).
IEC 60335-2-58	NOTE	Harmonized as EN 60335-2-58:2005 (modified).
IEC 60601-1	NOTE	Harmonized as EN 60601-1:1990 (not modified).
IEC 61010-2-010	NOTE	Harmonized as EN 61010-2-010:2003 (not modified).
IEC 61508	NOTE	Harmonized in EN 61508 series (not modified).
ISO 10472	NOTE	Harmonized in EN ISO 10472 series (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE Where an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC 60079 (mod)	Series	Electrical apparatus for explosive gas atmospheres	EN 60079	Series
IEC 61770	- [1)]	Electric appliances connected to the water mains - Avoidance of backsiphonage and failure of hose-sets	EN 61770	1999 [2)]
ISO 3585	- [1)]	Borosilicate glass 3.3 - Properties	-	-
ISO 6718	- [1)]	Bursting discs and bursting disc devices	-	-

1) Undated reference.

2) Valid edition at date of issue.

NORME INTERNATIONALE

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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

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

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International Electrotechnical Commission
Международная Электротехническая Комиссия

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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 statute of a group safety publication in accordance with IEC Guide 104.

This document consolidates the requirements of four standards, IEC 61010-2-041, IEC 61010-2-042, IEC 61010-2-043 and IEC 61010-2-045, which are withdrawn, and aligns them with the second edition (2001) of IEC 61010-1:*Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements*.

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

FDIS	Report on voting
66/353/FDIS	66/358/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.

This Part 2-040 is intended to be used in conjunction with IEC 61010-1. It was established on the basis of the second edition (2001) of that standard. Consideration may be given to future editions of, or amendments to, IEC 61010-1.

This Part 2-040 supplements or modifies the corresponding clauses in IEC 61010-1 so as to convert that publication into the IEC standard *Safety requirements for sterilizers and washer-disinfectors used to treat medical materials.*

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”, “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 test: in italic type;*
   - terms used throughout this standard which have been defined in Clause 3: SMALL ROMAN CAPITALS;
2) subclauses, figures, tables and notes which are additional to those in Part 1 are numbered starting from 101.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site 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:

This International Standard 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 are:

a) STERILIZERS and disinfectors using steam;

b) STERILIZERS and disinfectors using toxic gas, toxic aerosol or toxic vapour;

c) STERILIZERS and disinfectors using hot air or hot inert gas, and

d) washer disinfectors.

1.1.2 Equipment excluded from scope

Add the following note to item g):

NOTE IEC 60601-1(definition 2.2.15 modified) 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.

Add the following new second paragraph:

This standard also does not apply to the following types of equipment:

aa) equipment for use in hazardous gas atmospheres (see IEC 60079) except for an atmosphere created inside equipment by the use of a flammable sterilizing agent (see 13.0);

bb) environmental cabinets (see IEC 61010-1);

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

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

ee) dishwashers (see IEC 60335, Parts 2-5 and 2-58).

1.2.1 Aspects included in scope

Replacement:

Replace item g) and the note by the following new text and note:

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

NOTE Attention is drawn to the existence of additional requirements which may be specified by national authorities responsible for the health and safety of labour forces. In particular, national and other regulations or codes apply for the safety of automatic loading and unloading systems.

1.2.2 Aspects excluded from scope

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.

2 Normative references

This clause of Part 1 is applicable except as follows:

Additions:

IEC 60079 (all parts), *Electrical apparatus for explosive gas atmospheres*

IEC 61770, *Electrical appliances connected to the water MAINS – Avoidance of back-siphonage and failure of hose-sets*

ISO 3585, *Borosilicate glass 3.3 – Properties*

ISO 6718, *Bursting discs and bursting disc devices*

3 Terms and definitions

This clause of Part 1 is applicable except as follows:

Addition:

3.2.101
CHAMBER
the 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