SVENSK STANDARD SS-EN IEC 61010-2-040

Fastställd	Utgåva	Sida	Ansvarig kommitté
2022-01-26	3	1 (1+41)	SEK TK 66

Elektrisk utrustning för mätning, styrning och för laboratorieändamål – Säkerhet – Del 2-040: Särskilda fordringar på sterilisatorer och diskdesinfektorer för behandling av medicinsk materiel

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

Som svensk standard gäller europastandarden EN IEC 61010-2-040:2021. Den svenska standarden innehåller den officiella engelska språkversionen av EN IEC 61010-2-040:2021.

Nationellt förord

Europastandarden EN IEC 61010-2-040:2021

består av:

– **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC
– **IEC 61010-2-040, Third edition, 2020 - 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**

utarbetad inom International Electrotechnical Commission, IEC.

Standarden ska användas tillsammans med SS-EN 61010-1, utgåva 2, 2010 och dess separat utgivna tillägg.

Tidigare fastställd svensk standard SS-EN 61010-2-040, utgåva 2, 2015, gäller ej fr o m 2024-11-26.

ICS 19.080.00; 71.040.10

Denna standard är fastställd av SEK Svensk Elstandard,
som också kan lämna upplysningar om **sakinnehållet** i standarden.
Postadress: Box 1284, 164 29 KISTA
Telefon: 08 - 444 14 00.
E-post: sek@elstandard.se. Internet: www.elstandard.se

Standarder underlättar utvecklingen och höjer elsäkerheten

Det finns många fördelar med att ha gemensamma tekniska regler för bl a mätning, säkerhet och provning och för utförande, skötsel och dokumentation av elprodukter och elanläggningar.

Genom att utforma sådana standarder blir säkerhetsfordringar tydliga och utvecklingskostnaderna rimliga samtidigt som marknadens acceptans för produkten eller tjänsten ökar.

Många standarder inom elområdet beskriver tekniska lösningar och metoder som åstadkommer den elsäkerhet som föreskrivs av svenska myndigheter och av EU.

SEK är Sveriges röst i standardiseringsarbetet inom elområdet

SEK Svensk Elstandard svarar för standardiseringen inom elområdet i Sverige och samordnar svensk medverkan i internationell och europeisk standardisering. SEK är en ideell organisation med frivilligt deltagande från svenska myndigheter, företag och organisationer som vill medverka till och påverka utformningen av tekniska regler inom elektrotekniken.

SEK samordnar svenska intressenters medverkan i SEKs tekniska kommittéer och stödjer svenska experters medverkan i internationella och europeiska projekt.

Stora delar av arbetet sker internationellt

Utformningen av standarder sker i allt väsentligt i internationellt och europeiskt samarbete. SEK är svensk nationalkommitté av International Electrotechnical Commission (IEC) och Comité Européen de Normalisation Electrotechnique (CENELEC).

Standardiseringsarbetet inom SEK är organiserat i referensgrupper bestående av ett antal tekniska kommittéer som speglar hur arbetet inom IEC och CENELEC är organiserat.

Arbetet i de tekniska kommittéerna är öppet för alla svenska organisationer, företag, institutioner, myndigheter och statliga verk. Den årliga avgiften för deltagandet och intäkter från försäljning finansierar SEKs standardiseringsverksamhet och medlemsavgift till IEC och CENELEC.

Var med och påverka!

Den som deltar i SEKs tekniska kommittéarbete har möjlighet att påverka framtida standarder och får tidig tillgång till information och dokumentation om utvecklingen inom sitt teknikområde. Arbetet och kontakterna med kollegor, kunder och konkurrenter kan gynnsamt påverka enskilda företags affärsutveckling och bidrar till deltagarnas egen kompetensutveckling.

Du som vill dra nytta av dessa möjligheter är välkommen att kontakta SEKs kansli för mer information.

SEK Svensk Elstandard
Box 1284
164 29 Kista
Tel 08-444 14 00
www.elstandard.se

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 61010-2-040

November 2021

ICS 19.080; 71.040.10

Supersedes EN 61010-2-040:2015 and all of its amendments and corrigenda (if any)

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 61010-2-040:2020)

Exigences 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 61010-2-040:2020)

Sicherheitsbestimmungen für elektrische Mess-, Steuer-, Regel- und Laborgeräte - Teil 2-040: Besondere Anforderungen an Sterilisatoren und Reinigungs-Desinfektionsgeräte für die Behandlung medizinischen Materials (IEC 61010-2-040:2020)

This European Standard was approved by CENELEC on 2020-06-18. 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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN IEC 61010-2-040:2021 E

European foreword

The text of document 66/699/CDV, future edition 3 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 IEC 61010-2-040:2021.

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) 2022-05-26
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2024-11-26

This document supersedes EN 61010-2-040:2015 and all of its amendments and corrigenda (if any).

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

This document has been prepared under a Standardization Request given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s) / Regulation(s).

For relationship with EU Directive(s) / Regulation(s), see informative Annex ZZ, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice

The text of the International Standard IEC 61010-2-040:2020 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
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 60601-1:2005	NOTE	Harmonized as EN 60601-1:2006 (not modified)
IEC 61010-2-010	NOTE	Harmonized as EN IEC 61010-2-010
IEC 62061	NOTE	Harmonized as EN 62061
IEC 62304	NOTE	Harmonized as EN 62304
ISO 10472 (series)	NOTE	Harmonized as EN ISO 10472 (series)

ISO 12100:2010	NOTE	Harmonized as EN ISO 12100:2010 (not modified)
ISO 13849 (series)	NOTE	Harmonized as EN ISO 13849 (series)
ISO 14971	NOTE	Harmonized as EN ISO 14971

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1 Where 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.

Annex ZA of EN 61010-1:2010/A1:2019 is applicable, with the following additions:

Publication	Year	Title	EN/HD and IEC/ISO	Year
IEC 61770	-	Electric appliances connected to the water mains — Avoidance of back-siphonage and failure of hose-sets	EN 61770 +A11	2009 2018
ISO 3585	-	Borosilicate glass 3.3 — Properties	ISO 3585	1998
ISO 4126-1	-	Safety devices for protection against excessive pressure — Safety valves	ISO 4126-1	2013
ISO 4126-2	-	Safety devices for protection against excessive pressure — Part 2: Bursting disc safety devices	ISO 4126-2	2018

IEC 61010-2-040

Edition 3.0 2020-05

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

Exigences de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire –
Partie 2-040: Exigences particulières pour sterilisateurs et laveurs desinfecteurs utilisés pour traiter le matériel médical

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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.

This third edition cancels and replaces the second edition published in 2015. This edition constitutes a technical revision.

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

a) it is established on the basis of the third edition (2010) of IEC 61010-1 and its Amendment 1 (2016);
b) added tolerance for stability of a.c. voltage test equipment to 6.8.3.1;

c) the status of a Group Safety Publication has been removed (this does not change the technical requirements in the document).

The text of this International Standard is based on the following documents:

CDV	Report on voting
66/699/CDV	66/716/RVC

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

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

The reader's attention is drawn to the fact that Annex G lists all of the "in-some-country" clauses on differing practices of a less permanent nature relating to the subject of this standard.

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 to be used in conjunction with IEC 61010-1. It was established on the basis of the third edition (2010) of IEC 61010-1 and its Amendment 1 (2016), hereinafter referred to as Part 1.

This Part 2-040 supplements or modifies the corresponding clauses in Part 1 so as to convert that publication into the IEC standard: *Particular requirements for STERILIZERS and WASHER-DISINFECTORS used to treat medical materials*.

Where a particular subclause of Part 1 is not mentioned in this Part 2-040, that subclause applies as far as is reasonable. Where this Part 2-040 states "addition", "modification", "replacement", or "deletion", the relevant requirement, test specification or note in Part 1 shall 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 document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document 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 60601-1:2005, 3.63, defines "medical electrical equipment" as follows (notes to entry are omitted):

Electrical equipment, having an applied part or transferring energy to or from the patient or detecting such energy transfer to or from the patient and which is:

a) provided with not more than one connection to a particular supply MAINS; and

b) intended by its manufacturer to be used:

   1) in the diagnosis, treatment, or monitoring of a patient; or

   2) for compensation or alleviation of disease, injury or disability.

Addition:

Add the following new second paragraph after the lettered list:

This document does not apply to the following types of equipment:

aa) equipment for use in hazardous atmospheres (see IEC 60079); however this document does apply to an atmosphere created inside equipment by a flammable sterilizing agent (see 13.2.101 and 13.2.102);

bb) laboratory equipment for the heating of materials for purposes other 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 (all parts)), 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 backsiphonage and failure of hose-sets*

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*