

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 61010-2-040:2015 sisaldab Euroopa standardi EN 61010-2-040:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 61010-2-040:2015 consists of the English text of the European standard EN 61010-2-040:2015.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 11.09.2015.	Date of Availability of the European standard is 11.09.2015.
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ICS 19.080, 71.040.10

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EUROPEAN STANDARD

EN 61010-2-040

NORME EUROPÉENNE

EUROPÄISCHE NORM

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.

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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

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.

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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.

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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.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>Addition to Annex ZA of EN 61010-1:2010:</i>				
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	-

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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

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).