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2-040: ERINÕUDED MEDITSIINIMATERJALIDE
TÖÖTLEMISEKS KASUTAVATELE STERILISAATORITELE
JA DESINFITSEERIMIS-PESUSEADMETELE

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 IEC 61010-2-040:2021 sisaldab Euroopa standardi EN IEC 61010-2-040:2021 ingliskeelset teksti.	This Estonian standard EVS-EN IEC 61010-2-040:2021 consists of the English text of the European standard EN IEC 61010-2-040:2021.
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 and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 26.11.2021.	Date of Availability of the European standard is 26.11.2021.
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ICS 19.080, 71.040.10

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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)

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Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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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 (dop) 2022-05-26 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2024-11-26 document have to be withdrawn

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

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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

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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:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD and IEC/ISO</u>	<u>Year</u>
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

Annex ZZ (informative)

Relationship between this European standard and the safety objectives of Directive 2014/35/EU [2014 OJ L96] aimed to be covered

This European Standard has been prepared under a Commission's standardization request relating to harmonized standards in the field of the Low Voltage Directive, M/511, to provide one voluntary means of conforming to safety objectives of Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits [2014 OJ L96].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZZ.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding safety objectives of that Directive, and associated EFTA regulations.

Table ZZ.1 — Correspondence between this European standard and Annex I of Directive 2014/35/EU [2014 OJ L96]

Safety objectives of Directive 2014/35/EU (Annex I)	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
1. General conditions		
1 (a) the essential characteristics, the recognition and observance of which will ensure that electrical equipment will be used safely and in applications for which it was made, shall be marked on the electrical equipment, or, if this is not possible, on an accompanying document	5.1 5.2 5.3 5.4	
1 (b) the electrical equipment, together with its component parts, shall be made in such a way as to ensure that it can be safely and properly assembled and connected	5.4 6.6 6.10 6.11 Annex F	
1 (c) the electrical equipment shall be so designed and manufactured as to ensure that protection against the hazards set out in points 2 and 3 is assured, providing that the equipment is used in applications for which it was made and is adequately maintained	5.4 Annex F 17 (for hazards not covered by clauses 6-16) See also the details in points 2 and 3	

Safety objectives of Directive 2014/35/EU (Annex I)	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
2. Protection against hazards arising from the electrical equipment Measures of a technical nature shall be laid down in accordance with point 1, in order to ensure that:		
2 (a) persons and domestic animals are adequately protected against the danger of physical injury or other harm which might be caused by direct or indirect contact	4, 6.1 – 6.11, 9.6, 11.6, 14.4, Annex D, Annex F, Annex K	
2 (b) temperatures, arcs or radiation which would cause a danger, are not produced	4, 4.4.4.2, 6.3.1.b) 2), 6.3.2 b) 2), 7.101, 7.102, 7.103, 7.104, 7.106, 7.109, 7.110, 9.5, 9.6, 11.102 i) and j), 10.1 -10.5, 12	
2 (c) persons, domestic animals and property are adequately protected against non-electrical dangers caused by the electrical equipment which are revealed by experience	4, 4.4, 7.2- 7.7, 7.101-7.110, 9, 11.101-11.104, 12.3, 12.5, 12.6, 13.1, 13.2, 13.101, 13.102, 16.2	
2 (d) the insulation is suitable for foreseeable conditions	6.7, Annex K	
3. Protection against hazards which may be caused by external influences on the electrical equipment Technical measures shall be laid down in accordance with point 1, in order to ensure that the electrical equipment:		
3 (a) meets the expected mechanical requirements in such a way that persons, domestic animals and property are not endangered	4, 7, 8	
3 (b) is resistant to non-mechanical influences in expected environmental conditions, in such a way that persons, domestic animals and property are not endangered	1.4, 4, 6.7.2.2.1, 10.5, 11.6, 14.3, 14.8, 15	
3 (c) does not endanger persons, domestic animals and property in foreseeable conditions of overload	4, 7.110, 9, 11.7, 14, 16.1	

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

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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 stérilisateurs et laveurs désinfecteurs utilisés pour traiter le matériel médical



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INTERNATIONAL STANDARD

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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

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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;