BSI Standards Publication

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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National foreword

This British Standard is the UK implementation of EN IEC 61010-2-040:2021. It is identical to IEC 61010-2-040:2020. It supersedes BS EN 61010-2-040:2015, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee EPL/66, Safety of measuring, control and laboratory equipment.

A list of organizations represented on this committee can be obtained on request to its committee manager.

This publication has been prepared under a mandate given to the European Standards Organizations by the European Commission and the European Free Trade Association. It is intended to support requirements of the EU legislation detailed in the European Foreword. A European Annex, usually Annex ZA or ZZ, describes how this publication relates to that EU legislation.

For the Great Britain market (England, Scotland and Wales), if UK Government has designated this publication for conformity with UKCA marking (or similar) legislation, it may contain an additional National Annex. Where such a National Annex exists, it shows the correlation between this publication and the relevant UK legislation. If there is no National Annex of this kind, the relevant Annex ZA or ZZ in the body of the European text will indicate the relationship to UK regulation applicable in Great Britain. References to EU legislation may need to be read in accordance with the UK designation and the applicable UK law. Further information on designated standards can be found at www.bsigroup.com/standardsandregulation.

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Amendments/corrigenda issued since publication

Date	Text affected

EUROPEAN STANDARD **EN IEC 61010-2-040**

EUROPÄISCHE NORM

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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.

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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

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 13849 (series)	NOTE	Harmonized as EN ISO 13849 (series)
ISO 14971	NOTE	Harmonized as EN ISO 14971

(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

(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	

2014/35/EU (Annex I)	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.

WARNING 2 — Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

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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);