



BSI Standards Publication

Safety requirements for electrical equipment for measurement, control, and laboratory use

Part 2-101: Safety requirements for in vitro diagnostic (IVD) medical equipment

National foreword

This British Standard is the UK implementation of EN IEC 61010-2-101:2022+A11:2022. It is derived from IEC 61010-2-101:2018. It supersedes BS EN 61010-2-101:2017, which will be withdrawn on 26 September 2025.

The start and finish of text introduced or altered by amendment A11 is indicated in the text by tags. Tags indicating changes to text carry the number of the CENELEC amendment. For example, text altered by CENELEC amendment A11 is indicated by A11 A11.

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.

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Published by BSI Standards Limited 2023

ISBN 978 0 539 18045 9

ICS 11.040.55; 19.080; 71.040.10

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 April 2023.

Amendments/corrigenda issued since publication

Date	Text affected
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English Version

Safety requirements for electrical equipment for measurement,
control, and laboratory use - Part 2-101: Safety requirements for
in vitro diagnostic (IVD) medical equipment
(IEC 61010-2-101:2018)

Exigences de sécurité pour appareils électriques de
mesurage, de régulation et de laboratoire - Partie 2-101:
Exigences particulières pour le matériel médical de
diagnostic in vitro (DIV)
(IEC 61010-2-101:2018)

Sicherheitsbestimmungen für elektrische Mess-, Steuer-,
Regel- und Laborgeräte - Teil 2-101: Besondere
Anforderungen an In-vitro-Diagnostik (IVD) Medizingeräte
(IEC 61010-2-101:2018)

This European Standard was approved by CENELEC on 2022-09-26. 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, Türkiye 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

European foreword

The text of document 66/644/CDV, future edition 3 of IEC 61010-2-101, 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 61010-2-101:2022.

The following dates are fixed:

- latest date by which the document has to be implemented at national (dop) 2023-09-26 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2025-09-26 document have to be withdrawn

This document supersedes EN 61010-2-101:2017 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.

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 61010-2-101:2018 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 62061	NOTE	Harmonized as EN IEC 62061
IEC 62366-1	NOTE	Harmonized as EN 62366-1
ISO 15223-1	NOTE	Harmonized as EN ISO 15223-1

European foreword to amendment A11

This document (EN IEC 61010-2-101:2022/A11:2022) has been prepared by CLC/TC 66X "Safety of measuring, control, and laboratory equipment".

The following dates are fixed:

- latest date by which this document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2023-09-26
- latest date by which the national standards conflicting with this document have to be withdrawn (dow) 2025-09-26

This document amends EN IEC 61010-2-101:2022.

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 is read in conjunction with EN 61010-1:2010 + A1:2019 as modified by EN IEC 61010-2-101:2022 which results in the complete text of EN IEC 61010-2-101:2022. This A11 describes how that text is modified.

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.

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 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 as impacted by EN 61010-1:2010/A1:2019 is applicable except as follows:

Addition:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
		Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment	EN IEC 61326-2-6	2021
		Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 3-1: Immunity requirements for safety-related systems and for equipment intended to perform safety-related functions (functional safety) - General industrial applications	EN 61326-3-1	-
		Safety of machinery – Functional safety of safety-related electrical, electronic and programmable electronic control systems	EN IEC 62061	2021
		Medical devices - Part 1: Application of usability engineering to medical devices	EN 62366-1	-
		Safety of machinery - Safety-related parts of control systems - Part 1: General principles for design	EN ISO 13849-1	2015
		Safety of machinery - Emergency Stop Function - Principles For Design	EN ISO 13850	-
ISO 14971	-	Medical devices - Application of risk management to medical devices	EN ISO 14971	-
ISO 18113-5	-	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instruments for self-testing	EN ISO 18113-5	-



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR
MEASUREMENT, CONTROL AND LABORATORY USE –****Part 2-101: Particular requirements for
in vitro diagnostic (IVD) medical equipment**

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 61010-2-101 has been prepared by IEC technical committee 66: Safety of measuring, control and laboratory equipment.

It has the status of a group safety publication, as specified in IEC Guide 104.

This document has been prepared in close collaboration with Working Group CENELEC BTTF 88.1.

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) adaptation of changes introduced by Amendment 1 of IEC 61010-1;
- b) added tolerance for stability of AC voltage test equipment to Clause 6.

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

CDV	Report on voting
66/644/CDV	66/669/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.

A list of all parts of the IEC 61010 series, under the general title: *Safety requirements for electrical equipment for measurement, control, and laboratory use*, may be found on the IEC website.

This Part 2-101 is intended to be used in conjunction with IEC 61010-1. It was established on the basis of the third edition (2010) and its Amendment 1 (2016).

This Part 2-101 supplements or modifies the corresponding clauses in IEC 61010-1 so as to convert that publication into the IEC standard: *Particular requirements for in vitro diagnostic (IVD) medical equipment*.

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 smaller 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. 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.