OHUTUSNÕUDED ELEKTRILISTELE MÕÕTMIS-, JUHTIMIS- JA LABORATOORIUMISEADMETELE. OSA 2-101: OHUTUSNÕUDED IN VITRO DIAGNOSTILISTELE (IVD) MEDITSIINISEADMETELE

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)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN IEC 61010-2-101:2022 +A11:2022 sisaldab Euroopa standardi EN IEC 61010-2-101:2022 ja selle muudatuse A11:2022 ingliskeelset teksti.	This Estonian standard EVS-EN IEC 61010-2-101:2022+A11:2022 consists of the English text of the European standard EN IEC 61010-2-101:2022 and its amendment A11:2022.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 11.11.2022, muudatus A11 11.11.2022.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation. Date of Availability of the European standard is 11.11.2022, for A11 11.11.2022.
Muudatusega A11 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega [A11] [A11]. Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The start and finish of text introduced or altered by amendment A11 is indicated in the text by tags [A11] [A11]. The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.55; 19.080

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 61010-2-101 + A11

November 2022

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Supersedes EN 61010-2-101:2017

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. Amendment A11 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 and its amendment the status of a national standard without any alteration.

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- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2025-09-26

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

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

A11 Amendment A11 European foreword

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.

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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. A11

IEC 61010-2-101

Edition 3.0 2018-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

GROUP SAFETY PUBLICATION
PUBLICATION GROUPÉE DE SÉCURITÉ

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

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 61010-2-101:2018-10(en-fr)

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SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL AND LABORATORY USE –

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

FOREWORD

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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.

SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL AND LABORATORY USE –

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

1 Scope and object

This clause of Part 1 is applicable except as follows:

1.1.1 [A11] General [A11]

Replacement:

Replace the text, except the first paragraph, with the following new text:

[A11] This part of IEC 61010 provides particular safety requirements to equipment intended for in vitro diagnostic (IVD) medical purposes, including self-test IVD medical purposes. It is intended to be used in conjunction with the manufacturer's risk management but not to replace it.

NOTE 1 A good design practice of an equipment starts from the beginning with a risk management process according to ISO 14971, which provides requirement and guidance for a comprehensive risk management process and identifies hazards and risks related with the equipment. [A11]

IVD medical equipment, whether used alone or in combination, is intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue samples, derived from the human body, solely or principally for the purpose of providing information concerning one or more of the following:

- a physiological or pathological state; or
- a congenital abnormality;
- the determination of safety and compatibility with potential recipients;
- the monitoring of therapeutic measures.

Self-test IVD medical equipment is intended by the manufacturer for use by lay persons in a home environment.

[A11] NOTE 2 A system, as specified by its manufacturer, is a combination of items of equipment, at least one of these is inter-connected to another item. In the following text the term equipment is used for single equipment and systems.

It is possible that all or part of the equipment falls within the scope of one or more other Part 2 standards of IEC 61010 as well as within the scope of this document. In that case, the requirements of those other Part 2 standards will also apply. [A11]

1.1.2 [A11] Exclusions from the scope [A11]

Addition:

Add the following new item:

aa) equipment within the scope of IEC 61010-2-081 unless it is specifically intended by the manufacturer to be used for in vitro diagnostic examination.

1.2 Object

1.2.1 Aspects included in scope

[A11] *Replace the first paragraph with the following:*

The purpose of the requirements of this document is to ensure that HAZARDS to the OPERATOR, the SERVICE PERSONNEL and the surrounding area are reduced to a tolerable level. [A11]

Addition:

Add the following two new items:

aa) biohazards;

bb) hazardous chemical substances.

[A11] cc) any other energy sources (see Clause 201) [A11]

1.2.2 Aspects excluded from scope

Addition:

Add the following new item and note:

[A11] *Delete item b).* [A11]

[A11] c) EMC requirements, except when related to safety (see the IEC 61326 series); [A11]

aa) the handling or manipulation outside the equipment of material under analysis.

NOTE Requirements covering these subjects are the responsibility of committees preparing the relevant standards.

2 Normative references

This clause of Part 1 is applicable except as follows:

Addition:

Add the following new references to the list:

[A11] EN IEC 61326-2-6:2021, *Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment*

EN 61326-3-1, *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 IEC 62061:2021, *Safety of machinery - Functional safety of safety-related control systems*

EN 62366-1, *Medical devices - Part 1: Application of usability engineering to medical devices*

EN ISO 13849-1:2015, *Safety of machinery - Safety-related parts of control systems - Part 1: General principles for design (ISO 13849-1:2015)*

EN ISO 13850, *Safety of machinery - Emergency stop function - Principles for design (ISO 13850)* [A11]

ISO 14971, *Medical devices – Application of risk management to medical devices*

ISO 18113-5, *In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 5: In vitro diagnostic instruments for self-testing*

3 Terms and definitions