

<b>STN</b>	<b>Bezpečnostné požiadavky na elektrické zariadenia na meranie, riadenie a laboratórne použitie Časť 2-101: Osobitné požiadavky na diagnostické zdravotnícke zariadenia <i>in vitro</i> (IVD)</b>	<b>STN EN IEC 61010-2-101</b>  36 2000
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Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Safety requirements for in vitro diagnostic (IVD) medical equipment

Táto norma obsahuje anglickú verziu európskej normy.  
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 01/23

Obsahuje: EN IEC 61010-2-101:2022, IEC 61010-2-101:2018

Oznámením tejto normy sa od 26.09.2025 ruší  
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**EN IEC 61010-2-101**

NORME EUROPÉENNE

EUROPÄISCHE NORM

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)

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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**

**EN IEC 61010-2-101:2022 (E)****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- latest date by which the national standards conflicting with the (dow) 2025-09-26 document have to be withdrawn

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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



# IEC 61010-2-101

Edition 3.0 2018-10

# INTERNATIONAL STANDARD

# NORME INTERNATIONALE

GROUP SAFETY PUBLICATION  
PUBLICATION GROUPEE 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)**



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## CONTENTS

FOREWORD.....	3
1 Scope and object.....	5
2 Normative references.....	6
3 Terms and definitions .....	6
4 Tests.....	6
5 Marking and documentation .....	7
6 Protection against electric shock.....	11
7 Protection against mechanical HAZARDS.....	11
8 Resistance to mechanical stresses.....	13
9 Protection against the spread of fire .....	13
10 Equipment temperature limits and resistance to heat.....	13
11 Protection against HAZARDS from fluids and solid foreign objects.....	13
12 Protection against radiation, including laser sources, and against sonic and ultrasonic pressure .....	14
13 Protection against liberated gases and substances, explosion and implosion .....	14
14 Components and subassemblies.....	14
15 Protection by interlocks.....	14
16 HAZARDS resulting from application.....	15
17 RISK assessment .....	15
Annexes .....	15
Annex L (informative) Index of defined terms.....	16
Bibliography .....	17
Table 1 – Symbols .....	8



## 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

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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 Equipment included in scope**

*Replacement:*

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

This part of IEC 61010 applies to equipment intended for in vitro diagnostic (IVD) medical purposes, including self-test IVD medical purposes.

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.

NOTE If all or part of the equipment falls within the scope of one or more other Part 2 standards of the IEC 61010 series as well as within the scope of this document, consideration is given to those other Part 2 standards.

##### **1.1.2 Equipment excluded from scope**

*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**

*Addition:*

*Add the following two new items:*

- aa) biohazards;
- bb) hazardous chemical substances.

### 1.2.2 Aspects excluded from scope

*Addition:*

*Add the following new item and note:*

- 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:*

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*

**koniec náhľadu – text ďalej pokračuje v platenej verzii STN**