SLOVENSKI STANDARD
oSIST prEN 61010-2-101:2018

01-februar-2018

Varnostne zahteve za električno opremo za meritve, nadzor in laboratorijsko uporabo - 2-101. del: Posebne zahteve za diagnostično in vitro (IVD) medicinsko opremo (IEC 61010-2-101:201X (EQV)

Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Safety requirements for in vitro diagnostic (IVD) medical equipment IEC 61010-2-101:201X (EQV)

Ta slovenski standard je istoveten z: **prEN 61010-2-101:2017**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment
19.080	Električno in elektronsko preskušanje	Electrical and electronic testing

oSIST prEN 61010-2-101:2018 **en,fr,de**

66/644/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER:	
IEC 61010-2-101 ED3	
DATE OF CIRCULATION:	CLOSING DATE FOR VOTING:
2017-12-01	**2018-02-23**
SUPERSEDES DOCUMENTS:	
66/630A/RR	

IEC TC 66 : SAFETY OF MEASURING, CONTROL AND LABORATORY EQUIPMENT	
SECRETARIAT: United Kingdom	SECRETARY: Mr David Hyde
OF INTEREST TO THE FOLLOWING COMMITTEES:	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.
FUNCTIONS CONCERNED: ☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☐ SAFETY	
☒ SUBMITTED FOR CENELEC PARALLEL VOTING	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING
Attention IEC-CENELEC parallel voting The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting. The CENELEC members are invited to vote through the CENELEC online voting system.	

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

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

NOTE FROM TC/SC OFFICERS:

This CDV is intended only to align IEC 61010-2-101:2015 with IEC 61010-1:2010 and its amendment 1:2016. A revision this soon is justified by the large number of significant changes introduced by this amendment 1. With this revision IEC 61010-2-101 will be in line with the latest requirements of IEC 61010-1 + A1.

This document contains no technical changes to already accepted base documents (IEC 61010-1:2010 and its amendment 1:2016 and IEC 61010-2-101:2015) but one; Clause 6.8.3.1 is modified because otherwise it would need a specific European deviation in order to be harmonised to the LVD 2014/35/EU (ref. NAC assessment of IEC 61010-1/A1). Further technical development is reserved for a new amendment or edition to be initiated separately as necessary.

This alignment is realised as a new 3rd edition of IEC 61010-2-101 simply because of document control; the previous edition 2.0 is based on the third edition of IEC 61010-1:2010 (without the Amendment 1:2016) and amending it to incorporate the contents of IEC 61010-1 Amendment 1 would need an unnecessary repeating of the requirements in that amendment 1 that are not particular for the equipment in the scope of IEC 61010-2-101. Furthermore, technically, one would need to follow 4 documents in parallel to get the full text of this part 2 (61010-1:2010, 61010-1 A1:2016, 61010-2-101:2015, and 61010-2-101 A1).With this approach, and when the consolidated version of IEC 61010-1:2010/A1:2016 conveniently is published, only two documents are needed.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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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8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.

9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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

This ~~second~~ third edition cancels and replaces the ~~first~~ second edition published in 2015~~02~~. It constitutes a technical revision and includes the following ~~significant~~ changes from the ~~first~~ second edition, as well as ~~numerous other~~a few editorial changes:

- adaptation of changes introduced by Amendment 1 of IEC 61010-1;

- added tolerance for stability of a.c. voltage test equipment to Clause 6.
- ~~.~~

The text of this standard is based on the following documents:

FDIS	Report on voting
66/xxx/FDIS	66/xxx/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication 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: *Safety 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.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication 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 by the following:

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 IEC 61010 as well as within the scope of this standard, considerations have to be given to those other part 2 standards.

1.1.2 Equipment excluded from scope

Addition:

Add the following item:

aa) Equipment in the scope of IEC 61010-2-081 unless they are specifically intended by their manufacturer to be used for in vitro diagnostic examination.

1.2 Object

1.2.1 Aspects included in scope

Addition:

Add two items:

aa) biohazards;

bb) hazardous chemical substances.

1.2.2 Aspects excluded from scope

Addition:

Add the following 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 relevant standards.

2 Normative references

This clause of Part 1 is applicable except as follows:

Addition:

Add the following references:

IEC 62061, *Safety of machinery – Functional safety of safety-related electrical, electronic and programmable electronic control systems*

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) – In vitro diagnostic instruments for selftesting*

ISO 13849 (all parts), *Safety of machinery – Safety-related parts of control systems*

~~ISO 13857, *Safety of machinery – Safety distances to prevent hazard zones being reached by upper and lower limbs*~~

3 Terms and definitions

This clause of Part 1 is applicable except as follows:

3.1 Equipment and states of equipment

Addition:

Add the following terms and definitions:

3.1.101
SAMPLE ZONE
area where OPERATOR access is typically unintended; the inside of this zone presents mechanical HAZARDS and a more likely probability of biohazardous human skin puncture

3.1.102
LOADING ZONE
area of automated equipment where an OPERATOR handles sample or reagent material.

3.5.12 **RESPONSIBLE BODY**

Addition:

Add the following note:

NOTE 1 This is not the European Community responsible authority.

4 Tests

This clause of Part 1 is applicable.

5 Marking and documentation

This clause of Part 1 is applicable except as follows:

5.1.1 General

Replacement:

Replace the third paragraph by the following:

Letter symbols for quantities and units shall be in accordance with IEC 60027. Internationally recognized symbols, including those of Table 1, shall be used as far as possible. If other additional symbols are required, it shall not be possible to confuse them with the internationally recognized symbols. There are no colour requirements for symbols. Graphic symbols shall be explained in the documentation.

Table 1 – Symbols

Addition:

Add the following symbols to Table 1:

Number	Symbol	Publication	Description
101	 Background colour – optional; Symbol colour – optional; Outline / outline colour – optional;	ISO 7000- 0659 (2004-01)	Biological RISKS
102		ISO 7000- 2492 (2004-01)	Batch code

5.1.2 Identification

Replacement:

Replace the text by the following:

Equipment shall, as a minimum, be marked with the following information:

a) manufacturer's name or trade mark, and the address. The address shall include at least the city and country;

NOTE 1 National regulation may require more details on the address than required in a).

b) model number, name, or other means of identifying the equipment;

The following additional information shall be marked on the equipment or packaging or in the instructions for use:

1) the serial number, for example SN XXXX or alternatively the batch code, preceded by 'LOT', using symbol 102 of Table 1;
2) the following information:
   i) a clear indication that the equipment is IVD medical equipment;
   ii) if applicable, a clear indication that the equipment is self-test IVD medical equipment;
   iii) if a potential RISK is posed, the identification of detachable components by manufacturer and part identification, and where appropriate the batch code, etc.
3) instructions for use shall require that the OPERATOR only use consumables that are within their expiration date. Where this is required by regulation, the name and address of the authorized representative of the manufacturer.

   NOTE 2 For example, in the European Union this is the natural or legal person as established within the European Community.

5.1.5 TERMINALS, connections and operating devices

Addition:

Add the following subclause:

5.1.5.101 Gas and liquid connections

If necessary for safety, the equipment shall be clearly marked near to the connector on the equipment with;

a) a means of identifying the gas or liquid to be used. Where no internationally recognized symbol (including chemical formulae) exists, the equipment shall be marked with symbol 14 of Table 1;
b) the maximum permitted pressure, or alternatively symbol 14 of Table 1 (see 5.4.3).

Conformity is checked by inspection.

Addition:

Add the following subclause:

5.1.101 Transport and storage

Packaging of equipment shall be labelled to indicate any special conditions for transport or storage (see 5.4.102).

Conformity is checked by inspection.

~~5.2 Warning markings~~

~~*Replacement:*~~

~~*Replace the first paragraph by the following:*~~

~~Warning Markings specified in 5.1.5.1, 5.1.5.2 c), 5.1.5.2 d), 5.1.5.101, 6.1.2 b), 7.3.2 b) 3), 7.4, 10.1, 13.2.2 and 13.101 shall meet the following requirements:~~