SLOVENSKI STANDARD
SIST EN 61010-2-101:2017

01-julij-2017

Varnostne zahteve za električno opremo za meritve, nadzor in laboratorijsko uporabo - 2-101. del: Posebne zahteve za diagnostično medicinsko opremo in vitro (IVD) (IEC 61010-2-101:2015)

Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for laboratory equipment for in vitro diagnostic (IVD) medical equipment (IEC 61010-2-101:2015)

Sicherheitsbestimmungen für elektrische Mess-, Steuer-, Regel- und Laborgeräte - Teil 2 -101: Besondere Anforderungen an In-vitro-Diagnostik (IVD)-Medizingeräte (IEC 61010-2-101:2015)

Règles de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire - Partie 2-101: Prescriptions particulières pour les appareils médicaux de diagnostic in vitro (DIV) (IEC 61010-2-101:2015)

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

ICS:

11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems
19.080	Električno in elektronsko preskušanje	Electrical and electronic testing
71.040.10	Kemijski laboratoriji. Laboratorijska oprema	Chemical laboratories. Laboratory equipment

SIST EN 61010-2-101:2017 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61010-2-101

February 2017

ICS 11.040.55; 19.080

Supersedes EN 61010-2-101:2002

English Version

Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment (IEC 61010-2-101:2015)

Règles de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire - Partie 2-101: Exigences particulières pour les appareils médicaux de diagnostic in vitro (DIV)
(IEC 61010-2-101:2015)

Sicherheitsbestimmungen für elektrische Mess-, Steuer-, Regel- und Laborgeräte - Teil 2-101: Besondere Anforderungen an In-vitro-Diagnostik (IVD)-Medizingeräte
(IEC 61010-2-101:2015)

This European Standard was approved by CENELEC on 2015-02-27. 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.

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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.

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

European foreword

The text of document 66/545/FDIS, future edition 2 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 61010-2-101:2017.

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) 2017-08-24
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2020-02-24

This document supersedes EN 61010-2-101:2002.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 61010-2-101:2015 was approved by CENELEC as a European Standard without any modification.

The Bibliography of EN 61010-1:2010 is applicable except as follows:

In the bibliography of EN 61010-1:2010, the following note has to be **added** for the standard indicated:

ISO 15223-1	NOTE	Harmonized as EN ISO 15223-1.

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 When 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 is applicable, except as follows:

Publication	Year	Title	EN/HD	Year
Addition:				
ISO 13857	-	Safety of machinery - Safety distances to prevent hazard zones being reached by upper and lower limbs	EN ISO 13857	-
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	-

Annex ZZ
(informative)

Relationship between this European Standard and the essential requirements of Directive 98/79/EC [OJ L 331] aimed to be covered

This European Standard has been prepared under a Commission's standardisation request, M/252, concerning the development of European Standards relating to *in vitro* diagnostic medical devices, to provide one voluntary means of conforming to essential requirements of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices [OJ L 331].

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 essential requirements of that Directive, and associated EFTA regulations.

NOTE 1 This standard is intended to be applied in its entirety only. Selected clauses or subclauses may be not applicable due to the specific type of equipment under consideration. It is necessary to understand and apply Clauses 1 to 4. It is also recommended to understand and apply those clauses which contain general requirements related to a specific subclause. Elements of the standard that are not cited in Table ZZ.1 may be relevant for the appropriate fulfilment of certain essential requirements through indirect reference, and for safety and performance aspects of the device, that are not addressed through essential requirements.

NOTE 2 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 98/79/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 3 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements Part A: 1, 2 and 5; Part B: 1.2, 2, 3, 5, 6 and 7 of the Directive.

NOTE 4 This Annex ZZ is based on normative references according to Annex ZA, replacing the references in the core text.

NOTE 5 When an Essential Requirement does not appear in Table ZZ.1, it means that it is not addressed by this European Standard.

Table ZZ.1 – Correspondence between this European Standard and Annex I of Directive 98/79/EC [OJ L 331]

Essential Requirements of Directive 98/79/EC	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
A GENERAL REQUIREMENTS		
1	Clauses 6 to 13, Clause 17	Fully covered for the hazards identified in Clauses 6 to 13. Clause 17 covers hazards and risks not addressed by the clauses above. See especially Note 2 above.
2	Clauses 6 to 16, Clause 17	Covered. Clause 17 by applying EN ISO 14971.
B DESIGN AND MANUFACTURING REQUIREMENTS		
1.2	5.4.102, 8.101, Clause 13	Partially covered. Special design considerations for transport and storage are not addressed.
2.1	7.3.1, 7.3.3, 7.3.101, Clause 11, 13.101 and Clause 17	Partially covered. This safety standard does not address the risks in device manufacturing processes.
3.1	5.4.6, 6.6.1, 6.6.2	Partially covered with respect to the effects of the device being assessed to the safety of a combination. This safety standard does not address performance of a device.
3.2	Clause 11, Clause 13	Covered.
3.3 indent one	7.4, 7.5, 11.7, 16.2	Covered.
3.3 indent two	Clause 8, 10.5, 11.3, 11.6	Partially covered with respect to mechanical and temperature effects and penetration of substances.
3.4	Clause 9 and 13.2	Covered.
3.5	5.4.101	Covered.
3.6	16.2	Partially covered with respect to hazards.
5.1	Clause 12	Covered.
5.3	5.4.3 j)	Partially covered with respect to protective measures.
6.3	Clause 6	Covered.
6.4.1	Clause 7, Clause 13 and Clause 15	Partially covered. Third paragraph requirements are not specifically addressed.
6.4.3	12.5	Covered.
6.4.4	5.1.5, 6.10, 6.11 and 13.101	Covered.
6.4.5	10.1	Covered.
8.1	Clause 5	Partially covered with respect to safe use of the device.

Essential Requirements of Directive 98/79/EC	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
8.2	5.1.1	Covered.
8.4 (a)	5.1.2 a)	Partially covered. This standard does not address the specifics of imported devices (authorized representative).
8.4 (b)	5.1.2 b)	Partially covered. Limited to details related to the identification of the device.
8.4 (d)	5.1.2 1)	Covered.
8.4 (g)	5.1.2 2) i)	Covered.
8.4 (h)	5.1.101	Partially covered. Particular conditions for handling are not addressed.
8.4 (j)	5.2	Covered.
8.4 (k)	5.1.2 2) ii)	Covered.
8.5	5.4.1	Partially covered. Requirements for the label are not addressed.
8.6	5.1.2 1), 5.1.2 2) iii)	Covered.
8.7 (a) Referring to: 8.4 (a) 8.4 (h) 8.4 (i) 8.4 (j)	 5.4.1 c) 5.4.102, 5.4.4 i) 5.4.4 5.4.3, 5.4.4	Partially covered. This standard does not address the specifics of imported devices (authorized representative). Covered. Covered. Covered.
8.7 (s)	5.4.101 and 13.101	Covered

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.

IEC 61010-2-101

Edition 2.0 2015-01

INTERNATIONAL STANDARD

NORME INTERNATIONALE

GROUP SAFETY PUBLICATION
PUBLICATION GROUPÉE DE SÉCURITÉ

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

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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

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

This second edition cancels and replaces the first edition published in 2002. It constitutes a technical revision and includes the following significant changes from the first edition, as well as numerous other changes:

- excluded IEC 61010-2-081 (general laboratory equipment) from the scope. This separates IEC 61010-2-081 and IEC 61010-2-101 equipment;