SVENSK STANDARD SS-EN 61010-2-101

Fastställd	Utgåva	Sida	Ansvarig kommitté
2017-03-15	2	1 (1+23)	SEK TK 66

Elektrisk utrustning för mätning, styrning och för laboratorieändamål – Säkerhet – Del 2-101: Särskilda fordringar på medicinsk utrustning för in vitro-diagnostik (IVD)

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

Som svensk standard gäller europastandarden EN 61010-2-101:2017. Den svenska standarden innehåller den officiella engelska språkversionen av EN 61010-2-101:2017.

Nationellt förord

Europastandarden EN 61010-2-101:2017

består av:

– **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC
– **IEC 61010-2-101, Second edition, 2015 - Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment**

utarbetad inom International Electrotechnical Commission, IEC.

Tidigare fastställd svensk standard SS-EN 61010-2-101, utgåva 1, 2003, gäller ej fr o m 2020-02-24.

ICS 11.040.55; 19.080.00

Denna standard är fastställd av SEK Svensk Elstandard,
som också kan lämna upplysningar om **sakinnehållet** i standarden.
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Standarder underlättar utvecklingen och höjer elsäkerheten

Det finns många fördelar med att ha gemensamma tekniska regler för bl a mätning, säkerhet och provning och för utförande, skötsel och dokumentation av elprodukter och elanläggningar.

Genom att utforma sådana standarder blir säkerhetsfordringar tydliga och utvecklingskostnaderna rimliga samtidigt som marknadens acceptans för produkten eller tjänsten ökar.

Många standarder inom elområdet beskriver tekniska lösningar och metoder som åstadkommer den elsäkerhet som föreskrivs av svenska myndigheter och av EU.

SEK är Sveriges röst i standardiseringsarbetet inom elområdet

SEK Svensk Elstandard svarar för standardiseringen inom elområdet i Sverige och samordnar svensk medverkan i internationell och europeisk standardisering. SEK är en ideell organisation med frivilligt deltagande från svenska myndigheter, företag och organisationer som vill medverka till och påverka utformningen av tekniska regler inom elektrotekniken.

SEK samordnar svenska intressenters medverkan i SEKs tekniska kommittéer och stödjer svenska experters medverkan i internationella och europeiska projekt.

Stora delar av arbetet sker internationellt

Utformningen av standarder sker i allt väsentligt i internationellt och europeiskt samarbete. SEK är svensk nationalkommitté av International Electrotechnical Commission (IEC) och Comité Européen de Normalisation Electrotechnique (CENELEC).

Standardiseringsarbetet inom SEK är organiserat i referensgrupper bestående av ett antal tekniska kommittéer som speglar hur arbetet inom IEC och CENELEC är organiserat.

Arbetet i de tekniska kommittéerna är öppet för alla svenska organisationer, företag, institutioner, myndigheter och statliga verk. Den årliga avgiften för deltagandet och intäkter från försäljning finansierar SEKs standardiseringsverksamhet och medlemsavgift till IEC och CENELEC.

Var med och påverka!

Den som deltar i SEKs tekniska kommittéarbete har möjlighet att påverka framtida standarder och får tidig tillgång till information och dokumentation om utvecklingen inom sitt teknikområde. Arbetet och kontakterna med kollegor, kunder och konkurrenter kan gynnsamt påverka enskilda företags affärsutveckling och bidrar till deltagarnas egen kompetensutveckling.

Du som vill dra nytta av dessa möjligheter är välkommen att kontakta SEKs kansli för mer information.

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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.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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

Ref. No. EN 61010-2-101:2017 E

SEK Svensk Elstandard

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	-

CONTENTS

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

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;

- updated Biohazard and Lot symbols in Table 1 in Clause 5;
- added requirement for within expiration consumables and authorized representative details in Instructions for Use to Clause 5;
- added requirement for gas or liquid markings and ratings to Clause 5;
- added requirement to include OPERATOR instructions to deal with consumable or sample spills, jams or breakage inside equipment, disposal of hazardous waste, personal protection, RISK reduction procedures relating to flammable liquids, burns from surfaces, and loading and unloading of sample and reagents in Instructions for Use to Clause 5;
- added requirement for manufacturer to provide instructions on equipment transport, storage and removal from use to Clause 5;
- added normative reference ISO 18113-5 for instructions for use of self-test IVD medical equipment in Clause 5;
- added requirement for OPERATOR maintenance instructions to Clause 7;
- added requirements for sample zones and loading zones to Clause 7;
- excluded equipment whose size and weight make unintentional movement unlikely from drop test in Clause 8;
- added requirement for biohazard marking to Clause 13;
- added requirement for interlock systems containing electric/electronic or programmable components to Clause 15;
- added informative reference to Usability standard IEC 62366 to Clause 16;
- replaced Clause 17 with requirements of ISO 14971 for RISK assessment.
- Annex BB Instructions for use for self-testing IVD Medical Equipment deleted and a reference given to ISO 18113-5 in Clause 5.

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

FDIS	Report on voting
66/545/FDIS	66/560/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).

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:

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