SLOVENSKI STANDARD
SIST EN 61010-2-101:2003

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

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

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

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)

Ta slovenski standard je istoveten z: **EN 61010-2-101:2002**

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 61010-2-101:2003 **en**

EUROPEAN STANDARD **EN 61010-2-101**

NORME EUROPÉENNE

EUROPÄISCHE NORM November 2002

ICS 11.040.55 19.080

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 61010-2-101:2002, modified)

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)
(CEI 61010-2-101:2002, modifiée)

Sicherheitsbestimmungen für elektrische Mess-, Steuer-, Regel- und Laborgeräte
Teil 2-101: Besondere Anforderungen an In-Vitro-Diagnostik-(IVD)-Medizingeräte
(IEC 61010-2-101:2002, modifiziert)

This European Standard was approved by CENELEC on 2002-09-01. 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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and United Kingdom.

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Ref. No. EN 61010-2-101:2002 E

Foreword

The text of document 66/261/FDIS, future edition 1 of IEC 61010-2-101, prepared by IEC TC 66, Safety of measuring, control, and laboratory equipment, together with common modifications prepared by CLC/SR 66 following deliberations in CLC/BTTF 88-1, was submitted to the Unique Acceptance Procedure and was approved by CENELEC as EN 61010-2-101 on 2002-09-01.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2003-09-01

– latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2005-09-01

This Part 2-101 is to be used in conjunction with EN 61010-1:2001, Safety requirements for electrical equipment for measurement, control and laboratory use -- Part 1: General requirements. Consideration may be given to future editions of, or amendments to, EN 61010-1.

This Part 2-101 supplements or modifies the corresponding clauses of EN 61010-1 so as to convert it into the European Standard: Safety requirements for in vitro diagnostic (IVD) medical equipment.

Where a particular clause or subclause of Part 1 is not mentioned in this Part 2-101, that clause or subclause applies as far as is reasonable. Where this Part 2-101 states "addition", "modification" or "replacement", the relevant text of Part 1 is to 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 or figures which are additional to those in Part 1 are numbered starting from 101, the additional annexes are lettered AA, BB, etc.

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annexes AA and ZA are normative and annex BB is informative.
Annex ZA has been added by CENELEC.

_____

Endorsement notice

The text of the International Standard IEC 61010-2-101:2002 was approved by CENELEC as a European Standard with agreed common modifications as given below.

COMMON MODIFICATIONS

Contents

For annex BB, **replace** "(normative)" by "(informative)".

5.4.4 Equipment operation

Add the following new note:

NOTE 4 The requirements of this standard cover safety aspects only. For further requirements on instructions for use, see EN 591 for IVD medical equipment for professional use, EN 592 for self-test IVD medical equipment. Additional guidance on suitable instructions for self-test IVD medical equipment is given in informative annex BB.

5.4.4.101 Self-test IVD medical equipment

Delete the text of this subclause and **replace** by "Void".

Annex BB

In the title, **replace** "(normative)" by "(informative)".

Bibliography

Add the following publications:

EN 591: *In vitro diagnostic systems - Requirements for user manuals for in vitro diagnostic instruments for professional use.*

EN 592: *In vitro diagnostic systems - Requirements for user manuals for in vitro diagnostic instruments for home use.*

Add the following note for IEC 60073:

NOTE Replaced by IEC 60073:2002, which is harmonized as EN 60073:2002.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

Addition *to annex ZA of EN 61010-1:*

Publication	Year	Title	EN/HD	Year
ISO 14971	2000	Medical devices – Application of risk management to medical devices	EN ISO 14971 + AC	2000 2002

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

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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

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.
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5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The 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.

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

It has the status of a group safety function, as specified in IEC Guide 104.

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

FDIS	Report on voting
66/261/FDIS	66/271/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 3.

This part 2 is intended to be used in conjunction with IEC 61010-1. It was established on the basis of the second edition (2001). Consideration may be given to future editions of, or amendments to, IEC 61010-1.

This part 2 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 or figures which are additional to those in part 1 are numbered starting from 101; the additional annexes are lettered AA and BB.

Annexes AA and BB form integral parts of this standard.

The committee has decided that the contents of this publication remain valid until 2004-12. At this date, in accordance with the committee’s decision, 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 Scope

Replacement:

This part 2 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, it will also need to meet the requirements of those other part 2 standards.

1.1.2 Equipment excluded from scope

Addition:

Add the following second paragraph:

Products for general laboratory use are not IVD medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination.