Irish Standard
I.S. EN 61010-2-101:2017

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

I.S. EN 61010-2-101:2017

Incorporating amendments/corrigenda/National Annexes issued since publication:

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1 Swift Square,	F +353 1 807 3838	T +353 1 857 6730
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National Foreword

I.S. EN 61010-2-101:2017 is the adopted Irish version of the European Document EN 61010-2-101:2017, Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

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In line with international standards practice the decimal point is shown as a comma (,) throughout this document.

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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)

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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.

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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)	 5.4.1 c)	Partially covered. This standard does not address the specifics of imported devices (authorized representative).
8.4 (h)	5.4.102, 5.4.4 i)	Covered.
8.4 (i)	5.4.4	Covered.
8.4 (j)	5.4.3, 5.4.4	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

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

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 61010-2-101:2015-01(en-fr)

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

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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.