ILNAS

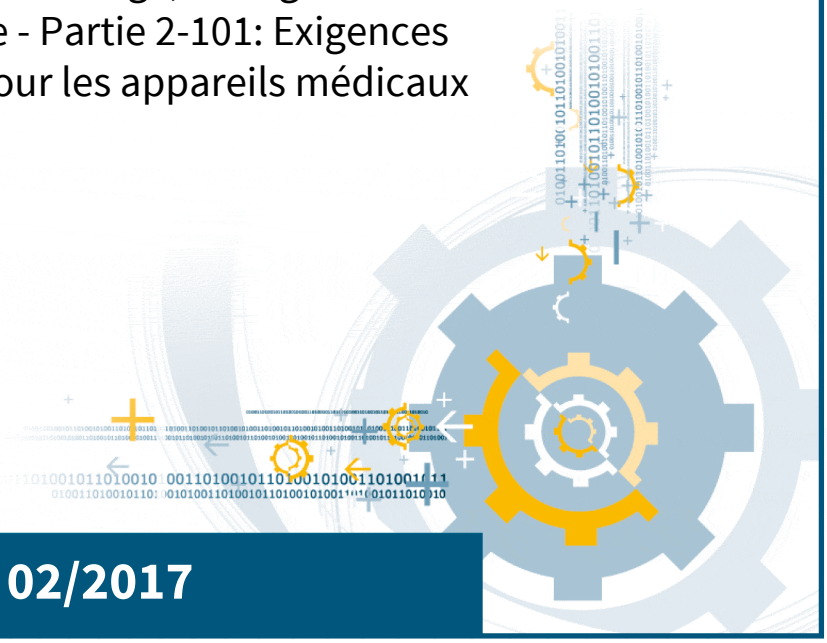
Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

# ILNAS-EN 61010-2-101:2017

## Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro

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: Exigences particulières pour les appareils médicaux



02/2017

**National Foreword**

This European Standard EN 61010-2-101:2017 was adopted as Luxembourgish Standard ILNAS-EN 61010-2-101:2017.

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- Participate in the design of standards
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# EUROPEAN STANDARD
# NORME EUROPÉENNE
# EUROPÄISCHE NORM

**EN 61010-2-101**

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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.

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

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

## 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.<br>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.<br>Clause 17 by applying EN ISO 14971. |
| **B DESIGN AND MANUFACTURING REQUIREMENTS** | | |
| 1.2 | 5.4.102, 8.101, Clause 13 | Partially covered.<br>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.<br>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.<br>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.<br>This standard does not address the specifics of imported devices (authorized representative). |
| 8.4 (b) | 5.1.2 b) | Partially covered.<br>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.<br>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.<br>Requirements for the label are not addressed. |
| 8.6 | 5.1.2 1),<br>5.1.2 2) iii) | Covered. |
| 8.7 (a)<br>Referring to:<br>8.4 (a) | <br><br>5.4.1 c) | Partially covered.<br><br>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.