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INTERNATIONAL STANDARD

colour inside

GROUP SAFETY PUBLICATION

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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

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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.

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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

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, ~~it will also need to meet the requirements of~~ considerations have to be given to those other part 2 standards.

1.1.2 Equipment excluded from scope

Addition:

Add the following item:

aa) ~~Products for general laboratory use are not IVD medical devices unless such products, in view of their characteristics,~~ 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

~~*Replacement:*~~

~~*Replace the first sentence by the following:*~~

~~The purpose of the requirements of this standard is to ensure that the design and the methods of construction used provide a high degree of protection at a TOLERABLE RISK for the OPERATOR and the surrounding area, using RISK management where appropriate (see annex AA).~~

Addition:

Add two items:

~~h~~ aa) biohazards;

~~i~~ bb) hazardous chemical substances.

1.2.2 Aspects excluded from scope

Addition:

Add the following item and note:

~~g~~ 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~~:2000~~, *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*

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)

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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:

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bb) hazardous chemical substances.

1.2.2 Aspects excluded from scope

Addition:

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COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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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)

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La Norme internationale IEC 61010-2-101 a été établie par le comité d'études 66 de l'IEC: Sécurité des appareils de mesure, de commande et de laboratoire.

Cette norme a le statut de publication groupée de sécurité, conformément au Guide 104 de l'IEC.

La préparation de cette norme a été réalisée en étroite collaboration avec le groupe de travail CENELEC BTTF 88.1.

Cette deuxième édition annule et remplace la première édition parue en 2002. Cette édition constitue une révision technique et inclut les modifications techniques majeures suivantes par rapport à la première édition, ainsi que de nombreuses autres modifications:

- exclusion de l'IEC 61010-2-081 (appareils d'usage général de laboratoire) du domaine d'application, ce qui distingue les appareils de l'IEC 61010-2-081 et ceux de l'IEC 61010-2-101;
- mise à jour des symboles Danger biologique et Lot dans le Tableau 1 à l'Article 5;
- ajout d'une exigence relative aux consommables possédant une date d'expiration et aux informations concernant le représentant autorisé dans les Instructions d'utilisation à l'Article 5;
- ajout d'une exigence relative aux marquages et caractéristiques assignées des gaz et liquides à l'Article 5;
- ajout d'une exigence incluant des instructions à l'OPERATEUR permettant de couvrir les déversements, bourrages ou bris de consommables ou de prélèvements à l'intérieur des appareils, l'élimination des déchets dangereux, la protection individuelle, les procédures de réduction de RISQUE applicables aux liquides inflammables, brûlures causées par des surfaces, ainsi que le chargement et le déchargement de prélèvements et de réactifs dans les Instructions d'utilisation à l'Article 5;
- ajout d'une exigence imposant au fabricant de fournir des instructions relatives au transport, au stockage et au retrait d'utilisation des appareils à l'Article 5;
- ajout de la référence normative ISO 18113-5 relative aux instructions d'utilisation des appareils médicaux d'autodiagnostic DIV à l'Article 5;
- ajout d'exigences relatives aux instructions d'entretien par l'OPERATEUR à l'Article 7;
- ajout d'exigences relatives aux zones de prélèvement et aux zones de chargement à l'Article 7;
- exclusion des appareils dont la taille et le poids rendent improbable un mouvement involontaire de l'essai de chute à l'Article 8;
- ajout d'une exigence relative au marquage des dangers biologiques à l'Article 13;
- ajout d'une exigence relative aux systèmes de verrouillage incluant des composants électriques/électroniques ou programmables à l'Article 15;
- ajout d'une référence informative à la Norme d'aptitude à l'utilisation IEC 62366 à l'Article 16;
- remplacement de l'Article 17 par les exigences de l'ISO 14971 concernant l'évaluation du RISQUE.
- suppression des instructions d'utilisation de l'Annexe BB relatives aux appareils médicaux d'autodiagnostic DIV et ajout d'une référence à l'ISO 18113-5 à l'Article 5.

Le texte de cette norme est issu des documents suivants:

FDIS	Rapport de vote
66/545/FDIS	66/560/RVD

Toute information sur le vote ayant abouti à l'approbation de cette norme se trouve dans le rapport de vote indiqué dans le tableau ci-dessus.

Cette publication a été rédigée selon les Directives ISO/IEC, Partie 2.

Une liste de toutes les parties de la série IEC 61010, publiées sous le titre général: *Règles de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire*, peut être consultée sur le site web de l'IEC.

La présente Partie 2-101 doit être utilisée conjointement avec l'IEC 61010-1. Elle a été établie sur la base de la troisième édition (2010).

La présente Partie 2-101 complète ou modifie les articles correspondants de l'IEC 61010-1 de façon à la transformer en norme IEC: *Règles de sécurité pour les appareils médicaux de diagnostic in vitro (DIV).*

Lorsqu'un paragraphe particulier de la Partie 1 n'est pas mentionné dans cette Partie 2, ce paragraphe s'applique pour autant qu'il est raisonnable. Lorsque cette partie spécifie «addition», «modification», «remplacement», ou «suppression», l'exigence, la modalité d'essai ou la note correspondante de la Partie 1 doit être adaptée en conséquence.

Dans la présente norme:

1) les caractères d'imprimerie suivants sont employés:
   - exigences: caractères romains;
   - NOTES: petits caractères romains;
   - *conformité et essai: caractères italiques;*
   - termes définis à l'Article 3 et utilisés dans toute cette norme: PETITES CAPITALES EN CARACTERES ROMAINS;
2) les paragraphes, figures, tableaux et notes complémentaires à ceux de la Partie 1 sont numérotés à partir de 101. Les annexes complémentaires sont nommées à partir de AA.

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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)

1 Domaine d'application et objet

Cet article de la Partie 1 est applicable, à l'exception de ce qui suit:

1.1.1 Appareils inclus dans le domaine d'application

Remplacement:

Remplacer le texte par ce qui suit:

La présente partie de l'IEC 61010 s'applique aux appareils destinés aux applications médicales de diagnostic in vitro (DIV), y compris aux appareils médicaux d'autodiagnostic DIV.

Les appareils médicaux de diagnostic in vitro DIV, utilisés seuls ou en combinaison avec d'autres appareils, sont destinés par le fabricant à l'examen in vitro de spécimens, y compris les prélèvements de sang et de tissus d'origine humaine, dans le but unique ou principal de donner des informations sur un ou plusieurs des éléments suivants:

- état physiologique ou pathologique; ou
- anomalie congénitale;
- détermination de la sécurité et de la compatibilité de receveurs potentiels;
- contrôle et suivi des mesures thérapeutiques.

Les appareils médicaux d'autodiagnostic DIV sont conçus par le fabricant pour être utilisés par un non-initié dans un environnement domestique.

NOTE Si l'équipement dans sa totalité ou quelques-uns de ses sous-ensembles relèvent du domaine d'application d'une ou plusieurs autres Parties 2 de la norme IEC 61010 ainsi que du domaine d'application de la présente norme, il est nécessaire de tenir compte de ces autres Parties 2.

1.1.2 Appareils exclus du domaine d'application

Addition:

Ajouter le point suivant:

aa) Les appareils couverts par le domaine d'application de l'IEC 61010-2-081, sauf s'ils sont spécifiquement destinés par leur fabricant à être utilisés à des fins de diagnostic in vitro.

1.2 Objet

1.2.1 Aspects inclus dans le domaine d'application

Addition:

Ajouter deux points:

aa) dangers biologiques;

bb) produits chimiques dangereux.

1.2.2 Aspects exclus du domaine d'application

Addition:

Ajouter le point et la note suivants:

aa) la manutention ou la manipulation de substances analysées en dehors de l'équipement.

NOTE Les exigences applicables à ces sujets sont de la responsabilité des comités préparant les normes appropriées.

2 Références normatives

Cet article de la Partie 1 est applicable, à l'exception de ce qui suit:

Addition:

Ajouter les références suivantes:

ISO 14971, *Dispositifs médicaux – Application de la gestion des risques aux dispositifs médicaux*

ISO 18113-5, *Dispositifs médicaux de diagnostic in vitro — Informations fournies par le fabricant (étiquetage) — Instruments de diagnostic in vitro pour auto-tests*

ISO 13857, *Sécurité des machines – Distances de sécurité empêchant les membres supérieurs et inférieurs d'atteindre les zones dangereuses*