IEC 61010-2-101

Edition 3.0 2018-10
REDLINE VERSION

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

ICS 11.040.55; 19.080

ISBN 978-2-8322-6114-9

Warning! Make sure that you obtained this publication from an authorized distributor.

CONTENTS

FOREWORD....3
1 Scope and object....6
2 Normative references....7
3 Terms and definitions....7
4 Tests....8
5 Marking and documentation....8
6 Protection against electric shock....12
7 Protection against mechanical HAZARDS....13
8 Resistance to mechanical stresses....14
9 Protection against the spread of fire....15
10 Equipment temperature limits and resistance to heat....15
11 Protection against HAZARDS from fluids and solid foreign objects....15
12 Protection against radiation, including laser sources, and against sonic and ultrasonic pressure....15
13 Protection against liberated gases and substances, explosion and implosion....15
14 Components and subassemblies....15
15 Protection by interlocks....16
16 HAZARDS resulting from application....16
17 RISK assessment....16
Annexes....16
Annex L (informative) Index of defined terms....17
Bibliography....18

Table 1 – Symbols....9

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 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.
2) The formal decisions or agreements of 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 IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

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

This third edition cancels and replaces the second edition published in 2015. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) adaptation of changes introduced by Amendment 1 of IEC 61010-1;
b) added tolerance for stability of AC voltage test equipment to Clause 6.

The text of this International Standard is based on the following documents:

CDV	Report on voting
66/644/CDV	66/669/RVC

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

This document 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) and its Amendment 1 (2016).

This Part 2-101 supplements or modifies the corresponding clauses in IEC 61010-1 so as to convert that publication into the IEC standard: *Particular 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 and additional list items are lettered from aa).

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

IMPORTANT – The "colour inside" logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this publication using a colour printer.

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, except the first paragraph, with the following new text:

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 the IEC 61010 series as well as within the scope of this document, considerations ~~have to be~~ is given to those other Part 2 standards.

1.1.2 Equipment excluded from scope

Addition:

Add the following new item:

aa) equipment within the scope of IEC 61010-2-081 unless ~~they are~~ it is specifically intended by the~~ir~~ manufacturer to be used for in vitro diagnostic examination.

1.2 Object

1.2.1 Aspects included in scope

Addition:

Add the following two new items:

aa) biohazards;

bb) hazardous chemical substances.

1.2.2 Aspects excluded from scope

Addition:

Add the following new 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 the relevant standards.

2 Normative references

This clause of Part 1 is applicable except as follows:

Addition:

Add the following new references to the list:

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) – Part 5: In vitro diagnostic instruments for self-testing*

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

IEC 61010-2-101

Edition 3.0 2018-10

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

Exigences de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire –
Partie 2-101: Exigences particulières pour le matériel médical de diagnostic in vitro (DIV)

IEC 61010-2-101:2018-10(en-fr)

CONTENTS

FOREWORD....3
1 Scope and object....5
2 Normative references....6
3 Terms and definitions....6
4 Tests....6
5 Marking and documentation....7
6 Protection against electric shock....11
7 Protection against mechanical HAZARDS....11
8 Resistance to mechanical stresses....13
9 Protection against the spread of fire....13
10 Equipment temperature limits and resistance to heat....13
11 Protection against HAZARDS from fluids and solid foreign objects....13
12 Protection against radiation, including laser sources, and against sonic and ultrasonic pressure....14
13 Protection against liberated gases and substances, explosion and implosion....14
14 Components and subassemblies....14
15 Protection by interlocks....14
16 HAZARDS resulting from application....15
17 RISK assessment....15
Annexes....15
Annex L (informative) Index of defined terms....16
Bibliography....17

Table 1 – Symbols....8

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 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.
2) The formal decisions or agreements of 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 IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. 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.

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

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

This third edition cancels and replaces the second edition published in 2015. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) adaptation of changes introduced by Amendment 1 of IEC 61010-1;

b) added tolerance for stability of AC voltage test equipment to Clause 6.

The text of this International Standard is based on the following documents:

CDV	Report on voting
66/644/CDV	66/669/RVC

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

This document 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) and its Amendment 1 (2016).

This Part 2-101 supplements or modifies the corresponding clauses in IEC 61010-1 so as to convert that publication into the IEC standard: *Particular 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 and additional list items are lettered from aa).

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document 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, except the first paragraph, with the following new text:

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 the IEC 61010 series as well as within the scope of this document, consideration is given to those other Part 2 standards.

1.1.2 Equipment excluded from scope

Addition:

Add the following new item:

aa) equipment within the scope of IEC 61010-2-081 unless it is specifically intended by the manufacturer to be used for in vitro diagnostic examination.

1.2 Object

1.2.1 Aspects included in scope

Addition:

Add the following two new items:

aa) biohazards;

bb) hazardous chemical substances.

1.2.2 Aspects excluded from scope

Addition:

Add the following new 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 the relevant standards.

2 Normative references

This clause of Part 1 is applicable except as follows:

Addition:

Add the following new references to the list:

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) – Part 5: In vitro diagnostic instruments for self-testing*

SOMMAIRE

AVANT-PROPOS 19
1 Domaine d'application et objet 21
2 Références normatives 22
3 Termes et définitions 22
4 Essais 23
5 Marquage et documentation 23
6 Protection contre les chocs électriques 28
7 Protection contre les DANGERS mécaniques 28
8 Résistance aux contraintes mécaniques 29
9 Protection contre la propagation du feu 30
10 Limites de température de l'appareil et résistance à la chaleur 30
11 Protection contre les DANGERS des fluides et des corps solides étrangers 30
12 Protection contre les radiations, y compris les sources laser, et contre la pression acoustique et ultrasonique 30
13 Protection contre les émissions de gaz et substances, les explosions et les implosions 30
14 Composants et sous-ensembles 31
15 Protection par systèmes de verrouillage 31
16 DANGERS résultant de l'application 31
17 Appréciation du RISQUE 31
Annexes 32
Annexe L (informative) Index des termes définis 33
Bibliographie 34

Tableau 1 – Symboles 24

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

_____

EXIGENCES DE SÉCURITÉ POUR APPAREILS ÉLECTRIQUES DE MESURAGE, DE RÉGULATION ET DE LABORATOIRE –

Partie 2-101: Exigences particulières pour le matériel médical de diagnostic in vitro (DIV)

AVANT-PROPOS

1) La Commission Electrotechnique Internationale (IEC) est une organisation mondiale de normalisation composée de l'ensemble des comités électrotechniques nationaux (Comités nationaux de l'IEC). L'IEC a pour objet de favoriser la coopération internationale pour toutes les questions de normalisation dans les domaines de l'électricité et de l'électronique. A cet effet, l'IEC – entre autres activités – publie des Normes internationales, des Spécifications techniques, des Rapports techniques, des Spécifications accessibles au public (PAS) et des Guides (ci-après dénommés "Publication(s) de l'IEC"). Leur élaboration est confiée à des comités d'études, aux travaux desquels tout Comité national intéressé par le sujet traité peut participer. Les organisations internationales, gouvernementales et non gouvernementales, en liaison avec l'IEC, participent également aux travaux. L'IEC collabore étroitement avec l'Organisation Internationale de Normalisation (ISO), selon des conditions fixées par accord entre les deux organisations.
2) Les décisions ou accords officiels de l'IEC concernant les questions techniques représentent, dans la mesure du possible, un accord international sur les sujets étudiés, étant donné que les Comités nationaux de l'IEC intéressés sont représentés dans chaque comité d'études.
3) Les Publications de l'IEC se présentent sous la forme de recommandations internationales et sont agréées comme telles par les Comités nationaux de l'IEC. Tous les efforts raisonnables sont entrepris afin que l'IEC s'assure de l'exactitude du contenu technique de ses publications; l'IEC ne peut pas être tenue responsable de l'éventuelle mauvaise utilisation ou interprétation qui en est faite par un quelconque utilisateur final.
4) Dans le but d'encourager l'uniformité internationale, les Comités nationaux de l'IEC s'engagent, dans toute la mesure possible, à appliquer de façon transparente les Publications de l'IEC dans leurs publications nationales et régionales. Toutes divergences entre toutes Publications de l'IEC et toutes publications nationales ou régionales correspondantes doivent être indiquées en termes clairs dans ces dernières.
5) L'IEC elle-même ne fournit aucune attestation de conformité. Des organismes de certification indépendants fournissent des services d'évaluation de conformité et, dans certains secteurs, accèdent aux marques de conformité de l'IEC. L'IEC n'est responsable d'aucun des services effectués par les organismes de certification indépendants.
6) Tous les utilisateurs doivent s'assurer qu'ils sont en possession de la dernière édition de cette publication.
7) Aucune responsabilité ne doit être imputée à l'IEC, à ses administrateurs, employés, auxiliaires ou mandataires, y compris ses experts particuliers et les membres de ses comités d'études et des Comités nationaux de l'IEC, pour tout préjudice causé en cas de dommages corporels et matériels, ou de tout autre dommage de quelque nature que ce soit, directe ou indirecte, ou pour supporter les coûts (y compris les frais de justice) et les dépenses découlant de la publication ou de l'utilisation de cette Publication de l'IEC ou de toute autre Publication de l'IEC, ou au crédit qui lui est accordé.
8) L'attention est attirée sur les références normatives citées dans cette publication. L'utilisation de publications référencées est obligatoire pour une application correcte de la présente publication.
9) L'attention est attirée sur le fait que certains des éléments de la présente Publication de l'IEC peuvent faire l'objet de droits de brevet. L'IEC ne saurait être tenue pour responsable de ne pas avoir identifié de tels droits de brevets et de ne pas avoir signalé leur existence.

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.

Elle a le statut d'une publication groupée de sécurité conformément au Guide IEC 104.

Ce document a été élaboré en étroite collaboration avec le groupe de travail CENELEC BTTF 88.1.

Cette troisième édition annule et remplace la deuxième édition parue en 2015. Cette édition constitue une révision technique.

Cette édition inclut les modifications techniques majeures suivantes par rapport à l'édition précédente:

a) adaptation des modifications introduites par l'Amendement 1 de l'IEC 61010-1;
b) ajout à l'Article 6 de la tolérance pour la stabilité du matériel d'essai en tension alternative.

Le texte de cette Norme internationale est issu des documents suivants:

CDV	Rapport de vote
66/644/CDV	66/669/RVC

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de cette Norme internationale.

Ce document a été rédigé selon les Directives ISO/IEC, Partie 2.

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

Cette Partie 2-101 est destinée à être utilisée conjointement avec l'IEC 61010-1. Elle a été établie sur la base de la troisième édition (2010) et de son Amendement 1 (2016).

La présente Partie 2-101 complète ou modifie les articles correspondants de l'IEC 61010-1 de façon à transformer cette publication en norme IEC: *Exigences particulières pour le matériel médical de diagnostic in vitro (DIV).*

Lorsqu'un paragraphe particulier de la Partie 1 n'est pas mentionné dans la présente Partie 2, ce paragraphe s'applique pour autant que cela soit raisonnable. Lorsque cette partie indique «addition», «modification», «remplacement» ou «suppression», il convient en conséquence d'adapter l'exigence, la modalité d'essai ou la note correspondante de la Partie 1.

Dans la présente norme:

1) les caractères d'imprimerie suivants sont utilisés:
   – exigences: caractères romains;
   – NOTES: petits caractères romains;
   – *conformité et essais: caractères italiques;*
   – termes définis à l'Article 3 et utilisés dans toute cette norme: PETITES CAPITALES EN CARACTÈRES ROMAINS;
2) les paragraphes, figures, tableaux et notes qui viennent en supplément de ceux de la Partie 1 sont numérotés à partir de 101. Les annexes complémentaires sont désignées à partir de AA et les listes de termes additionnels à partir de aa).

Le comité a décidé que le contenu de ce document ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous "http://webstore.iec.ch" dans les données relatives au document recherché. A cette date, le document sera

- reconduit,
- supprimé,
- remplacé par une édition révisée, ou
- amendé.

EXIGENCES DE SÉCURITÉ POUR APPAREILS ÉLECTRIQUES DE MESURAGE, DE RÉGULATION ET DE LABORATOIRE –

Partie 2-101: Exigences particulières pour le matériel médical de diagnostic in vitro (DIV)

1 Domaine d'application et objet

L'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, excepté le premier alinéa, par le nouveau texte suivant:

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'autotest DIV.

Le matériel médical DIV, utilisé seul ou en combinaison avec d'autres appareils, est destiné par le fabricant à l'examen in vitro de prélèvements, y compris les prélèvements de sang et de tissus d'origine humaine, dans le but unique ou principal de fournir 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.

Le matériel médical d'autotest DIV est conçu par le fabricant pour être utilisé par un non-initié dans un environnement domestique.

NOTE Si une ou toutes les parties de l'appareil relèvent du domaine d'application d'une ou de plusieurs autres Parties 2 de la série IEC 61010, ainsi que du domaine d'application du présent document, ces autres Parties 2 sont prises en compte.

1.1.2 Appareils exclus du domaine d'application

Addition:

Ajouter le nouveau point suivant:

aa) les appareils relevant du domaine d'application de l'IEC 61010-2-081, sauf s'ils sont spécifiquement destinés par le 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 les deux nouveaux points suivants:

aa) dangers biologiques;

bb) produits chimiques dangereux.

1.2.2 Aspects exclus du domaine d'application

Addition:

Ajouter le nouveau point suivant et la nouvelle note suivante:

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

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

2 Références normatives

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

Addition:

Ajouter les nouvelles références suivantes à la liste:

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) – Partie 5: Instruments de diagnostic in vitro pour auto-test*