

INTERNATIONAL STANDARD

NORME INTERNATIONALE

GROUP SAFETY PUBLICATION
PUBLICATION GROUPEE 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)**



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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 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.

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- withdrawn,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

Withdrawn