Sikkerhedskrav til elektrisk udstyr til måling, styring og laboratoriebrug – Del 2-101: Særlige krav til in vitro-diagnostisk (IVD) medicinsk udstyr

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

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November 2022

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English Version

Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Safety 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)

Sicherheitsbestimmungen für elektrische Mess-, Steuer-, Regel- und Laborgeräte - Teil 2-101: Besondere Anforderungen an In-vitro-Diagnostik (IVD) Medizingeräte

This amendment A11 modifies the European Standard ; it was approved by CENELEC on 26 September 2022. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment 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 amendment 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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Contents

Page

European foreword 3
1 Modifications to 1.1.1, "Equipment included in scope" 4
2 Modifications to 1.1.2, "Equipment excluded from scope" 4
3 Modifications to 1.2.1, "Aspects included in scope" 4
4 Modifications to 1.2.2, "Aspects excluded from scope" 4
5 Modifications to Clause 2, "Normative references" 5
6 Modifications to Clause 3.2, “Parts and accessories” 5
7 Modifications to Clause 3.5, “Safety terms” 5
8 Modifications to Table 1 in 5.1.3, “Mains supply” 6
9 Modification to Clause 5.1, “Marking” 6
10 Modification to Clause 5.4.3 “Equipment transportation, installation and assembly instructions” 6
11 Modifications to Clause 7, "Protection against mechanical HAZARDS" 6
12 Modifications to Clause 8, "Resistance to mechanical stresses" 7
13 Modifications to Clause 10, "Equipment temperature limits and resistance to heat" 8
14 Modifications to Clause 12, "Protection against radiation, including laser sources, and against sonic and ultrasonic pressure" 9
15 Modifications to Clause 13, "Protection against liberated gases and substances, explosion and implosion" 10
16 Modifications to Clause 14, "Components and subassemblies" 10
17 Modifications to Clause 15, "Protection by interlocks" 11
18 Modifications to Clause 16, "HAZARDS resulting from application" 13
19 Modifications to Clause 17, "RISK assessment" 14
20 Addition of Clause 201, "Disconnecting from energy sources" 15
21 Modifications to Annex J, "RISK assessment” 15
22 Modifications to "Bibliography" 17
23 Addition of Annex ZA, “Normative references to international publications with their corresponding European publications” 18
Annex ZA (normative) Normative references to international publications with their corresponding European publications 19

European foreword

This document (EN IEC 61010-2-101:2022/A11:2022) has been prepared by CLC/TC 66X "Safety of measuring, control, and laboratory equipment".

The following dates are fixed:

- latest date by which this document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2023-09-26
- latest date by which the national standards conflicting with this document have to be withdrawn (dow) 2025-09-26

This document amends EN IEC 61010-2-101:2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

This document is read in conjunction with EN 61010-1:2010 + A1:2019 as modified by EN IEC 61010-2-101:2022 which results in the complete text of EN IEC 61010-2-101:2022. This A11 describes how that text is modified.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Safety requirements for electrical equipment for measurement, control, and laboratory use –

Part 2-101:
Safety requirements for in vitro diagnostic (IVD) medical equipment

1 Modifications to 1.1.1, "Equipment included in scope"

Replace the title as follows:

"**1.1.1 General**"

Replace the second paragraph with the following:

"This part of IEC 61010 provides particular safety requirements to equipment intended for in vitro diagnostic (IVD) medical purposes, including self-test IVD medical purposes. It is intended to be used in conjunction with the manufacturer's RISK management but not to replace it.

NOTE 1 A good design practice of an equipment starts from the beginning with a RISK management process according to ISO 14971, which provides requirement and guidance for a comprehensive RISK management process and identifies HAZARDS and risks related with the equipment."

Replace the note with the following:

"

NOTE 2 A system, as specified by its manufacturer, is a combination of items of equipment, at least one of these is inter-connected to another item. In the following text the term equipment is used for single equipment and systems.

It is possible that 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 document. In that case, the requirements of those other Part 2 standards will also apply."

2 Modifications to 1.1.2, "Equipment excluded from scope"

Replace the title as follows:

"**1.1.2 Exclusions from the scope**"

3 Modifications to 1.2.1, "Aspects included in scope"

Replace the first paragraph with the following:

"The purpose of the requirements of this document is to ensure that HAZARDS to the OPERATOR, the SERVICE PERSONNEL and the surrounding area are reduced to a tolerable level."

Add the following item to the list:

"cc) any other energy sources (see Clause 201)"

4 Modifications to 1.2.2, "Aspects excluded from scope"

Delete item b).

Replace item c) with the following:

"c) EMC requirements, except when related to safety (see the IEC 61326 series);"

5 Modifications to Clause 2, "Normative references"

Add the following references:

"

EN IEC 61326-2-6:2021, *Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment*

EN 61326-3-1, *Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 3-1: Immunity requirements for safety-related systems and for equipment intended to perform safety-related functions (functional safety) – General industrial applications*

EN IEC 62061:2021, *Safety of machinery – Functional safety of safety-related control systems*

EN 62366-1, *Medical devices – Part 1: Application of usability engineering to medical devices*

EN ISO 13849-1:2015, *Safety of machinery – Safety-related parts of control systems – Part 1: General principles for design (ISO 13849-1:2015)*

EN ISO 13850, *Safety of machinery – Emergency stop function – Principles for design (ISO 13850)*

"