SLOVENSKI STANDARD
SIST EN IEC 61326-2-6:2021

01-september-2021

Nadomešča:
SIST EN 61326-2-6:2013

Električna oprema za merjenje, nadzor in laboratorijsko uporabo - Zahteve za elektromagnetno združljivost (EMC) - 2-6. del: Posebne zahteve - In vitro diagnostična (IVD) medicinska oprema (IEC 61326-2-6:2020)

Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment (IEC 61326-2-6:2020)

Elektrische Mess-, Steuer-, Regel- und Laborgeräte - EMV-Anforderungen - Teil 2-6: Besondere Anforderungen - Medizinische In-vitro-Diagnosegeräte (IVD) (IEC 61326-2-6:2020)

Matériel électrique de mesure, de commande et de laboratoire - Exigences relatives à la CEM - Partie 2-6: Exigences particulières - Matériel médical de diagnostic in vitro (IVD) (IEC 61326-2-6:2020)

Ta slovenski standard je istoveten z: **EN IEC 61326-2-6:2021**

ICS:

11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems
19.080	Električno in elektronsko preskušanje	Electrical and electronic testing
33.100.01	Elektromagnetna združljivost na splošno	Electromagnetic compatibility in general

SIST EN IEC 61326-2-6:2021 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 61326-2-6

June 2021

ICS 25.040.40; 17.220.20; 33.100.20

Supersedes EN 61326-2-6:2013 and all of its amendments and corrigenda (if any)

English Version

Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment (IEC 61326-2-6:2020)

Matériel électrique de mesure, de commande et de laboratoire - Exigences relatives à la CEM - Partie 2-6: Exigences particulières - Matériel médical de diagnostic in vitro (IVD)
(IEC 61326-2-6:2020)

Elektrische Mess-, Steuer-, Regel- und Laborgeräte - EMV-Anforderungen - Teil 2-6: Besondere Anforderungen - Medizinische In-vitro-Diagnosegeräte (IVD)
(IEC 61326-2-6:2020)

This European Standard was approved by CENELEC on 2020-12-02. 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.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN IEC 61326-2-6:2021 E

European foreword

The text of document 65A/979/FDIS, future edition 3 of IEC 61326-2-6, prepared by SC 65A "System aspects" of IEC/TC 65 "Industrial-process measurement, control and automation" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 61326-2-6:2021.

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) 2021-12-04
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2024-06-04

This document supersedes EN 61326-2-6:2013 and all of its amendments and corrigenda (if any).

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 has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association.

Endorsement notice

The text of the International Standard IEC 61326-2-6:2020 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-1-2:2014	NOTE	Harmonized as EN 60601-1-2:2015 (not modified)
ISO 18113-1:2009	NOTE	Harmonized as EN ISO 18113-1:2011 (not modified)

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where 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.

The Annex ZA of EN IEC 61326-1:2021 applies with the following addition:

Publication	Year	Title	EN/HD	Year
IEC 61326-1	2020	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements	EN IEC 61326-1	2021
ISO 14971	2019	Medical devices – Application of risk management to medical devices	EN ISO 14971	2019

IEC 61326-2-6

Edition 3.0 2020-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

Matériel électrique de mesure, de commande et de laboratoire – Exigences relatives à la CEM – Partie 2-6: Exigences particulières – Matériel médical de diagnostic in vitro (IVD)

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL AND LABORATORY USE – EMC REQUIREMENTS –

Part 2-6: Particular requirements – 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 61326-2-6 has been prepared by subcommittee 65A: System aspects, of IEC technical committee 65: Industrial-process measurement, control and automation.

This third edition cancels and replaces the second published in 2012. This edition constitutes a technical revision.

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

– update of the document with respect to IEC 61326-1:2020.

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

FDIS	Report on voting
65A/979/FDIS	65A/990/RVD

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.

In this document the following print types are used:

– Terms used throughout this document which have been defined in Clause 3 of this document and of IEC 61326-1:2020: SMALL CAPITALS.

This part of IEC 61326 is to be used in conjunction with IEC 61326-1:2020 and follows the same numbering of clauses, subclauses, tables and figures.

When a particular subclause of IEC 61326-1 is not mentioned in this part, that subclause applies as far as is reasonable. When this standard states “addition”, “modification” or “replacement”, the relevant text in IEC 61326-1 is to be adapted accordingly.

NOTE The following numbering system is used:

– subclauses, tables and figures that are numbered starting from 101 are additional to those in IEC 61326-1;
– unless notes are in a new subclause or involve notes in IEC 61326-1, they are numbered starting from 101 including those in a replaced clause or subclause;
– additional annexes are lettered AA, BB, etc.

A list of all parts of the IEC 61326 series, under the general title *Electrical equipment for measurement, control and laboratory use – EMC requirements,* can be found on the IEC website.

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.

ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL AND LABORATORY USE – EMC REQUIREMENTS –

Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment

1 Scope

In addition to the scope of IEC 61326-1, this part of IEC 61326 specifies minimum requirements for immunity and emissions regarding electromagnetic compatibility for IN VITRO DIAGNOSTIC (IVD) MEDICAL EQUIPMENT, taking into account the particularities and specific aspects of this electrical equipment and their electromagnetic environment.

2 Normative references

Clause 2 of IEC 61326-1:2020 applies, except as follows:

Addition:

IEC 61326-1:2020, *Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements*

ISO 14971:2019, *Medical devices – Application of risk management to medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 61326-1 apply, except as follows.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

Addition:

3.101
in vitro diagnostic medical equipment
instruments and apparatus intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease

Note 1 to entry: Such instruments or apparatus are intended for use in the collection, preparation, and examination of specimens taken from the human body without direct or wired patient connection with the device.

Note 2 to entry: IVD: In vitro diagnostic.

3.102
professional healthcare facility environment
environment where professional healthcare is administered