

STN	Elektrické zariadenia na meranie, riadenie a laboratórne použitie Požiadavky na elektromagnetickú kompatibilitu Časť 2-6: Osobitné požiadavky Diagnostické zdravotnícke zariadenia in vitro (IVD)	STN EN IEC 61326-2-6 35 6508
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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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 08/21

Obsahuje: EN IEC 61326-2-6:2021, IEC 61326-2-6:2020

Oznámením tejto normy sa od 04.06.2024 ruší
STN EN 61326-2-6 (35 6508) z decembra 2013

133308

EUROPEAN STANDARD

EN IEC 61326-2-6

NORME EUROPÉENNE

EUROPÄISCHE NORM

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)

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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

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 (dop) 2021-12-04 level by publication of an identical national standard or by endorsement
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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:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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

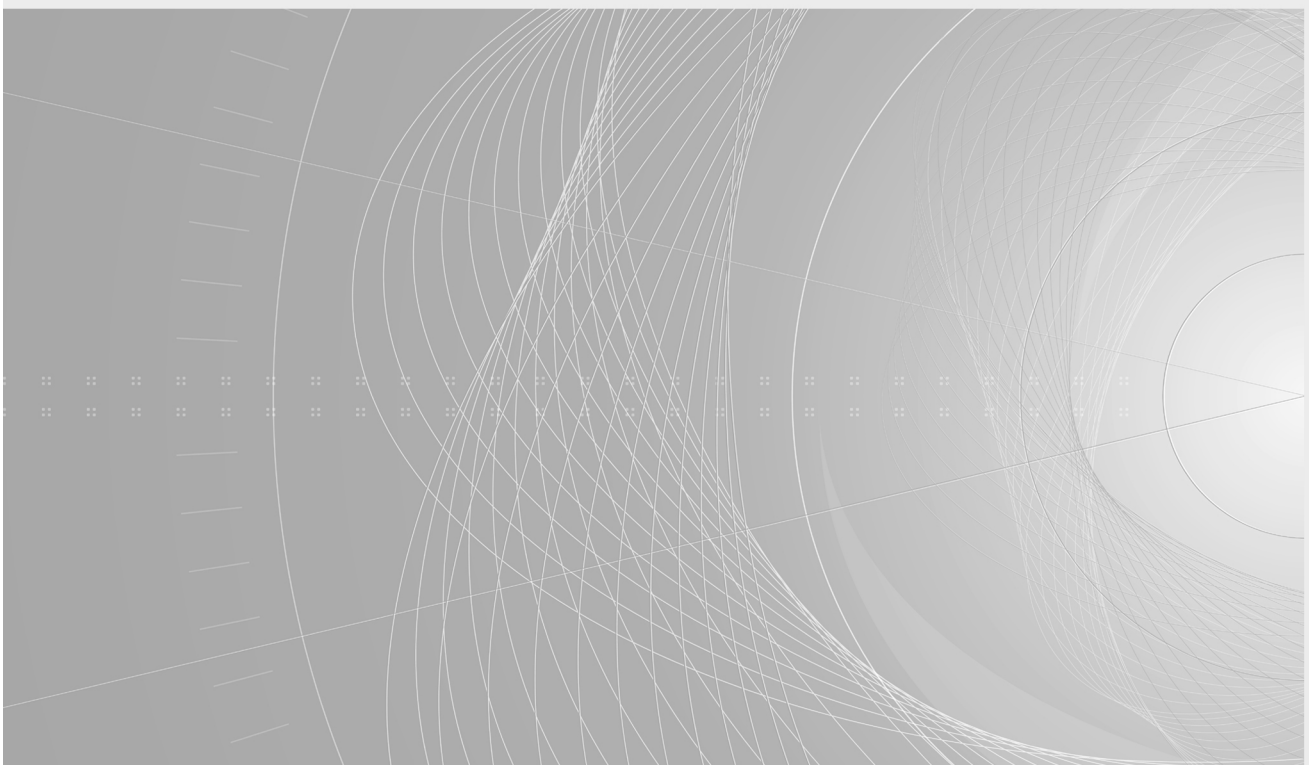
Edition 3.0 2020-10

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)**





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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)**

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ELECTROTECHNICAL
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COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 17.220.20; 25.040.40; 33.100.20

ISBN 978-2-8322-8983-9

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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

FOREWORD

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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*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN