
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 61326-2-6:2025)

Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment (IEC 61326-2-6:2025)

Elektrische Mess-, Steuer-, Regel- und Laborgeräte - EMV-Anforderungen - Teil 2-6: Besondere Anforderungen - Medizinische In-vitro-Diagnosegeräte (IVD) (IEC 61326-2-6:2025)

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 (IEC 61326-2-6:2025) (IVD)

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Ta slovenski standard je istoveten z: EN IEC 61326-2-6:2025

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 61326-2-6:2025**en,fr,de**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN IEC 61326-2-6

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ICS 17.220.20; 25.040.40; 33.100.20

Supersedes EN IEC 61326-2-6:2021

English Version

**Electrical equipment for measurement, control and laboratory
use - EMC requirements - Part 2-6: Particular requirements - In
vitro diagnostic (IVD) medical electrical equipment
(IEC 61326-2-6:2025)**

Matériel électrique de mesure, de commande et de
laboratoire - Exigences relatives à la CEM - Partie 2-6:
Exigences particulières - Matériel électromédical de
diagnostic in vitro (DIV)
(IEC 61326-2-6:2025)

Elektrische Mess-, Steuer-, Regel- und Laborgeräte - EMV-
Anforderungen - Teil 2-6: Besondere Anforderungen -
Medizinische In-vitro-Diagnosegeräte (IVD)
(IEC 61326-2-6:2025)

This European Standard was approved by CENELEC on 2025-07-23. 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.

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
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EN IEC 61326-2-6:2025 (E)**European foreword**

The text of document 65A/1174/FDIS, future edition 4 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 61326-2-6:2025.

The following dates are fixed:

- latest date by which the document has to be implemented at national (dop) 2026-08-31 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2028-08-31 document have to be withdrawn

This document supersedes EN IEC 61326-2-6:2021 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 is read in conjunction with EN IEC 61326-1:2021.

This document has been prepared under a standardization request addressed to CENELEC by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

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.

Endorsement notice

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The text of the International Standard IEC 61326-2-6:2025 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 standard indicated:

IEC 60601-1-2:2014	NOTE	Approved as EN 60601-1-2:2015 (not modified)
IEC 60601-1-11:2015	NOTE	Approved as EN 60601-1-11:2015 (not modified)
IEC 61010-2-101:2018	NOTE	Approved as EN IEC 61010-2-101:2022 (not modified)
ISO 18113-1:2022	NOTE	Approved as EN ISO 18113-1:2024 (not modified)
ISO/TR 24971:2020	NOTE	Approved as CEN ISO/TR 24971:2020 (not modified)
ISO 14971:2007	NOTE	Approved as EN ISO 14971:2019 (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.

Annex ZA of Part 1 is applicable except as follows:

Addition:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 61010	series	Safety requirements for electrical equipment for measurement, control, and laboratory use	EN IEC 61010	series
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

<https://standards.iteh.ai/catalog/standards/sist/47c1e993-6bb5-4c89-be2b-c46bb4c1ed05/sist-en-iec-61326-2-6-2025>