SVENSK STANDARD

SS-EN IEC 61326-2-6, utg 4:2026

Fastställd	Sida	Ansvarig kommitté
2026-02-04	1 (36)	SEK TK 65

Elektrisk utrustning för mätning, styrning och för laboratorieändamål – EMC-fordringar – Del 2-6: Särskilda fordringar – Medicinsk utrustning för in vitro-diagnostik

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

Som svensk standard gäller europastandarden EN IEC 61326-2-6:2025. Den svenska standarden innehåller den officiella engelska språkversionen av EN IEC 61326-2-6:2025.

Nationellt förord

Europastandarden EN IEC 61326-2-6:2025

består av:

– **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC
– **IEC 61326-2-6, Fourth edition, 2025 - Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment**

utarbetad inom International Electrotechnical Commission, IEC.

Standarden ska användas tillsammans med SS-EN IEC 61326-1, utg 4:2021.

Tidigare fastställd svensk standard SS-EN IEC 61326-2-6, utg 3:2021 med eventuella tillägg, ändringar och rättelser gäller ej fr o m 2028-08-31.

ICS 17.220.20; 25.040.40; 33.100.20

Denna standard är fastställd av SEK Svensk Elstandard,
som också kan lämna upplysningar om **sakinnehållet** i standarden.
Postadress: Box 1042, 172 21 Sundbyberg
Telefon: 08 - 444 14 00.
E-post: sek@elstandard.se. Internet: elstandard.se

Standarder underlättar utvecklingen och höjer elsäkerheten

Det finns många fördelar med att ha gemensamma tekniska regler för bl a mätning, säkerhet och provning och för utförande, skötsel och dokumentation av elprodukter och elanläggningar.

Genom att utforma sådana standarder blir säkerhetsfordringar tydliga och utvecklingskostnaderna rimliga samtidigt som marknadens acceptans för produkten eller tjänsten ökar.

Många standarder inom elområdet beskriver tekniska lösningar och metoder som åstadkommer den elsäkerhet som föreskrivs av svenska myndigheter och av EU.

SEK är Sveriges röst i standardiseringsarbetet inom elområdet

SEK Svensk Elstandard svarar för standardiseringen inom elområdet i Sverige och samordnar svensk medverkan i internationell och europeisk standardisering. SEK är en ideell organisation med frivilligt deltagande från svenska myndigheter, företag och organisationer som vill medverka till och påverka utformningen av tekniska regler inom elektrotekniken.

SEK samordnar svenska intressenters medverkan i SEKs tekniska kommittéer och stödjer svenska experters medverkan i internationella och europeiska projekt.

Stora delar av arbetet sker internationellt

Utformningen av standarder sker i allt väsentligt i internationellt och europeiskt samarbete. SEK är svensk nationalkommitté av International Electrotechnical Commission (IEC) och Comité Européen de Normalisation Electrotechnique (CENELEC).

Standardiseringsarbetet inom SEK är organiserat i referensgrupper bestående av ett antal tekniska kommittéer som speglar hur arbetet inom IEC och CENELEC är organiserat.

Arbetet i de tekniska kommittéerna är öppet för alla svenska organisationer, företag, institutioner, myndigheter och statliga verk. Den årliga avgiften för deltagandet och intäkter från försäljning finansierar SEKs standardiseringsverksamhet och medlemsavgift till IEC och CENELEC.

Var med och påverka!

Den som deltar i SEKs tekniska kommittéarbete har möjlighet att påverka framtida standarder och får tidig tillgång till information och dokumentation om utvecklingen inom sitt teknikområde. Arbetet och kontakterna med kollegor, kunder och konkurrenter kan gynnsamt påverka enskilda företags affärsutveckling och bidrar till deltagarnas egen kompetensutveckling.

Du som vill dra nytta av dessa möjligheter är välkommen att kontakta SEKs kansli för mer information.

SEK Svensk Elstandard

Box 1042
172 21 Sundbyberg
Tel 08-444 14 00
elstandard.se

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 61326-2-6

August 2025

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)

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 61326-2-6:2025 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 level by publication of an identical national standard or by endorsement (dop) 2026-08-31
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2028-08-31

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

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.cencenelec.eu.

Annex ZA of Part 1 is applicable except as follows:

Addition:

Publication	Year	Title	EN/HD	Year
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

IEC 61326-2-6

Edition 4.0 2025-06

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

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)

ICS 17.220.20, 25.040.40, 33.100.20

ISBN 978-2-8327-0509-4

IEC 61326-2-6:2025-06(en-fr)

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical electrical 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.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) IEC draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at https://patents.iec.ch. IEC shall not be held responsible for identifying any or all such patent rights.

IEC 61326-2-6 has been prepared by subcommittee 65A: System aspects, of IEC technical committee 65: Industrial-process measurement, control and automation. It is an International Standard.

This fourth edition cancels and replaces the third edition published in 2020. This edition constitutes a technical revision.

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

– Update of the document with respect to test levels and documentation.

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

Draft	Report on voting
65A/1174/FDIS	65A/1180/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

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 are printed in 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.

If an IEC 61326-2-6 report is available, the report of IEC 61326-1 is integrated.

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 webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

1 Scope

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of IN VITRO DIAGNOSTIC MEDICAL ELECTRICAL EQUIPMENT (IVD MEE). This part of IEC 61326 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of IVD MEE in the presence of electromagnetic disturbances and to electromagnetic disturbances emitted by IVD MEE.

BASIC SAFETY with regard to electromagnetic disturbances is applicable to all IVD MEE.

NOTE 1 Performance with respect to electromagnetic disturbances other than ESSENTIAL PERFORMANCE is the subject of IEC 61326-1:2020

NOTE 2 IT equipment can be a part of an IVD MEE, if it is required to maintain BASIC SAFETY or ESSENTIAL PERFORMANCE.

2 Normative references

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.

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

Addition:

IEC 61010 (all parts), *Safety requirements for electrical equipment for measurement, control, and laboratory use*

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*