

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>See Eesti standard EVS-EN IEC 61326-2-6:2025 sisaldab Euroopa standardi EN IEC 61326-2-6:2025 ingliskeelset teksti.</p> <p>Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.</p> <p>Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 22.08.2025.</p> <p>Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.</p>	<p>This Estonian standard EVS-EN IEC 61326-2-6:2025 consists of the English text of the European standard EN IEC 61326-2-6:2025.</p> <p>This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.</p> <p>Date of Availability of the European standard is 22.08.2025.</p> <p>The standard is available from the Estonian Centre for Standardisation and Accreditation.</p>
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ICS 17.220.20, 25.040.40, 33.100.20

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EUROPEAN STANDARD

EN IEC 61326-2-6

NORME EUROPÉENNE

EUROPÄISCHE NORM

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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)

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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:

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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)

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)



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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 electrical equipment

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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*

3 Terms, definitions and abbreviations

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

3.1 Terms and definitions

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