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INTERNATIONAL STANDARD

colour inside

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

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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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.

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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.

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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

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:~~2012~~2020 applies, except as follows:

Addition:

IEC 61326-1:~~2012~~2020, *Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements*

ISO 14971:~~2007~~2019, *Medical devices – Application of risk management to medical devices*

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)

IEC 61326-2-6:2020-10(en-fr)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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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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Cette troisième édition annule et remplace la deuxième édition parue en 2012. Cette édition constitue une révision technique.

Cette édition inclut la modification technique majeure suivante par rapport à l'édition précédente:

– mise à jour du document par rapport à l'IEC 61326-1:2020.

Le texte de cette Norme internationale est issu des documents suivants:

FDIS	Rapport de vote
65A/979/FDIS	65A/990/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de cette Norme internationale.

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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)

1 Domaine d'application

En complément au domaine d'application de l'IEC 61326-1, la présente partie de l'IEC 61326 spécifie les exigences minimales pour l'immunité et les émissions relatives à la compatibilité électromagnétique des MATERIELS MEDICAUX DE DIAGNOSTIC IN VITRO (IVD – *in vitro diagnostic*), en prenant en compte les particularités et aspects spéc ifiques de ces matériels et de leur environnement électromagnétique.

2 Références normatives

L'Article 2 de l'IEC 61326-1:2020 s'applique, avec les exceptions suivantes:

Addition:

IEC 61326-1:2020, *Matériel électrique de mesure, de commande et de laboratoire – Exigences relatives à la CEM – Partie 1: Exigences générales*

ISO 14971:2019, *Dispositifs médicaux – Application de la gestion des risques aux dispositifs médicaux*