Mõõte-, juhtimis- ja laboratooriumi-elektriseadmed. Elektromagnetilise ühilduvuse nõuded. Osa 2-6: Erinõuded. Meditsiiniseadmete diagnostika in vitro

Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment (IEC 61326-2-6:2012)

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61326-2-6

May 2013

ICS 17.220; 25.040.40; 33.100

Supersedes EN 61326-2-6:2006

English version

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

(IEC 61326-2-6:2012)

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)
(CEI 61326-2-6:2012)

Elektrische Mess-, Steuer-, Regel- und Laborgeräte - EMV-Anforderungen - Teil 2-6: Besondere Anforderungen - Medizinische In-vitro-Diagnosegeräte (IVD)
(IEC 61326-2-6:2012)

This European Standard was approved by CENELEC on 2013-02-04. 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.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Management Centre: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 61326-2-6:2013 E

Foreword

The text of document 65A/631/FDIS, future edition 2 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 61326-2-6:2013.

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)	2013-11-04
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2016-02-04

This document supersedes EN 61326-2-6:2006.

EN 61326-2-6:2013 includes the following significant technical change with respect to EN 61326-2-6:2006:

- update of the document with respect to EN 61326-1:2013.

EN 61326-2-6:2013 is to be used in conjunction with EN 61326-1:2013 and follows the same numbering of clauses, subclauses, tables and figures.

When a particular subclause of EN 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 EN 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 EN 61326-1;

– unless notes are in a new subclause or involve notes in EN 61326-1, they are numbered starting from 101 including those in a replaced clause or subclause;

– additional annexes are lettered AA, BB, etc.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 61326-2-6:2012 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

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, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Addition *to the Annex ZA of EN 61326-1:2013*

Publication	Year	Title	EN/HD	Year
IEC 61326-1	2012	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements	EN 61326-1	2013
ISO 14971	2007	Medical devices - Application of risk management to medical devices	EN ISO 14971	2012

Annex ZZ
(informative)

Coverage of Essential Requirements of EU Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers only the essential requirements in B.3.3 (only with regard to electromagnetic disturbances) and B.6.2 as given in Annex I of EU Directive 98/79/EC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

NOTE: Other requirements and other EU Directives may be applicable to the products falling within the scope of this standard.

CONTENTS

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 series specifies minimum requirements for immunity and emissions regarding electromagnetic compatibility for *in vitro* diagnostic medical equipment, taking into account the particularities and specific aspects of this electrical equipment and their electromagnetic environment.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 61326-1:2012 applies, except as follows:

Addition:

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

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

3 Terms and definitions

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

Addition:

3.101
***in vitro* diagnostic medical equipment**
instruments and apparatus intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease

Note 1 to entry: Such instruments or apparatus are intended for use in the collection, preparation, and examination of specimens taken from the human body.

3.102
analyte
constituent of a sample with a measurable property

EXAMPLES In “mass of protein in 24-hour urine”, “protein” is the analyte and “mass” is the property. In “concentration of glucose in plasma”, “glucose” is the analyte and “concentration” is the property. In both cases, the full phrase designates the measurand.