SLOVENSKI STANDARD

SIST EN 61326-2-6:2007

01-januar-2007

Električna oprema za merjenje, kontrolo in laboratorijsko uporabo - Zahteve za elektromagnetno združljivost (EMC) - 2-6. del: Posebne zahteve - Diagnostična medicinska oprema in vitro (IVD) (IEC 61326-2-6:2005)

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

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

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)

Ta slovenski standard je istoveten z: **EN 61326-2-6:2006**

ICS:

11.100.10
25.040.40
33.100.01

SIST EN 61326-2-6:2007 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61326-2-6

May 2006

ICS 25.040.40; 33.100

Supersedes EN 61326:1997 + A1:1998 + A2:2001 + A3:2003

English version

Electrical equipment for measurement, control and laboratory use – EMC requirements
Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment
(IEC 61326-2-6:2005)

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 61326-2-6:2005)

Elektrische Mess-, Steuer-, Regel- und Laborgeräte – EMV-Anforderungen
Teil 2-6: Besondere Anforderungen – Medizinische In-vitro-Diagnosegeräte (IVD)
(IEC 61326-2-6:2005)

This European Standard was approved by CENELEC on 2005-12-01. 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 Central Secretariat or to any CENELEC member.

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CENELEC

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Ref. No. EN 61326-2-6:2006 E

Foreword

The text of document 65A/455/FDIS, future edition 1 of IEC 61326-2-6, prepared by SC 65A, System aspects, of IEC TC 65, Industrial-process measurement and control, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 61326-2-6 on 2005-12-01.

The EN 61326 series supersedes EN 61326:1997 + corrigendum September 1998 + A1:1998 + A2:2001 + A3:2003.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2006-12-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2009-02-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 98/79/EC. See Annex ZZ.

Annexes ZA and ZZ have been added by CENELEC.

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Endorsement notice

The text of the International Standard IEC 61326-2-6:2005 was approved by CENELEC as a European Standard without any modification.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application 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 Where an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC 60050-161	1990	International Electrotechnical Vocabulary Chapter 161: Electromagnetic compatibility	–	–
IEC 61326-1	2005	Electrical equipment for measurement, control and laboratory use – EMC requirements Part 1: General requirements	EN 61326-1	2006
ISO 14971	2000	Medical devices – Application of risk management to medical devices	EN ISO 14971	2000

Annex ZZ
(informative)

Coverage of Essential Requirements of EC 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 all relevant essential requirements as given in Annex I of the EC Directive 98/79/E.

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

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

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NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
IEC
61326-2-6

Première édition
First edition
2005-12

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)

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
Международная Электротехническая Комиссия

CODE PRIX
PRICE CODE K

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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 equipment

FOREWORD

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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 and control.

The IEC 61326 series cancels and replaces IEC 61326:2002 and constitutes a technical revision.

The text of this standard is based on the following documents:

FDIS	Report on voting
65A/455/FDIS	65A/459/RVD

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

It consists of the following parts, under the general title *Electrical equipment for measurement, control and laboratory use – EMC requirements:*

Part 1: General requirements – (Annexes A and B of IEC 61326: 2002 are integrated in the main body of IEC 61326-1)

Part 2-1: Sensitive test and measurement equipment for EMC unprotected applications (Annex D of IEC 61326:2002)

Part 2-2: Portable test, measuring and monitoring equipment used in low-voltage distribution systems (Annex E of IEC 61326:2002)

Part 2-3: Transducers with integrated or remote signal conditioning (includes Annex F of IEC 61326:2002)[1]

Part 2-4: Insulation monitoring devices according to IEC 61557-8 and for equipment for insulation fault location according to IEC 61557-9 [1]

Part 2-5: Test configurations, operational conditions and performance criteria for field devices with interfaces according to communication profile Family 3 Profile 3/2 [1]

Part 2-6: *In vitro* diagnostic (IVD) medical equipment

Part 3-1: Immunity requirements for equipment performing or intended to perform safety related functions (functional safety) – Part 3.1: General industrial applications (The matter of functional safety in Table 2 of IEC 61326:2002 is incorporated into IEC 61326-3-1)[1]

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

[1] To be published