SLOVENSKI STANDARD
SIST EN 60601-2-41:2010

01-marec-2010

Nadomeġļa:
SIST EN 60601-2-41:2002

Medicinska elektriļna oprema - 2-41. del: Posebne zahteve za osnovno varnost in bistvene lastnosti kirurġkih in diagnostiļnih svetilk (IEC 60601-2-41:2009)

Medical electrical equipment - Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis (IEC 60601-2-41:2009)

Medizinische elektrische Geräte - Teil 2-41: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Operationsleuchten und Untersuchungsleuchten (IEC 60601-2-41:2009)

Appareils électromédicaux - Partie 2-41: Exigences particulières pour la sécurité de base et les performances essentielles des éclairages chirurgicaux et des éclairages de diagnostic (CEI 60601-2-41:2009)

Ta slovenski standard je istoveten z: **EN 60601-2-41:2009**

ICS:

11.040.30	Operacijski instrumenti in materiali	Surgical instruments and materials
11.040.55	Diagnostiļna oprema	Diagnostic equipment
29.140.40	Svetila	Luminaires

SIST EN 60601-2-41:2010 **en,fr**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-41

December 2009

ICS 11.040.20; 11.040.55; 11.040.99

Supersedes EN 60601-2-41:2000

English version

Medical electrical equipment - Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis (IEC 60601-2-41:2009)

Appareils électromédicaux -
Partie 2-41: Exigences particulières
pour la sécurité de base
et les performances essentielles
des éclairages chirurgicaux
et des éclairages de diagnostic
(CEI 60601-2-41:2009)

Medizinische elektrische Geräte -
Teil 2-41: Besondere Festlegungen
für die Sicherheit einschließlich
der wesentlichen Leistungsmerkmale
von Operationsleuchten
und Untersuchungsleuchten
(IEC 60601-2-41:2009)

This European Standard was approved by CENELEC on 2009-11-01. 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.

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 Central Secretariat has the same status as the official versions.

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

CENELEC

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

Central Secretariat: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 60601-2-41:2009 E

Foreword

The text of document 62D/773/FDIS, future edition 2 of IEC 60601-2-41, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-41 on 2009-11-01.

This European Standard supersedes EN 60601-2-41:2000.

EN 60601-2-41:2000 was revised to be consistent with EN 60601-1:2006.

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)	2010-08-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2012-11-01

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 MDD (93/42/EEC). See Annex ZZ.

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-41:2009 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 standards indicated:

IEC 60598-1	NOTE	Harmonized as EN 60598-1:2008 (modified).
IEC 60598-2-1	NOTE	Harmonized as EN 60598-2-1:1989 (not modified).
IEC 60598-2-4	NOTE	Harmonized as EN 60598-2-4:1997 (not modified).
IEC 60598-2-22	NOTE	Harmonized as EN 60598-2-22:1998 (modified).
IEC 60598-2-25	NOTE	Harmonized as EN 60598-2-25:1994 (not modified).
ISO 9680	NOTE	Harmonized as EN ISO 9680:2007 (not modified)

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

Annex ZA of EN 60601-1:2006 applies, except as follows:

Publication	Year	Title	EN/HD	Year
Addition:				
IEC 60417	data-base	Graphical symbols for use on equipment	-	-
IEC 60598-2-9	-[1)]	Luminaires - Part 2: Particular requirements - Section 9: Photo and film luminaires (non-professional)	EN 60598-2-9	1989[2)]
ISO 11664-1	-[1)]	Colorimetry - Part 1: CIE standard colorimetric observers	-	-
CIE 13.3	-[1)]	Method of measuring and specifying colour rendering of light sources	-	-
CIE 15	-[1)]	Colorimetry	-	-
CIE 69	-[1)]	Methods of characterizing illuminance meters and luminance meters: Performance, characteristics and specifications	-	-

[1)] Undated reference.
[2)] Valid edition at date of issue.

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 93/42/EEC.

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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IEC 60601-2-41

Edition 2.0 2009-08

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis

Appareils électromédicaux –
Partie 2-41: Exigences particulières pour la sécurité de base et les performances essentielles des éclairages chirurgicaux et des éclairages de diagnostic

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis

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, 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.
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9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International standard IEC 60601-2-41 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 2000. This edition constitutes a technical revision to be consistent with the third edition of the IEC 60601-1.

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

FDIS	Report on voting
62D/773/FDIS	62D/787/RVD

Full information on the voting for the approval of this particular 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.

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An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

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.