SLOVENSKI STANDARD

SIST EN 60601-2-57:2011

01-junij-2011

Medicinska električna oprema - 2-57. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme z nelaserskim svetlobnim virom, namenjene za terapevtsko, diagnostično, nadzorovalno in kozmetično/estetsko uporabo (IEC 60601-2-57:2011)

Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use (IEC 60601-2-57:2011)

Medizinische elektrische Geräte - Teil 2-57: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Geräten mit Nicht-Laser-Lichtquellen für die Anwendung in der Therapie, Diagnose, Überwachung und für kosmetische/ästhetische Zwecke (IEC 60601-2-57:2011)

Appareils électromédicaux - Partie 2-57: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à source de lumière non-laser prévus pour des utilisations thérapeutiques, de diagnostic, de surveillance et de cosmétique/esthétique (CEI 60601-2-57:2011)

Ta slovenski standard je istoveten z: **EN 60601-2-57:2011**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment
11.040.60	Terapevtska oprema	Therapy equipment

SIST EN 60601-2-57:2011 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-57

April 2011

ICS 11.040.50; 11.040.60

English version

Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

(IEC 60601-2-57:2011)

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This European Standard was approved by CENELEC on 2011-03-07. 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, Croatia, 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

Management Centre: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 60601-2-57:2011 E

Foreword

The text of document 76/438/FDIS, future edition 1 of IEC 60601-2-57, prepared by IEC TC 76, Optical radiation safety and laser equipment, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-57 on 2011-03-07.

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

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)	2011-12-07
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2014-03-07

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 60601-2-57:2011 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 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:

Addition:

Publication	Year	Title	EN/HD	Year
IEC 60947-3	-	Low-voltage switchgear and controlgear - Part 3: Switches, disconnectors, switch-disconnectors and fuse-combination units	EN 60947-3	-
IEC 62471 (mod)	-	Photobiological safety of lamps and lamp systems	EN 62471	-
ISO 3864-2	-	Graphical symbols - Safety colours and safety signs - Part 2: Design principles for product safety labels		-

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 all relevant essential requirements as given in Annex I of the EU 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 EU Directives may be applicable to the products falling within the scope of this standard.

IEC 60601-2-57

Edition 1.0 2011-01

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

Medical electrical equipment –
Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

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, Publicly Available Specifications (PAS) 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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International Standard IEC 60601-2-57 has been prepared by IEC technical committee TC 76: Optical radiation safety and laser equipment

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

FDIS	Report on voting
76/438/FDIS	76/441/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.

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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.