SVENSK STANDARD SS-EN 60601-2-41

Fastställd	Utgåva	Sida	Ansvarig kommitté
2010-03-29	2	1 (1+41)	SEK TK 62

Elektrisk utrustning för medicinskt bruk – Säkerhet och väsentliga prestanda – Del 2-41: Särskilda fordringar på ljusarmaturer för kirurgi och diagnostik

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

Som svensk standard gäller europastandarden EN 60601-2-41:2009. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-2-41:2009.

Nationellt förord

Europastandarden EN 60601-2-41:2009

består av:

– **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC
– **IEC 60601-2-41, Second edition, 2009 - Medical electrical equipment - Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis**

utarbetad inom International Electrotechnical Commission, IEC.

Standarden ska användas tillsammans med SS-EN 60601-1, utgåva 2, 2006.

Tidigare fastställd svensk standard SS-EN 60601-2-41, utgåva 1, 2000, gäller ej fr o m 2012-11-01.

ICS 11.040.20; 11.040.55; 11.040.99

Denna standard är fastställd av SEK Svensk Elstandard,
som också kan lämna upplysningar om **sakinnehållet** i standarden.
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Standarder underlättar utvecklingen och höjer elsäkerheten

Det finns många fördelar med att ha gemensamma tekniska regler för bl a säkerhet, prestanda, dokumentation, utförande och skötsel av elprodukter, elanläggningar och metoder. Genom att utforma sådana standarder blir säkerhetskraven tydliga och utvecklingskostnaderna rimliga samtidigt som marknadens acceptans för produkten eller tjänsten ökar.

Många standarder inom elområdet beskriver tekniska lösningar och metoder som åstadkommer den elsäkerhet som föreskrivs av svenska myndigheter och av EU.

SEK är Sveriges röst i standardiseringsarbetet inom elområdet

SEK Svensk Elstandard svarar för standardiseringen inom elområdet i Sverige och samordnar svensk medverkan i internationell och europeisk standardisering. SEK är en ideell organisation med frivilligt deltagande från svenska myndigheter, företag och organisationer som vill medverka till och påverka utformningen av tekniska regler inom elektrotekniken.

SEK samordnar svenska intressenters medverkan i SEKs tekniska kommittéer och stödjer svenska experters medverkan i internationella och europeiska projekt.

Stora delar av arbetet sker internationellt

Utformningen av standarder sker i allt väsentligt i internationellt och europeiskt samarbete. SEK är svensk nationalkommitté av International Electrotechnical Commission (IEC) och Comité Européen de Normalisation Electrotechnique (CENELEC).

Standardiseringsarbetet inom SEK är organiserat i referensgrupper bestående av ett antal tekniska kommittéer som speglar hur arbetet inom IEC och CENELEC är organiserat.

Arbetet i de tekniska kommittéerna är öppet för alla svenska organisationer, företag, institutioner, myndigheter och statliga verk. Den årliga avgiften för deltagandet och intäkter från försäljning finansierar SEKs standardiseringsverksamhet och medlemsavgift till IEC och CENELEC.

Var med och påverka!

Den som deltar i SEKs tekniska kommittéarbete har möjlighet att påverka framtida standarder och får tidig tillgång till information och dokumentation om utvecklingen inom sitt teknikområde. Arbetet och kontakterna med kollegor, kunder och konkurrenter kan gynnsamt påverka enskilda företags affärsutveckling och bidrar till deltagarnas egen kompetensutveckling.

Du som vill dra nytta av dessa möjligheter är välkommen att kontakta SEKs kansli för mer information.

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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)

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

SEK Svensk Elstandard

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.

CONTENTS

INTRODUCTION

This particular standard concerns the basic safety and essential performance of SURGICAL LUMINAIRES and LUMINAIRES FOR DIAGNOSIS.

It amends and supplements IEC 60601-1 (third Edition 2005), hereinafter referred to as the general standard.

The requirements of this particular standard take priority over those of the general standard, entitled “Medical electrical equipment Part 1: General requirements for basic safety and essential performance.

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general standard[1)] applies, except as follows:

201.1.1 *Scope

Replacement:

This particular standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of SURGICAL LUMINAIRES AND LUMINAIRES FOR DIAGNOSIS, hereafter referred to as ME EQUIPMENT.

This particular standard does not apply to

– headlights;
– endoscopes, laparoscopes and their light sources, which are covered by IEC 60601-2-18;
– luminaires used in dentistry, which are covered by ISO 9680;
– luminaires for general purposes, which are covered by IEC 60598-2-1 and IEC 60598-2-4;
– luminaires dedicated to therapeutic purposes;
– special purpose lights with different conditions of use such as UV lights for dermatological diagnosis, slit lamps for ophthalmology, lights for surgical microscopes and lights for surgical navigation systems;
– lights connected to surgical instruments;
– luminaires of an emergency lighting, which are covered by IEC 60598-2-22.

NOTE See also 4.2 of the general standard.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for SURGICAL LUMINAIRES and LUMINAIRES FOR DIAGNOSIS as defined in 201.3.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

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1) The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

Clause 2 of the general standard applies except as follows:

Addition:

IEC 60417, *Graphical symbols for use on equipment*

IEC 60598-2-9, *Luminaires – Part 2: Particular requirements. Section Nine: Photo and film luminaires (non-professional)*

ISO 11664-1, *Colorimetry – Part 1: CIE standard colorimetric observers*

CIE 13.3, *Method of Measuring and Specifying Colour Rendering Properties of Light Sources*

CIE 15, *Colorimetry*