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SVENSK STANDARD SS-EN 60601-2-41

Handläggande organ	Fastställd	Utgåva	Sida	Ingår i
Svenska Elektriska Kommissionen, SEK	2000-09-01	1	1 (1+38)	SEK Översikt 62
				Reg 486 03 68

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

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

Som svensk standard gäller europastandarden EN 60601-2-41:2000. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-2-41:2000.

Nationellt förord

Europastandarden EN 60601-2-41:2000

består av:

– **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC
– **IEC 60601-2-41, First edition, 2000 - Medical electrical equipment - Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis**

utarbetad inom International Electrotechnical Commission, IEC.

Standarden skall användas tillsammans med SS-EN 60601-1, Elektromedicinsk utrustning - Säkerhet - Del 1: Allmänna fordringar, och dess separat utgivna ändringar och tillägg.

Till SS-EN 60601-1 utges en serie tilläggsstandarder som anger allmänna fordringar på säkerhet som är tillämpliga på

– en grupp av elektrisk utrustning för medicinskt bruk, t ex radiologisk utrustning
– särskilda egenskaper hos all elektrisk utrustning för medicinskt bruk, ej särskilt behandlade i SS-EN 60601-1, t ex elektromagnetisk kompatibilitet.

ICS 11.040.30; 11.040.55; 11.040.99

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EUROPEAN STANDARD **EN 60601-2-41**

NORME EUROPÉENNE

EUROPÄISCHE NORM June 2000

ICS 11.040.30; 11.040.55; 11.040.99

English version

Medical electrical equipment
Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis
(IEC 60601-2-41:2000)

Appareils électromédicaux
Partie 2-41: Règles particulières de sécurité pour les éclairages chirurgicaux et les éclairages de diagnostic
(CEI 60601-2-41:2000)

Medizinische elektrische Geräte
Teil 2-41: Besondere Festlegungen für die Sicherheit von Operationsleuchten und Untersuchungsleuchten
(IEC 60601-2-41:2000)

This European Standard was approved by CENELEC on 2000-04-01. 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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 60601-2-41:2000 E

Foreword

The text of document 62D/344/FDIS, future edition 1 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 2000-04-01.

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)	2001-01-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2003-04-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annex ZA is normative and annexes AA and ZB are informative.
Annexes ZA and ZB have been added by CENELEC.

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Endorsement notice

The text of the International Standard IEC 60601-2-41:2000 was approved by CENELEC as a European Standard without any modification.

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Annex ZA (normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

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

Publication	Year	Title	EN/HD	Year
IEC 60417	Series	Graphical symbols for use on equipment	EN 60417	Series
IEC 60598-2-9	1987	Luminaires Part 2: Particular requirements Section 9: Photo and film luminaires (non-professional)	EN 60598-2-9	1989
IEC 60695-1-1	1995	Fire hazard testing Part 1: Guidance for assessing fire hazard of electrotechnical products Section 1: General guidance	EN 60695-1-1[1)]	1995
ISO/CIE 10527	1991	CIE standard colorimetric observers	-	-
CIE 13.3	1995	Method of measuring and specifying colour rendering of light sources	-	-
CIE 15.2	1986	Colorimetry	-	-
CIE 69	1987	Methods of characterizing illuminance meters and luminance meters: Performance, characteristics and specifications	-	-

1) EN 60695-1-1 is replaced by EN 60695-1-1:2000, which is based on IEC 60695-1-1:1999.

Annex ZB (informative)

Other international publications with the references of the relevant European publications

Publication	Year	Title	EN/HD	Year
IEC 60364-7-710 [2)]		Electrical installations of buildings Part 7: Requirements for special installations or locations -- Section 710: Medical locations and associated areas	-	-
IEC 60598-1 (mod)	1996	Luminaires Part 1: General requirements and tests	EN 60598-1	1997
IEC 60598-2-1	1979	Part 2: Particular requirements Section 1: Fixed general purpose luminaires	EN 60598-2-1 [3)]	1989
IEC 60598-2-4	1997	Part 2: Particular requirements Section 4: Portable general purpose luminaires	EN 60598-2-4	1997
IEC 60598-2-22 (mod)	1997	Part 2-22: Particular requirements - Luminaires for emergency lighting	EN 60598-2-22 + corr. February	1998 1999
IEC 60598-2-25 + corr. September	1994 1994	Part 2: Particular requirements Section 25: Luminaires for use in clinical areas of hospitals and health care buildings	EN 60598-2-25	1994
IEC 60601-1 A1 A2 + corr. June	1988 1991 1995 1995	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + corr. July A1 + corr. July A2 A13	1990 1994 1993 1994 1995 1996
IEC 60601-2-18	1996	Part 2: Particular requirements for the safety of endoscopic equipment	EN 60601-2-18	1996
ISO 9680 + corr. 1	1993 1995	Dental operating light	EN ISO 9680	1996

2) To be published.
3) EN 60598-2-1 includes A1:1987 to IEC 60598-2-1.

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SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

MEDICAL ELECTRICAL EQUIPMENT –

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

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows.

1 Scope and object

This clause of the General Standard applies except as follows:

*1.1 Scope

Addition:

This Particular Standard details the requirements to be applied to SURGICAL LUMINAIRES and LUMINAIRES FOR DIAGNOSIS as defined in 2.101 to 2.105, hereinafter referred to as EQUIPMENT.

This 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 of an emergency lighting, which are covered by IEC 60598-2-22.

NOTE Luminaires used in clinical areas of hospitals other than those defined in 2.101 to 2.105 are covered by IEC 60598-2-25.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety of SURGICAL LUMINAIRES and LUMINAIRES FOR DIAGNOSIS.

1.3 Particular Standards

Addition:

This Particular Standard refers to IEC 60601-1 (1988): *Medical electrical equipment – Part 1: General requirements for safety*, as amended by its amendment 1 (1991) and its amendment 2 (1995).

For brevity, IEC 60601-1 is referred to in this Particular Standard either as the General Standard or as the General Requirement(s).