

**Elektrilised meditsiiniseadmed. Osa 2-41: Erinõuded kirurgias ja diagnoosimisel kasutatavate valgustite esmasele ohutusele ja olulistele toimimisnäitajatele**

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

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 60601-2-41:2010 sisaldab Euroopa standardi EN 60601-2-41:2009 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 28.02.2010 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 23.12.2009.

Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN 60601-2-41:2010 consists of the English text of the European standard EN 60601-2-41:2009.

This standard is ratified with the order of Estonian Centre for Standardisation dated 28.02.2010 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.

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The standard is available from Estonian standardisation organisation.

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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**

## 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.

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### 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)

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## 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:*

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

<sup>1)</sup> Undated reference.

<sup>2)</sup> 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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## 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<sup>1)</sup> 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.

<sup>1)</sup> 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*

CIE 69, *Methods of characterizing illuminance meters and luminance meters: Performance, characteristics and specifications*

### **201.3 Terms and definitions**

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, apply, except as follows:

NOTE An index of defined terms is found beginning on page 39.

#### **201.3.63**

##### **MEDICAL ELECTRICAL EQUIPMENT**

*Addition:*

NOTE See Figure 201.101 as an example of possible POWER SUPPLIES for SURGICAL LUMINAIRES.

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