SVENSK STANDARD SS-EN 60601-2-22

Fastställd	Utgåva	Sida	Ansvarig kommitté
2013-03-15	3	1 (1+27)	SEK TK 62

Elektrisk utrustning för medicinskt bruk – Säkerhet och väsentliga prestanda – Del 2-22: Särskilda fordringar på laserutrustning för kirurgi, terapi, diagnostik eller för kosmetiskt bruk

Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

Som svensk standard gäller europastandarden EN 60601-2-22:2013. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-2-22:2013.

Nationellt förord

Europastandarden EN 60601-2-22:2013

består av:

– **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC
– **IEC 60601-2-22, Third edition, 2007**[*)] **- Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment**

utarbetad inom International Electrotechnical Commission, IEC.

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

Tidigare fastställd svensk standard SS-EN 60601-2-22, utgåva 2, 1996, gäller ej fr o m 2015-11-29.

[*)] Amendment No 1:2012 till IEC 60601-22:2007 är inarbetat i texten och markerat med rött och ett lodrätt streck i marginalen.

ICS 11.040.01; 31.260

Denna standard är fastställd av SEK Svensk Elstandard,
som också kan lämna upplysningar om **sakinnehållet** i standarden.
Postadress: SEK, Box 1284, 164 29 KISTA
Telefon: 08 - 444 14 00. *Telefax*: 08 - 444 14 30
E-post: sek@elstandard.se. *Internet*: www.elstandard.se

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.

SEK Svensk Elstandard
Box 1284
164 29 Kista
Tel 08-444 14 00
www.elstandard.se

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-22

January 2013

ICS 11.040.01; 31.260

Supersedes EN 60601-2-22:1996

English version

Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

(IEC 60601-2-22:2007 + A1:2012)

Appareils électromédicaux -
Partie 2-22: Règles particulières pour la sécurité de base et les performances essentielles des appareils chirurgicaux, esthétiques, thérapeutiques et de diagnostic à laser
(CEI 60601-2-22:2007 + A1:2012)

Medizinische elektrische Geräte -
Teil 2-22: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale für chirurgische, kosmetische, therapeutische und diagnostische Lasergeräte
(IEC 60601-2-22:2007 + A1:2012)

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 60601-2-22:2013 E

SEK Svensk Elstandard

Foreword

The texts of document 76/359/FDIS, future edition 3 of IEC 60601-2-22, and document 76/444/CDV, future amendment 1 to edition 3 of IEC 60601-2-22, prepared by IEC/TC 76 "Optical radiation safety and laser equipment" were submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-22:2013, based on IEC 60601-2-22:2007 + A1:2012.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2013-08-29
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2015-11-29

This document supersedes EN 60601-2-22:1996.

EN 60601-2-22:2013 includes the following significant technical changes with respect to EN 60601-2-22:1996:

This third edition takes account of the recently published new editions of the General Standard EN 60601-1 and Group safety publication EN 60825-1. Additionally, it addresses technical and safety issues which have arisen in the time following the previous second edition.

This standard is to be read in conjunction with EN 60601-1:2006.

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.

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

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standards IEC 60601-2-22:2007 + A1:2012 were approved by CENELEC as a European Standard without any modification.

The Bibliography of EN 60601-1:2006 applies, except as follows:

In the Bibliography of EN 60601-1:2006, the following note has to be added for the standard indicated:

IEC 60664-3:2003	NOTE	Harmonised as EN 60664-3:2003 (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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

***Add** to Annex ZA of EN 60601-1:2006 the following new references:*

IEC 60825-1	2007	Safety of laser products - Part 1: Equipment classification and requirements	EN 60825-1	2007
IEC 60947-3	-	Low-voltage switchgear and controlgear - Part 3: Switches, disconnectors, switch-disconnectors and fuse-combination units	EN 60947-3	-
IEC 61010-1	-	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements	EN 61010-1	-

CONTENTS

INTRODUCTION 6

201.1 Scope, object and related standards 7
201.2 Normative references 9
201.3 Terms and definitions 9
201.4 General requirements 11
201.5 General requirements for testing ME EQUIPMENT 11
201.6 Classification of ME EQUIPMENT and ME SYSTEMS 11
201.7 ME EQUIPMENT identification, marking and documents 11
201.8 Protection against electrical HAZARDS from ME EQUIPMENT 13
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS 14
201.10 Protection against unwanted and excessive radiation HAZARDS 14
201.11 Protection against excessive temperatures and other HAZARDS 15
201.12 Accuracy of controls and instruments and protection against hazardous outputs 16
201.13 HAZARDOUS SITUATIONS and fault conditions 17
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 18
201.15 Construction of ME EQUIPMENT 18
201.16 ME SYSTEMS 19
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS 19

Annexes 19
Annex D (informative) Symbols on marking 19
Annex AA (informative) Particular guidance and rationale 22

Bibliography 24
Index of defined terms used in this particular standard 25

Table D.1 – General symbols 19

INTRODUCTION

This particular standard amends and supplements IEC 60601-1 (third edition, 2005: *Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance*).

This standard also refers to IEC 60825-1 (2007).

The requirements of this standard are the minimum that need to be complied with, in order to achieve a reasonable level of safety and reliability during operation and application of medical laser equipment.

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. Understanding of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revisions necessitated by changes in clinical practice or by developments in technology.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

201.1 Scope, object and related standards

Clause 1 of the General Standard applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of laser equipment for either surgical, therapeutic, medical diagnostic, cosmetic, or veterinary applications, intended for its use on humans or animals, classified as a CLASS 3B or CLASS 4 LASER PRODUCT as defined by 3.22 and 3.23 in IEC 60825-1, hereafter referred to as LASER EQUIPMENT.

Throughout this International Standard, light emitting diodes (LED) are included whenever the word “laser” is used.

NOTE 1 Refer to Definition 3.49 in IEC 60825-1.

NOTE 2 Laser products for these applications classified as a CLASS 1, 1M, 2, 2M or CLASS 3R LASER PRODUCT, are covered by IEC 60825-1 and IEC 60601-1.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the General Standard.

NOTE See also 4.2 of the General Standard.

This standard can also be applied to surgical, cosmetic, therapeutic and diagnostic laser equipment used for compensation or alleviation of disease, injury or disability.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for the safety of surgical, cosmetic, therapeutic and diagnostic laser equipment.

NOTE Laser classification (IEC 60825-1) must not be confused with electrical classification (IEC 60601-1).

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the General Standard and Clause 2 of this particular standard.

IEC 60601-1-3 does not apply.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in this standard 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.

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 sections, clauses and subclauses of this particular standard corresponds to that of the General Standard or applicable collateral standard. 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 or figures which are additional to those of the General Standard are numbered starting from 201.101, 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 section, clause or subclause in this particular standard, the section, 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.

Concerning LASER RADIATION safety of laser equipment, IEC 60825-1 applies, except that the relevant requirements are specified, changed or amended in this particular standard.

Clauses and subclauses of the General Standard and IEC 60825-1, which are not applicable to laser equipment for medical applications, are not necessarily indicated as "not applicable".

201.2 Normative references

Clause 2 of the General Standard applies, except as follows:

Addition:

IEC 60825-1:2007, *Safety of laser products – Part 1: Equipment classification and requirements*

IEC 60947-3, *Low-voltage switchgear and controlgear – Part 3: Switches, disconnectors, switch-disconnectors and fuse-combination units*

IEC 61010-1, *Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements*