SLOVENSKI STANDARD
SIST EN 60601-2-22:2013

01-marec-2013

Medicinska električna oprema - 2-22. del: Posebne varnostne zahteve ter bistvene lastnosti kirurške, terapevtske in diagnostične laserske opreme

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

Medizinische elektrische Geräte - Teil 2-22: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale für chirurgische, therapeutische und diagnostische Lasergeräte

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

Ta slovenski standard je istoveten z: **EN 60601-2-22:2013**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment
11.040.60	Terapevtska oprema	Therapy equipment
31.260	Optoelektronika, laserska oprema	Optoelectronics. Laser equipment

SIST EN 60601-2-22:2013 **en**

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)

This European Standard was approved by CENELEC on 2012-11-29. 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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre 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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey 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 60601-2-22:2013 E

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	-

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, except the following:

- ER 1 to ER 7.1
- ER 7.4
- ER 7.5, Paragraph 2 and 3
- ER 13.6 (q)

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive[s] concerned.

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this standard.

IEC 60601-2-22

Edition 3.1 2012-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.01, 31.260

ISBN 978-2-8322-0443-6

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

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.

2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.

3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.

4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.

5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.

6) All users should ensure that they have the latest edition of this publication.

7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.

8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.

9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

This consolidated version of IEC 60601-2-22 consists of the third edition (2007) [documents 76/359/FDIS and 76/363/RVD] and its amendment 1 (2012) [documents 76/444/CDV and 76/477/RVC]. It bears the edition number 3.1.

The technical content is therefore identical to the base edition and its amendment and has been prepared for user convenience. A vertical line in the margin shows where the base publication has been modified by amendment 1. Additions and deletions are displayed in red, with deletions being struck through.

International standard IEC 60601-2-22 has been prepared by IEC subcommittee 76: Optical radiation safety and laser equipment.

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

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

The committee has decided that the contents of the base publication and its amendments will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.