

SLOVENSKI STANDARD

SIST EN IEC 60601-2-22:2020

01-december-2020

Nadomešča:

SIST EN 60601-2-22:2013

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

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

Medizinische elektrische Geräte - Teil 2-22: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale für chirurgische, kosmetische, 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 IEC 60601-2-22:2020

ICS:

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

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en

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN IEC 60601-2-22

October 2020

ICS 11.040.01; 31.260

Supersedes EN 60601-2-22:2013 and all of its
amendments and corrigenda (if any)

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 60601-2-22:2019)

Appareils électromédicaux - Partie 2-22: Exigences
particulières pour la sécurité de base et les performances
essentielles des appareils chirurgicaux, esthétiques,
thérapeutiques et de diagnostic à laser
(IEC 60601-2-22:2019)

Medizinische elektrische Geräte - Teil 2-22: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale für chirurgische,
therapeutische und diagnostische Lasergeräte
(IEC 60601-2-22:2019)

This European Standard was approved by CENELEC on 2019-12-25. 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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.



European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

EN IEC 60601-2-22:2020 (E)**European foreword**

The text of document 76/580/CDV, future edition 4 of IEC 60601-2-22, prepared by IEC/TC 76 "Optical radiation safety and laser equipment" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60601-2-22:2020.

The following dates are fixed:

- latest date by which the document has to be implemented at national (dop) 2021-04-30 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2023-10-30 document have to be withdrawn

This document supersedes EN 60601-2-22:2013 and all of its amendments and corrigenda (if any).

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

Endorsement notice
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The text of the International Standard IEC 60601-2-22:2019 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 60335-2-113:2016	NOTE	Harmonized as EN 60335-2-113:— ¹
IEC 61010-1	NOTE	Harmonized as EN 61010-1
IEC 60947-3	NOTE	Harmonized as EN 60947-3

¹ Under preparation. Stage at time of publication: FprEN 60335-2-113:2019.

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

The Annex ZA of EN 60601-1:2006/A12:2014 applies with the following additions:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60601-1	2005	Medical electrical equipment - Part 1:EN 60601-1 General requirements for basic safety and essential performance		2006
-	-		+ corrigendum Mar. 2010	
+ A1	2012		+ A1	2013
-	-		+ A12	2014
IEC 60825-1	2014	Safety of laser products - Part 1:EN 60825-1 Equipment classification and requirements		2014
-	-		/AC	2017

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IEC 60601-2-22

Edition 4.0 2019-11

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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: Exigences particulières pour la sécurité de base et les
performances essentielles des appareils chirurgicaux, esthétiques,
thérapeutiques et de diagnostic à laser

INTERNATIONAL
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ICS 11.040.50; 11.040.60; 31.260

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CONTENTS

FOREWORD	3
INTRODUCTION	6
201.1 Scope, object and related standards	7
201.2 Normative references	8
201.3 Terms and definitions	9
201.4 General requirements	12
201.5 General requirements for testing ME EQUIPMENT	12
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	12
201.7 ME EQUIPMENT identification, marking and documents	12
201.8 Protection against electrical HAZARDS from ME EQUIPMENT	15
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	16
201.10 Protection against unwanted and excessive radiation HAZARDS	16
201.11 Protection against excessive temperatures and other HAZARDS	20
201.12 Accuracy of controls and instruments and protection against HAZARDOUS OUTPUTS	20
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	21
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	23
201.15 Construction of ME EQUIPMENT	23
201.16 ME SYSTEMS	23
201.17 Electromagnetic compatibility of ME EQUIPMENT AND ME SYSTEMS	23
Annexes	24
Annex D (informative) Symbols on marking	24
Annex AA (informative) Particular guidance and rationale	26
Bibliography	28
Index of defined terms used in this document	29
Table D.1 – General symbols	24

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.
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- 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.

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

This fourth edition cancels and replaces the third edition published in 2007 and Amendment 1:2012. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

- a) it takes account of IEC 60601-1:2005/AMD1:2012 and IEC 60825-1:2014, which have been published since publication of the third edition;
- b) it addresses technical and safety issues which have arisen since publication of the third edition;

- c) the scope of this fourth edition differs from the scope of the third edition. It now includes CLASS 1C laser equipment, as defined in IEC 60825-1:2014, when the ENCLOSED LASER is CLASS 3B or 4;
- d) LED (light emitting diode) products are now excluded from this document as medical LED products may be covered by IEC 60601-2-57.

The text of this International Standard is based on the following documents:

CDV	Report on voting
76/580/CDV	76/610/RVC

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

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

In this document, 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 document, 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 document are preceded by the term “Clause” followed by the clause number. References to subclauses within this document are by number only.

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2:2018. For the purposes of this document, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this document;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

A list of all parts of the IEC 60601 and IEC 80601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "<http://webstore.iec.ch>" in the data related to the specific document. At this date, the document will be

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

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INTRODUCTION

This document amends and supplements IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

This document also refers to IEC 60825-1:2014. The requirements of this document 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 the reasons for these requirements will not only facilitate the proper application of this document but will, in due course, expedite any revisions necessitated by changes in clinical practice or by developments in technology.

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