ELEKTRILISED MEDITSIINISEADMED. OSA 2-22: ERINÕUDED KIRURGILISTE, KOSMEETILISTE, TERAPEUTILISTE JA DIAGNOSTILISTE LASERSEADMETE ESMASELE OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE

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)

EVS • EESTI STANDARDIMIS- JA AKREDITEERIMISKESKUS
ESTONIAN CENTRE FOR STANDARDISATION AND ACCREDITATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN IEC 60601-2-22:2020 +A11:2026 sisaldab Euroopa standardi EN IEC 60601-2-22:2020 ja selle muudatuse A11:2026 ingliskeelset teksti.	This Estonian standard EVS-EN IEC 60601-2-22:2020+A11:2026 consists of the English text of the European standard EN IEC 60601-2-22:2020 and its amendment A11:2026.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 30.10.2020, muudatused A11 23.01.2026.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation. Date of Availability of the European standard is 30.10.2020, for A11 23.01.2026.
Muudatusega A11 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega [A11] [A11]. Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The start and finish of text introduced or altered by amendment A11 is indicated in the text by tags [A11] [A11]. The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.01; 31.260

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 60601-2-22 + A11

October 2020, January 2026

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 electromedicaux - 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. Amendment A11 was approved by CENELEC on 2025-12-17. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard and its amendment the status of a national standard without any alteration.

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a

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

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

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

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.

A11 Amendment A11 European foreword

This document (EN IEC 60601-2-22:2020/A11:2026) has been prepared by CLC/TC 76 "Optical radiation safety and laser equipment".

The following dates are fixed:

• latest date by which this document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2027-01-31
• latest date by which the national standards conflicting with this document have to be withdrawn	(dow)	2029-01-31

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This document has been prepared under a standardization request addressed to CENELEC by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZZ, which is an integral part of this document.

Collateral standards in the IEC 60601 series are numbered IEC 60601-1-xx. The IEC maintains a catalogue of valid International Standards. Users of this document can consult this catalogue at "http://webstore.iec.ch" to determine which collateral standards have been published.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website. A11

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 électromedicaux –
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 60601-2-22:2019-11(en-fr)

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

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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 electromedicaux – 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 ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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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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.

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.

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[2] applies, except as follows:

201.1.1 Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of laser equipment for surgical, therapeutic, medical diagnostic, cosmetic or veterinary applications, intended for use on humans or animals, classified as LASER PRODUCT of CLASS 1C where the ENCLOSED LASER is of CLASS 3B or 4, or CLASS 3B, or CLASS 4.

MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEMS which incorporate lasers as sources of energy being transferred to the PATIENT or animal and where the lasers are specified as above, are referred to as “laser equipment” in this document.

NOTE 1 LASER PRODUCTS for these applications classified as a Class 1, Class 1M, CLASS 2, Class 2M or CLASS 3R LASER PRODUCT, are covered by IEC 60825-1:2014 and by the general standard.

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 to ME EQUIPMENT and to ME SYSTEMS, as relevant.

Hazards inherent in the intended physiological function of laser equipment within the scope of this document are not covered by specific requirements in this document except in 7.2.13, Physiological effects, of the general standard.

NOTE 2 See also 4.2, RISK MANAGEMENT process, of the general standard.

NOTE 3 If the laser equipment is CLASS 1C according to IEC 60825-1:2014 and is used as a laser appliance in a household, it is covered by IEC 60335-2-113:2016.

201.1.2 Object

Replacement:

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

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2 In this document, "the general standard" means IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012.

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this document.

201.1.4 Particular standards

Addition:

For brevity, IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 are referred to in this document as "the general standard". Collateral standards are referred to by their document number.

The numbering of sections, clauses and subclauses of this document 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 document.

"Addition" means that the text of this document 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 document.

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 document" is used to make reference to the general standard, any applicable collateral standards and this document taken together.

Where there is no corresponding section, clause or subclause in this document, 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 document.

Concerning laser radiation safety of laser equipment, IEC 60825-1:2014 applies, except for the relevant requirements that are specified, changed or amended in this document.

201.2 Normative references

Clause 2 of the general standard applies, except as follows:

Addition:

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

IEC 60825-1:2014, *Safety of laser products – Part 1: Equipment classification and requirements*

201.3 Terms and definitions

Clause 3 of the general standard applies, except as follows:

Addition:

201.3.201
AEL
ACCESSIBLE EMISSION LIMIT
maximum accessible emission permitted within a particular class where the accessible emission is the level of radiation determined at a position and with APERTURE stops (when the AEL is given in units of watts or joules) or limiting APERTURES (when the AEL is given in units of $W \cdot m^{-2}$ or $J \cdot m^{-2}$)

[SOURCE: IEC 60825-1:2014, 3.2 and 3.3, modified – The two definitions have been combined into one.]

201.3.202
AIMING BEAM
beam of optical radiation, producing a visible spot, intended for indication of the anticipated point of impact of the WORKING BEAM

201.3.203
AIMING LASER
laser emitting an AIMING BEAM

201.3.204
APERTURE
opening of the BEAM DELIVERY SYSTEM through which laser radiation is transmitted, thereby allowing human access to such radiation

[SOURCE: IEC 60825-1:2014, 3.8, modified – In the definition, "any opening in the protective housing of a laser product" has been replaced by "opening of the BEAM DELIVERY SYSTEM".]

201.3.205
BEAM DELIVERY SYSTEM
optical system which guides the laser radiation from its origin to the WORKING AREA

201.3.206
CLASS 1C
class of any LASER PRODUCT which is designed explicitly for contact application to the skin or non-ocular tissue

[SOURCE: IEC 60825-1:2014, 3.19, modified – The list and notes to entry have been deleted.]

201.3.207
CLASS 2
class of any LASER PRODUCT in the wavelength range from 400 nm to 700 nm which during operation does not permit human access to laser radiation in excess of the AEL of CLASS 2

[SOURCE: IEC 60825-1:2014, 3.21, modified – In the definition, "for applicable wavelengths and emission durations" and the text in parentheses have been deleted.]