SLOVENSKI STANDARD
SIST EN IEC 60601-2-57:2026

01-marec-2026

Nadomešča:
SIST EN 60601-2-57:2011

Medicinska električna oprema - 2-57. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme z nelaserskim svetlobnim virom, namenjene za terapevtsko, diagnostično, nadzorno in kozmetično/estetsko uporabo

Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

Medizinische elektrische Geräte - Teil 2-57: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Geräten mit Nicht-Laser-Lichtquellen für die Anwendung in der Therapie, Diagnose, Überwachung und für kosmetische/ästhetische Zwecke

Appareils électromédicaux - Partie 2-57: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à source de lumière non-laser prévus pour des utilisations thérapeutiques, de diagnostic, de surveillance et de cosmétique/esthétique

Ta slovenski standard je istoveten z: **EN IEC 60601-2-57:2026**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment
11.040.60	Terapevtska oprema	Therapy equipment

SIST EN IEC 60601-2-57:2026 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 60601-2-57

January 2026

ICS 11.040.50; 11.040.60

Supersedes EN 60601-2-57:2011

English Version

Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring, cosmetic and aesthetic use (IEC 60601-2-57:2023)

Appareils électromédicaux - Partie 2-57: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à source de lumière non laser destinés à des usages thérapeutiques, de diagnostic, de surveillance, cosmétiques et esthétiques (IEC 60601-2-57:2023)

Medizinische elektrische Geräte - Teil 2-57: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Geräten mit Nicht-Laser-Lichtquellen für die Anwendung in der Therapie, Diagnose, Überwachung und für kosmetische/ästhetische Zwecke (IEC 60601-2-57:2023)

This European Standard 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 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, Türkiye 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

Ref. No. EN IEC 60601-2-57:2026 E

European foreword

The text of document 76/734/FDIS, future edition 2 of IEC 60601-2-57, prepared by TC 76 "Optical radiation safety and laser equipment" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60601-2-57:2026.

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) 2027-01-31
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2029-01-31

This document supersedes EN 60601-2-57:2011 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.

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 EN IEC 60601-2-57:2026/A11:2026.

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.

Endorsement notice

The text of the International Standard IEC 60601-2-57:2023 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 standard indicated:

IEC 60335-2-113	NOTE	Approved as EN IEC 60335-2-113
IEC 60335-2-27	NOTE	Approved as EN 60335-2-27
IEC 60601-2-83:2019	NOTE	Approved as EN IEC 60601-2-83:2020 (not modified) + A11:2021

IEC 60601-2-57

Edition 2.0 2023-07

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 11.040.50, 11.040.60

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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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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IEC 60601-2-57 has been prepared by IEC technical committee 76: Optical radiation safety and laser equipment. It is an International Standard.

This second edition cancels and replaces the first edition published in 2011. This edition constitutes a technical revision.

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

a) This edition constitutes a major review of the previous edition and covers the recent development of LS EQUIPMENT. It now includes the RISK GROUP 1C (RG-1C). LS EQUIPMENT of RG-1C incorporates technical means which inhibit emission into free space when the APPLICATOR is not in GOOD CONTACT with the target tissue.

b) It now excludes LS EQUIPMENT of RG-1 and RG-2 as these are assumed to represent no hazard. RG-1C is only included if the incorporated light source is of RG-3.

c) It clarifies its relation to the concept of Risk Groups (RGs), as introduced in IEC 62471.

d) Although the previous edition was applicable to LS EQUIPMENT containing UV sources, more emphasis is given to UV applications of the equipment in this edition.

e) This edition excludes LS EQUIPMENT which is intended to be used on animals.

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

Draft	Report on voting
76/734/FDIS	76/737/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, in this document 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 2:2021. 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;

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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.

A list of all parts of the IEC 60601 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 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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