

STN	Zdravotnícke elektrické prístroje Časť 2-57: Osobitné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti prístrojov so svetelnými zdrojmi inými ako laserovými, určenými na terapeutické, diagnostické, monitorovacie, kozmetické a estetické používanie Zmena A11	STN EN IEC 60601-2-57/A11 36 4800
------------	--	---

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 04/26

STN EN IEC 60601-2-57 z apríla 2026 sa bez tejto zmeny A11 môže používať do 31.1.2029.

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

142427

Úrad pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky, 2026
Slovenská technická norma a technická normalizačná informácia je chránená zákonom č. 60/2018 Z. z. o technickej normalizácii v znení neskorších predpisov.

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN IEC 60601-2-57:2026/A11

January 2026

ICS 11.040.50; 11.040.60

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**

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

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

This amendment A11 modifies the European Standard EN IEC 60601-2-57:2026; it 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 amendment 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 amendment 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

EN IEC 60601-2-57:2026/A11:2026 (E)

Contents	Page
European foreword.....	3
Annex ZA (normative) Normative references to international publications with their corresponding European publications	4
Annex ZZ (informative) Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered	5

European foreword

This document (EN IEC 60601-2-57:2026/A11:2026) has been prepared by CLC/TC76 "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

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 this document.

Collateral standards in the IEC 60601 family 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.

koniec náhľadu – text ďalej pokračuje v platenej verzii STN