ICS 11.040.60 SLOVENSKÁ TECHNICKÁ NORMA September 2025

STN	**Zdravotnícke elektrické prístroje Časť 2-83: Osobitné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti prístrojov na domácu svetelnú terapiu Zmena A1**	**STN EN IEC 60601-2-83/A1** 36 4800

Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment

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. 08/25

STN EN IEC 60601-2-83 z augusta 2020 sa bez tejto zmeny A1 môže používať do 30. 6. 2028.

Obsahuje: EN IEC 60601-2-83:2020/A1:2025, IEC 60601-2-83:2019/AMD1:2022

140971

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 60601-2-83:2020/A1

June 2025

ICS 11.040.60

English Version

Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment (IEC 60601-2-83:2019/AMD1:2022)

Appareils électromédicaux - Partie 2-83: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de luminothérapie à domicile (IEC 60601-2-83:2019/AMD1:2022)

Medizinische elektrische Geräte - Teil 2-83: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Heim-Lichttherapiegeräten (IEC 60601-2-83:2019/AMD1:2022)

This amendment A1 modifies the European Standard EN IEC 60601-2-83:2020; it was approved by CENELEC on 2025-03-26. 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

Ref. No. EN IEC 60601-2-83:2020/A1:2025 E

European foreword

The text of document 62D/1931/CDV, future edition 1 of IEC 60601-2-83/AMD1, prepared by SC 62D "Particular medical equipment, software, and systems" of IEC/TC 62 "Medical equipment, software, and systems" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60601-2-83:2020/A1:2025.

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)	2026-06-30
• latest date by which the national standards conflicting with this document have to be withdrawn	(dow)	2028-06-30

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.

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 60601-2-83:2019/AMD1:2022 was approved by CENELEC as a European Standard without any modification.

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.cencenelec.eu.

Replace all references with the following:

Publication	Year	Title	EN/HD	Year
IEC 60601-1 + A1 + A2	2005 2012 2020	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	EN 60601-1 + A1 + A2	2006 2013 2021
IEC 60601-1-2 + A1	2014 2020	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests	EN 60601-1-2 + A1	2015 2021
IEC 60601-1-6 + A1 + A2	2010 2013 2020	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability	EN 60601-1-6 + A1 + A2	2010 2015 2021
IEC 60601-1-11 + A1	2015 2020	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	EN 60601-11 + A1	2015 2021
IEC 62471	2006	Photobiological safety of lamps and lamp systems	EN 62471	2008
ISO 3864-1	-	Graphical symbols – Safety colours and safety signs – Part 1: Design principles for safety signs and safety markings	-	-
ISO 15223-1	2021	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	EN ISO 15223-1	2021

Annex ZZ
(informative)

Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under standardisation request M/575 given to CENELEC by the European Commission to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117].

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZZ.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/745. This means that risks have to be ‘reduced as far as possible’, ‘reduced to the lowest possible level’, ‘reduced as far as possible and appropriate’, ‘removed or reduced as far as possible’, ‘eliminated or reduced as far as possible’, ’removed or minimized as far as possible’, or ‘minimized’, according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer’s policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in Table ZZ.1, it means that it is not addressed by this European Standard.

Table ZZ.1 — Correspondence between this European standard and Annex I of Regulation (EU) 2017/745 [OJ L 117]

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
1	201.6.101 201.7.2 201.7.9.2 201.7.9.2.17 201.10 211.8.3.1	Covered in respect of risks associated with the intended purpose and related to the design and manufacture of the device, the emission of optical radiation, and the use by lay operators in the home healthcare environment.
4	201.6 201.7 201.10 201.15 202 206 211	Covered in respect of risks associated with the intended purpose and related to the design and manufacture of the device, the emission of optical radiation, and the use by lay operators in the home healthcare environment.

General Safety and Performance Requirements of Regulation (EU) 2017/745	**Clause(s) / sub-clause(s) of this EN**	**Remarks / Notes**
5	201.7.2.3 201.7.2.13 201.7.2.13.101 201.7.9.2.2.101 201.7.9.2.17 201.10 206 211.8.3.1	Covered in respect of risks associated with the intended purpose of the device, the emission of optical radiation, and the use by lay operators in the home healthcare environment.
8	201.6 201.7 201.10 201.15 202 206 211	Covered. The technical requirements in the standard are conforming to the state of the art and ensure that known and foreseeable risks and undesirable side-effects are minimized and outweighed by the benefits to the patient/user.
10.1 (b)	201.7.2.13	Partly covered by a requirement to indicate presence of natural rubber latex, if applicable.
10.5	211.8.3.1	Covered in respect of ingress of water and particulate matter.
14.2 (a)	201.5.9.2.1 211.5	Covered in respect of the risk of injury related to accessible parts.
14.2 (b)	202.8.1.101	Covered concerning magnetic fields and external electrical influences.
14.2 (e)	211.8.3.1	Covered.
16.1 (a)	201.6.101 201.10	Covered in respect of exposure of patients, users and other persons to optical radiation.
16.1 (b)	201.7.9.2.2.101 201.7.9.2.17 201.10.106	First sentence only. Covered in respect of information as to the nature of emitted optical radiation and means of protection.
16.2 (a), first sentence only	201.10.105	Covered in respect of the control of emissions according to the skin pigmentation level.
16.3	201.6.101 201.10	Covered in respect of emission of unintended, stray and scattered optical radiation.

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
22.1	201.6 201.7 201.10 201.15 202 206 211	Covered in respect of risks associated with the intended purpose of the device, the emission of optical radiation, and the use by lay operators in the home healthcare environment.
23.1, first paragraph	201.7.2.13 201.7.2.13.101	Covered for safety and performance information appearing on the device itself.
23.1, first paragraph	201.7.2.3 201.7.9.2.2.101 201.7.9.2.17	Covered for safety and performance information appearing in the instructions for use.
23.1 (a)	201.7.1.2 201.7.2.3 201.7.2.13 201.7.2.13.101 201.7.9.2.2.101 201.7.9.2.17	Covered in respect of warning statements, symbols and safety signs on the device label and in the instructions for use.
23.1 (b)	201.7.2.3 201.7.2.13 201.7.2.13.101	Covered in respect of symbols and safety signs on the device label.
23.1 (g)	201.7.2.3 201.7.2.13 201.7.2.13.101 201.7.9.2.2.101 201.7.9.2.17	Covered in respect of residual risks related to the symbols, safety signs, warnings, cautions and other information on the device label and/or in the instructions for use as required by the indicated subclauses.
23.1 (h)	201.7.2.3 201.7.2.13 201.7.2.13.101	Covered in respect of symbols and safety signs on the device label and/or in the instructions for use applied in accordance with the requirements of the indicated subclauses.
23.2 (m)	201.7.2.3 201.7.2.13 201.7.2.13.101 201.7.9.2.2.101 201.7.9.2.17 211.8.3.1	Covered in respect of the symbols, safety signs, warnings, cautions and other information on the device label and/or in the instructions for use as required by the indicated subclauses.
23.4 (e)	201.7.9.2.17 (first paragraph, items b, c, d)	Covered.
23.4 (r)	201.7.9.2.17 (first paragraph, items b, c, d) 201.10	Covered.

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
23.4 (s), sixth dash	201.7.2.13	Covered in respect of warnings as regards the presence of natural rubber latex.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

IEC 60601-2-83

Edition 1.0 2022-12

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

Medical electrical equipment – Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment

Appareils électromédicaux – Partie 2-83: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de luminothérapie à domicile

IEC 60601-2-83:2019-05/AMD1:2022-12(en-fr)

IEC 60601-2-83

Edition 1.0 2022-12

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

Medical electrical equipment – Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment

Appareils électromédicaux – Partie 2-83: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de luminothérapie à domicile

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 11.040.60 ISBN 978-2-8322-6215-3

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment

AMENDMENT 1

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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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 document may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

Amendment 1 to IEC 60601-2-83:2019 has been prepared by subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems.

The text of this Amendment is based on the following documents:

Draft	Report on voting
62D/1931/CDV	62D/1962/RVC

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 Amendment 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/.

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.

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

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INTRODUCTION TO AMENDMENT 1

The first edition of IEC 60601-2-83 was published in May 2019. Since the publication of IEC 60601-2-83:2019, the IEC Subcommittee (SC) 62A has published amendments to the general and collateral standards, thus requiring amendments to the particular standards for alignment as discussed at the IEC SC 62D meeting in Shanghai, China, in October 2019.

Because this is an amendment to IEC 60601-2-83:2019, the style in force at the time of publication of IEC 60601-2-83 has been applied to this amendment. The style specified in ISO/IEC Directives Part 2:2021 has only been applied when implementing the new style guidance would not result in additional editorial changes.

Users of this document should note that when constructing the dated references to specific elements in a standard, such as definitions, amendments are only referenced if they modified the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference.

INTRODUCTION

Replace the existing last paragraph with:

This document is aligned with:

– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020;
– IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020;
– IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020; and

– IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020.

201.1 Scope, object and related standards

Replace the existing footnote 2 with:

2 The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

201.1.3 Collateral standards

Replace the first sentence of the second paragraph with:

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020, and IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020 apply as modified in Clauses 202, 206 and 211, respectively.

201.1.4 Particular standards

Replace the first sentence of the third paragraph with:

For brevity, IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are referred to in this particular standard as the general standard.

201.2 Normative references

Replace the existing references to IEC 60601-1-2, IEC 60601-1-6 and ISO 15223-1 with the following new references:

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*
IEC 60601-1-2:2014/AMD1:2020

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
IEC 60601-1-6:2010/AMD1:2013
IEC 60601-1-6:2010/AMD2:2020

ISO 15223-1:2021, *Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements*

Replace the existing references to IEC 60601-1 and IEC 60601-1-11 with the following new references:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*
IEC 60601-1-11:2015/AMD1:2020