ICS 11.040.60 SLOVENSKÁ TECHNICKÁ NORMA Júl 2021

STN	**Zdravotnícke elektrické prístroje Časť 2-83: Osobitné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti prístrojov na domácu svetelnú terapiu Zmena A11**	**STN EN IEC 60601-2-83/A11** 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. 06/21

STN EN IEC 60601-2-83 z augusta 2020 sa bez tejto zmeny A11 môže používať do 3. 11. 2023.

Obsahuje: EN IEC 60601-2-83:2020/A11:2021

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 60601-2-83:2020/A11

April 2021

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

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

Medizinische elektrische Geräte - Teil 2-83: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Heim-Lichttherapiegeräten

This amendment A11 modifies the European Standard EN IEC 60601-2-83:2020; it was approved by CENELEC on 2020-11-03. 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.

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

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EN IEC 60601-2-83:2020/A11:2021 (E)

European foreword

This document (EN IEC 60601-2-83:2020/A11:2021) has been prepared by CLC/TC 62 "*Electrical equipment in medical practice*".

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)	2021-10-02
• latest date by which the national standards conflicting with this document have to be withdrawn	(dow)	2023-11-03

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This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annexes ZZA and ZZB, which are an integral part of this document.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. However, for any use of this standard “within the meaning of Annex ZZ”, the user must always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When the IEC or ISO standard is referred to in the IEC text standard, this must be understood as a normative reference to the parallel EN standard, as outlined below, including the foreword and the Annexes ZZ.

NOTE 1 The way in which referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

NOTE 2 When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC 60601-1	2005	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
AMD1	2012		A1	2013
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	EN 60601-1-2	2015
IEC 60601-1-6	2010	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability	EN 60601-1-6	2010
AMD1	2013		A1	2015
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	EN 60601-11	2015
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	2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements	EN ISO 15223-1	2016