SLOVENSKI STANDARD
SIST EN IEC 60601-2-83:2020/A11:2021

01-junij-2021

Medicinska električna oprema - 2-83. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme za svetlobno terapijo na domu - Dopolnilo A11

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

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

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

Ta slovenski standard je istoveten z: **EN IEC 60601-2-83:2020/A11:2021**

ICS:

11.040.60	Terapevtska oprema	Therapy equipment

SIST EN IEC 60601-2-83:2020/A11:2021 **en**

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.

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, Turkey 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

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

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 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

Annex ZZA
(informative)

Relationship between this European standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European Standard has been prepared under a standardization request M/023 concerning the development of European standards related to medical devices given to CENELEC by the European Commission to provide a means of conforming to the Essential Requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements (ERs) of that Directive and associated EFTA regulations.

NOTE 1 The standard's scope is limited to the specific uses, environments, contexts, objective situations specifically indicated. It cannot provide for presumption of conformity in other conditions. Some clauses or subclauses may be not applicable due to the specific type of equipment under consideration.

NOTE 2 Only requirements contained in the normative parts of the text are relevant to the presumption of conformity of this standard. Informative parts may, however, support users to interpret such requirements correctly.

NOTE 3 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 Directive 93/42/EEC. This means that risks have to be reduced "as far as possible", "to a minimum", "to the lowest possible level", "minimized" or "removed", according to the wording of the corresponding essential requirement which must be interpreted and applied in such a way as to take account of technology and practice existing at the time of design and of technical and economical considerations compatible with a high level of protection of health and safety.

NOTE 4 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 5 For all parts of this standard that a) refer in their clauses to specific national legislation possibly exempting manufacturers from the thorough application of relevant provisions of this standard or b) link the completion of a relevant process/prescription to any discretional choice/power of manufacturers, the user of the standard should check that such clauses are in compliance with Directive 93/42/EEC.

NOTE 6 This Annex ZZ is based on Normative References according to Annex ZA, replacing the references in the core text.

WARNING 1: Other requirements and other EU Directives and Regulations may be applicable to the product(s) falling within the scope of this standard.

WARNING 2: 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.

Table ZZA.1 — Correspondence between the Essential Requirements of Directive 93/42/EEC and Clauses and Sub-clauses of this European standard

Essential Requirements of Directive 93/42/EEC	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
1	201.6.101 201.7.2 201.7.9.2 201.10 202.8.1.101 211.8.3.1	Covered in respect of risks associated with the intended purpose and related to the construction of the device, the emission of optical radiation, and the use by lay operators in the home healthcare environment.
2	All clauses of this standard	Covered.
6	201.6.101 201.10	Covered in respect of the emission of optical radiation with minimal side-effects.
7.1, dash 2	201.7.2.13	Partly covered by a requirement to indicate presence of natural rubber latex, if applicable.
7.6	211.8.3.1	Covered in respect of ingress of water and particulate matter.
9.2, dash 1	201.5.9.2.1 211.5	Covered in respect of the risk of injury related to accessible parts.
9.2, dash 2	202.8.1.101	Covered in respect of magnetic fields and external electrical influences.
11.1.1	201.6.101 201.10	Covered in respect of exposure of patients, users and other persons to optical radiation.
11.2.1, first sentence only	201.10.105	Covered in respect of control of emission according to the skin pigmentation level.
11.3.1	201.6.101 201.10	Covered in respect of emission of unintended, stray and scattered optical radiation.
11.4.1	201.7.9.2.2.101 201.7.9.2.17 201.10.106	Covered in respect of information as to the nature of emitted optical radiation and means of protection.
13.1	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.
13.2	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 in the instructions for use.

Essential Requirements of Directive 93/42/EEC	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
13.3 (k)	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.
13.6 (a)	201.7.2.13 201.7.9.2.2.101	Covered in respect of symbols and safety signs in the instructions for use.
13.6 (b)	201.7.9.2.17 (first paragraph)	Covered for performance.
13.6 (j)	201.7.9.2.17 (first paragraph)	Covered.

Home light therapy equipment falling within the scope of this standard is not machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery.

Annex ZZB
(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 a standardisation request 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 ZZB.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 The standard's scope is limited to the specific uses, environments, contexts, objective situations specifically indicated. It cannot provide for presumption of conformity in other conditions. Some clauses or subclauses may be not applicable due to the specific type of equipment under consideration.

NOTE 2 Only requirements contained in the normative parts of the text are relevant to the presumption of conformity of this standard. Informative parts may, however, support users to interpret such requirements correctly.

NOTE 3 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 4 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 5 For all parts of this standard that a) refer in their clauses to specific national legislation possibly exempting manufacturers from the thorough application of relevant provisions of this standard or b) link the completion of a relevant process/prescription to any discretional choice/power of manufacturers, the user of the standard should check that such clauses are in compliance with Regulation (EU) 2017/745.

NOTE 6 This Annex ZZ is based on normative references according to Annex ZA, replacing the references in the core text.

NOTE 7 When a General Safety and Performance Requirement does not appear in Table ZZB.1, it means that it is not addressed by this European Standard.

Table ZZB.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	All clauses	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.
5	201.7.2.3 201.7.2.13 201.7.2.13.101 201.7.9.2.2.101 201.7.9.2.17 201.10 211.8.3.1	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	All clauses	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.