SLOVENSKI STANDARD
SIST EN IEC 60601-2-2:2018/A1:2024

01-november-2024

Medicinska električna oprema - 2-2. del: Posebne zahteve za osnovno varnost in bistvene lastnosti visokofrekvenčne kirurške opreme in visokofrekvenčnega kirurškega pribora - Dopolnilo A1 (IEC 60601-2-2:2017/AMD1:2023)

Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories (IEC 60601-2-2:2017/AMD1:2023)

Medizinische elektrische Geräte - Teil 2-2: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Hochfrequenz-Chirurgiegeräten (IEC 60601-2-2:2017/AMD1:2023)

Appareils électromédicaux - Partie 2-2: Exigences particulières pour la sécurité de base et les performances essentielles des appareils d'électrochirurgie à courant haute fréquence et des accessoires d'électrochirurgie à courant haute fréquence (IEC 60601-2-2:2017/AMD1:2023)

Ta slovenski standard je istoveten z: **EN IEC 60601-2-2:2018/A1:2024**

ICS:

11.040.30	Operacijski instrumenti in materiali	Surgical instruments and materials

SIST EN IEC 60601-2-2:2018/A1:2024 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 60601-2-2:2018/A1

September 2024

ICS 11.040.30

English Version

Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories (IEC 60601-2-2:2017/AMD1:2023)

Appareils électromédicaux - Partie 2-2: Exigences particulières pour la sécurité de base et les performances essentielles des appareils d'électrochirurgie à courant haute fréquence et des accessoires d'électrochirurgie à courant haute fréquence
(IEC 60601-2-2:2017/AMD1:2023)

Medizinische elektrische Geräte - Teil 2-2: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Hochfrequenz-Chirurgiegeräten
(IEC 60601-2-2:2017/AMD1:2023)

This amendment A1 modifies the European Standard EN IEC 60601-2-2:2018; it was approved by CENELEC on 2024-07-31. 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

European foreword

The text of document 62D/2010/FDIS, future edition 6 of IEC 60601-2-2/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 60601-2-2:2018/A1:2024.

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) 2025-05-01
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2027-07-31

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.

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 60601-2-2:2017/AMD1:2023 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 60601-1-3	NOTE	Approved as EN 60601-1-3
IEC 60601-1-10	NOTE	Approved as EN 60601-1-10
IEC 60601-1-11	NOTE	Approved as EN 60601-1-11
IEC 60601-1-2	NOTE	Approved as EN 60601-1-2

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 EN 60601-1-2:2015 with:

Publication	Year	Title	EN/HD	Year
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
+ A1	2020		+ A1	2021

Replace EN 60601-1-8:2006 with:

Publication	Year	Title	EN/HD	Year
IEC 60601-1-8	2006	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	EN 60601-1-8	2007
-	-		+ AC	2010
+ A1	2012		+ A1	2013
-	-		+ AC	2014
-	-		+ A11	2017
+ A2	2020		+ A2	2021

Delete:

Publication	Year	Title	EN/HD	Year
IEC 61000-4-3	2006	Electromagnetic compatibility (EMC) - Part 4-3 : Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	-	-
IEC 61000-4-6	2013	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields	EN 61000-4-6	2014

Replace EN 55011:2016 with:

Publication	Year	Title	EN/HD	Year
CISPR 11 (mod)	2015	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement	EN 55011	2016
+ A1	2016		+ A1	2017
-	-		+ A11	2020
+ A2	2019		+ A2	2021