ICS 11.040.50 SLOVENSKÁ TECHNICKÁ NORMA September 2021

STN	**Zdravotnícke elektrické prístroje Časť 2-63: Osobitné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti stomatologických extraorálnych röntgenových prístrojov Zmena A2**	**STN EN 60601-2-63/A2** 36 4800

Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray 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. 08/21

STN EN 60601-2-63 z decembra 2015 sa bez tejto zmeny A2 môže používať do 16. 6. 2024.

Obsahuje: EN 60601-2-63:2015/A2:2021, IEC 60601-2-63:2012/AMD2:2021

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-63:2015/A2

June 2021

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English Version

Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment (IEC 60601-2-63:2012/A2:2021)

Appareils électromédicaux - Partie 2-63: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à rayonnement X dentaires extra-oraux (IEC 60601-2-63:2012/A2:2021)

Medizinische elektrische Geräte - Teil 2-63: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von extraoralen zahnärztlichen Röntgeneinrichtungen (IEC 60601-2-63:2012/A2:2021)

This amendment A2 modifies the European Standard EN 60601-2-63:2015; it was approved by CENELEC on 2021-06-16. 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

EN 60601-2-63:2015/A2:2021 (E)

European foreword

The text of document 62B/1232/FDIS, future IEC 60601-2-63/A2, prepared by SC 62B "Diagnostic imaging equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-63:2015/A2:2021.

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) 2022-03-16
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2024-06-16

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.

Endorsement notice

The text of the International Standard IEC 60601-2-63:2012/A2:2021 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.cenelec.eu.

Replace, in this clause modified by Amendment 1, under Addition, the reference to IEC/PAS 61910-1:2014 with:

Publication	Year	Title	EN/HD	Year
IEC 61910-1	2014	Medical electrical equipment - Radiation dose documentation - Part 1: Radiation dose structured reports for radiography and radioscopy	EN 61910-1	2014

IEC 60601-2-63

Edition 1.0 2021-05

INTERNATIONAL STANDARD

AMENDMENT 2

Medical electrical equipment – Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment

IEC 60601-2-63:2012-09/AMD2:2021-05(en)

IEC 60601-2-63

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INTERNATIONAL STANDARD

AMENDMENT 2

Medical electrical equipment – Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment

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FOREWORD

This second amendment has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62B/1232/FDIS	62B/1237/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.