SLOVENSKI STANDARD
SIST EN IEC 60601-1-3:2008/A2:2021

01-maj-2021

Medicinska električna oprema - 1-3. del: Splošne zahteve za osnovno varnost in bistvene lastnosti - Spremljevalni standard: Varstvo pred sevanjem pri rentgenski diagnostični opremi - Dopolnilo A2 (IEC 60601-1-3:2008/A2:2021)

Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment (IEC 60601-1-3:2008/A2:2021)

Medizinische elektrische Geräte - Teil 1-3: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Ergänzungsnorm: Strahlenschutz von diagnostischen Röntgengeräten (IEC 60601-1-3:2008/A2:2021)

Appareils électromédicaux - Partie 1-3: Exigences générales pour la sécurité de base et les performances essentielles - Norme collatérale: Radioprotection dans les appareils à rayonnement X de diagnostic (IEC 60601-1-3:2008/A2:2021)

Ta slovenski standard je istoveten z: **EN 60601-1-3:2008/A2:2021**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
13.280	Varstvo pred sevanjem	Radiation protection

SIST EN IEC 60601-1-3:2008/A2:2021 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1-3:2008/A2

March 2021

ICS 11.040.50; 13.280

English Version

Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment (IEC 60601-1-3:2008/A2:2021)

Appareils électromédicaux - Partie 1-3: Exigences générales pour la sécurité de base et les performances essentielles - Norme collatérale: Radioprotection dans les appareils à rayonnement X de diagnostic (IEC 60601-1-3:2008/A2:2021)

Medizinische elektrische Geräte - Teil 1-3: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Ergänzungsnorm: Strahlenschutz von diagnostischen Röntgengeräten (IEC 60601-1-3:2008/A2:2021)

This amendment A2 modifies the European Standard EN 60601-1-3:2008; it was approved by CENELEC on 2021-03-02. 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

Ref. No. EN 60601-1-3:2008/A2:2021 E

European foreword

The text of document 62B/1176/CDV, future IEC 60601-1-3/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 60601-1-3:2008/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) 2021–12–02
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2024–03–02

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.

Endorsement notice

The text of the International Standard IEC 60601-1-3:2008/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 the existing reference to EN 60601-1 with the following:

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
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
-	-		+ A12	2014
+ A2	2020		-	-

IEC 60601-1-3

Edition 2.0 2021-01

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 2
AMENDEMENT 2

Medical electrical equipment –
Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment

Appareils électromédicaux –
Partie 1-3: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Radioprotection dans les appareils à rayonnement X de diagnostic

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 11.040.50; 13.280

ISBN 978-2-8322-9330-0

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MEDICAL ELECTRICAL EQUIPMENT –

PART 1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-ray equipment

AMENDMENT 2

FOREWORD

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Amendment 2 to IEC 60601-1-3:2008 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:

Draft	Report on voting
62B/1176/CDV	62B/1227/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/standardsdev/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.

INTRODUCTION to Amendment 2

The purpose of this second amendment to IEC 60601-1-3:2008 is to introduce changes to reference the second amendment (2020) to IEC 60601-1:2005.

1.3.1 IEC 60601-1

Replace the existing first bullet, modified by Amendment 1, with:

- "the general standard" designates IEC 60601-1:2005+A1:2012+A2:2020;

Replace the existing second bullet, modified by Amendment 1, with:

- "this collateral standard" designates IEC 60601-1-3:2008+A1:2013+A2:2021;

2 Normative references

Replace the existing reference to IEC 60601-1 with the following new reference:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012
Amendment 2:2020

3 Terms and definitions

Replace, in the introductory paragraph, modified by Amendment 1, "IEC 60601-1:2005+A1:2012" *with* "IEC 60601-1:2005+A1:2012+A2:2020".

Index of defined terms used in this collateral standard

Replace the following terms, modified by Amendment 1, as follows:

INTENDED USE	IEC 60601-1:2005+A1:2012+A2:2020, 3.44
MANUFACTURER	IEC 60601-1:2005+A1:2012+A2:2020, 3.55
RISK MANAGEMENT	IEC 60601-1:2005+A1:2012+A2:2020, 3.107

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