

SLOVENSKI STANDARD
SIST EN IEC 60601-2-28:2020/A1:2026
01-december-2026

Medicinska električna oprema - 2-28. del: Posebne zahteve za osnovno varnost in bistvene lastnosti rentgenskih sestavov za medicinsko diagnostiko - Dopolnilo A1 (IEC 60601-2-28:2017/AMD1:2026)

Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis (IEC 60601-2-28:2017/AMD1:2026)

Medizinische elektrische Geräte - Teil 2-28: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Röntgenstrahlern für die medizinische Diagnostik (IEC 60601-2-28:2017/AMD1:2026)

Appareils électromédicaux - Partie 2-28: Exigences particulières pour la sécurité de base et les performances essentielles des gaines équipées pour diagnostic médical (IEC 60601-2-28:2017/AMD1:2026)

Ta slovenski standard je istoveten z: EN IEC 60601-2-28:2019/A1:2026

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN IEC 60601-2-28:2020/A1:2026 en

Sample Document

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN IEC 60601-2-28:2019/A1

October 2026

ICS 11.040.55

English Version

**Medical electrical equipment - Part 2-28: Particular requirements
for the basic safety and essential performance of X-ray tube
assemblies for medical diagnosis
(IEC 60601-2-28:2017/AMD1:2026)**

Appareils électromédicaux - Partie 2-28: Exigences
particulières pour la sécurité de base et les performances
essentiels des gaines équipées pour diagnostic médical
(IEC 60601-2-28:2017/AMD1:2026)

Medizinische elektrische Geräte - Teil 2-28: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von Röntgenstrahlern für
die medizinische Diagnostik
(IEC 60601-2-28:2017/AMD1:2026)

This amendment A1 modifies the European Standard EN IEC 60601-2-28:2019; it was approved by CENELEC on 2026-10-21. 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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Ref. No. EN IEC 60601-2-28:2019/A1:2026 E

EN IEC 60601-2-28:2019/A1:2026 (E)**European foreword**

The text of document 62B/1396/CDV, future edition 3 of IEC 60601-2-28/AMD1, prepared by SC 62B "Medical imaging 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 60601-2-28:2019/A1:2026.

The following dates are fixed:

- latest date by which the document has to be implemented at national (dop) 2027-10-31 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2029-10-31 document have to be withdrawn

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 60601-2-28:2017/AMD1:2026 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 60601-1-2	NOTE Approved as EN 60601-1-2
IEC 60601-1-6	NOTE Approved as EN 60601-1-6
IEC 60601-1-8	NOTE Approved as EN 60601-1-8
ISO 13732-1:2006	NOTE Approved as EN ISO 13732-1:2008 (not modified)

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 the following references:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60601-1-3	2008	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment	EN 60601-1-3	2008
-	-		+ corrigendum Mar.	2010
+ A1	2013		+ A1	2013
-	-		+ AC	2014
-	-		+ A11	2016
+ A2	2021		+ A2	2021
-	-		+ A12	2026
IEC 60336	-	Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Focal spot dimensions and related characteristics	EN IEC 60336	-
IEC 60522-1	-	Medical electrical equipment - Diagnostics X-rays - Part 1: Determination of quality equivalent filtration and permanent filtration	EN IEC 60522-1	-

Add the following reference:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60806	-	Determination of the maximum symmetrical radiation field of X-ray tube assemblies and X-ray source assemblies for medical diagnosis	EN IEC 60806	-