ILNAS

Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN IEC 60601-2-28:2019

Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical

Medizinische elektrische Geräte - Teil 2-28: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von

Appareils électromédicaux - Partie 2-28 : Exigences particulières pour la sécurité de base et les performances essentielles des gaines équipées pour diagnostic

09/2019

National Foreword

This European Standard EN IEC 60601-2-28:2019 was adopted as Luxembourgish Standard ILNAS-EN IEC 60601-2-28:2019.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

- Participate in the design of standards
- Foresee future developments
- Participate in technical committee meetings

https://portail-qualite.public.lu/fr/normes-normalisation/participer-normalisation.html

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN IEC 60601-2-28

September 2019

ICS 11.040.55

Supersedes EN 60601-2-28:2010 and all of its amendments and corrigenda (if any)

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)

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)

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)

This European Standard was approved by CENELEC on 2019-08-07. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard 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 European Standard 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

The text of document 62B/1040/FDIS, future edition 3 of IEC 60601-2-28, 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 IEC 60601-2-28:2019.

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) 2020-05-07
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2022-08-07

This document supersedes EN 60601-2-28:2010.

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 60601-2-28:2017 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 standards indicated:

IEC 60601-1-9	NOTE	Harmonized as EN 60601-1-9
IEC 60601-1-10	NOTE	Harmonized as EN 60601-1-10
IEC 61010-1:2010	NOTE	Harmonized as EN 61010-1:2010 (not modified)
ISO 13732-1	NOTE	Harmonized as EN ISO 13732-1

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.

The annex ZA of EN 60601-1:2006 applies, except as follows:

Publication	Year	Title	EN/HD	Year
Addition				
IEC 60336	-	Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Characteristics of focal spots	EN 60336	-
IEC 60522	-	Determination of the permanent filtration of X-ray tube assemblies	EN 60522	-
IEC TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
Replacement				
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
			+EN 60601-1-3:2008/corrigendum Mar. 2010	2010
			+A11	2016

IEC 60601-2-28

Edition 3.0 2017-06

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

Appareils électromédicaux –
Partie 2-28: Exigences particulières pour la sécurité de base et les performances essentielles des gaines équipées pour diagnostic médical

IEC 60601-2-28:2017-06(en-fr)

CONTENTS