ELEKTRILISED MEDITSIINISEADMED. OSA 2-60: ERINÕUDED HAMBARAVIS KASUTATAVATE SEADMETE ESMASELE OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE

Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 80601-2-60:2015 sisaldab Euroopa standardi EN 80601-2-60:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 80601-2-60:2015 consists of the English text of the European standard EN 80601-2-60:2015.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 22.05.2015.	Date of Availability of the European standard is 22.05.2015.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.01

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 80601-2-60

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English Version

Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment (IEC 80601-2-60:2012)

Appareils électromédicaux - Partie 2-60: Exigences particulières pour la sécurité de base et les performances essentielles des équipements dentaires (IEC 80601-2-60:2012)

Medizinische elektrische Geräte -- Teil 2-60: Besondere Festlegungen an die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Dental-Geräten (IEC 80601-2-60:2012)

This European Standard was approved by CENELEC on 2015-04-14. 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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, 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: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 80601-2-60:2015 E

Foreword

The text of document 62D/964/FDIS, future edition 1 of IEC 80601-2-60, prepared by SC 62D, "Electromedical equipment", of IEC/TC 62, "Electrical equipment in medical practice" and SC 6 "Dental equipment" of ISO/TC 106 "Dentistry" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 80601-2-60:2015.

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)	2016-01-14
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-04-14

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] 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, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 80601-2-60:2012 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 61810-7:2006	NOTE	Harmonized as EN 61810-7:2006 (not modified).
ISO 13732-1:2006	NOTE	Harmonized as EN ISO 13732-1:2008 (not modified).
ISO 17664:2004	NOTE	Harmonized as EN ISO 17664:2004 (not modified).
ISO 7494-2:2003	NOTE	Harmonized as EN ISO 7494-2:2003 (not modified).
ISO 21530:2004	NOTE	Harmonized as EN ISO 21530:2004 (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Annex ZA of EN 60601-1:2006 applies with the following exceptions:

Publication	Year	Title	EN/HD	Year
Replacement:				
IEC 60664-1	2007	Insulation coordination for equipment within low-voltage systems - Part 1: Principles, requirements and tests	EN 60664-1	2007
IEC 60825-1	-	Safety of laser products - Part 1: Equipment classification and requirements	EN 60825-1	-
Addition:				
IEC 60601-2-2	2009	Medical electrical equipment - Part 2-2: Particular requirements for basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	EN 60601-2-2 + A11	2009 2011
IEC 60601-2-22	2007	Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, therapeutic and diagnostic laser equipment	-	-
IEC 60601-2-57	2011	Medical electrical equipment - Part 2-57: Particular requirements for basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use	EN 60601-2-57	2011
IEC 60664-4	2005	Insulation coordination for equipment within low-voltage systems - Part 4: Consideration of high-frequency voltage stress	EN 60664-4 + corr. October	2006 2006
IEC 61180-1	-	High-voltage test techniques for low-voltage equipment - Part 1: Definitions, test and procedure requirements	EN 61180-1	-
IEC 61180-2	-	High-voltage test techniques for low-voltage equipment - Part 2: Test equipment	EN 61180-2	-
IEC 61810-1 + corr. February	2008 2010	Electromechanical elementary relays - Part 1: General requirements	EN 61810-1	2008
IEC 62471	-	Photobiological safety of lamps and lamp systems	EN 62471	-
ISO 1942	-	Dentistry - Vocabulary	EN ISO 1942	-

Publication	Year	Title	EN/HD	Year
ISO 7785-2	-	Dental handpieces - Part 2: Straight and geared angle handpieces	EN ISO 7785-2	-

Annex ZZ
(informative)

Coverage of Essential Requirements of EU Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and within its scope the Standard covers all relevant essential requirements given in Annex I of EU Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EU Directives can be applied to the products falling within the scope of this standard.

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