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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 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.
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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
essentiels 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)

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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

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- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-04-14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

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>Replacement:</i>				
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	-
<i>Addition:</i>				
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	-

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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.

CONTENTS

FOREWORD.....	3
201.1 Scope, object and related standards.....	5
201.2 Normative references	6
201.3 Terms and definitions	7
201.4 General requirements.....	8
201.5 General requirements for testing of ME EQUIPMENT	8
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	9
201.7 ME EQUIPMENT identification, marking and documents.....	9
201.8 Protection against electrical HAZARDS from ME EQUIPMENT	10
201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS	14
201.10 Protection against unwanted and excessive radiation HAZARDS.....	16
201.11 Protection against excessive temperatures and other HAZARDS.....	16
201.12 Accuracy of controls and instruments and protection against hazardous outputs	20
201.13 HAZARDOUS SITUATIONS and fault conditions	20
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	21
201.15 Construction of ME EQUIPMENT	21
201.16 ME SYSTEMS.....	21
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS.....	21
201.101 Cordless HAND-HELD and foot-operated control devices	21
Annexes	21
Annex AA (informative) Particular guidance and rationale.....	22
Bibliography.....	31
Index of defined terms used in this particular standard.....	32
Figure AA.1 – Example of APPLIED PARTS for DENTAL EQUIPMENT	23
Figure AA.2 – Calculation of LEAKAGE CURRENT	24
Figure AA.3 – Insulation problem of commutator DENTAL ELECTRICAL MOTOR.....	25
Figure AA.4 – Loading fan construction.....	29
Figure AA.5 – Load diagram with loading fan	30
Table 201.101 – Test voltages for solid insulation for SECONDARY CIRCUITS according to 201.8.5.2	10
Table 201.102 – Determination of TENSILE SAFETY FACTOR.....	15
Table 201.103 – Mass distribution	16
Table 201.104 – Allowable maximum temperatures for DENTAL HANDPIECE.....	17