ELEKTRILISED MEDITSIINISEADMED. OSA 1-12: ÜLDISED NÕUDED ESMASELE OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE. KOLLATERAALSTANDARD: NÕUDED KIIRABITEENUSTES KASUTATAVATELE ELEKTRILISTELE MEDITSIINISEADMETELE JA -SÜSTEEMIDELE

Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 60601-1-12:2015 sisaldab Euroopa standardi EN 60601-1-12:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-1-12:2015 consists of the English text of the European standard EN 60601-1-12:2015.
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

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1-12

May 2015

ICS 11.040

English Version

Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment (IEC 60601-1-12:2014)

Appareils électromédicaux - Partie 1-12: Exigences générales pour la sécurité de base et les performances essentielles - Norme collatérale: Exigences pour les appareils électromédicaux et les systèmes électromédicaux destinés à être utilisés dans l'environnement des services médicaux d'urgence (IEC 60601-1-12:2014)

Medizinische elektrische Geräte - Teil 1-12: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Ergänzungsnorm: Anforderungen an medizinische elektrische Geräte und medizinische elektrische Systeme in der Umgebung für den Notfalleinsatz (IEC 60601-1-12:2014)

This European Standard was approved by CENELEC on 2014-07-24. 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

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Ref. No. EN 60601-1-12:2015 E

Foreword

The text of document 62A/932/FDIS, future edition 1 of IEC 60601-1-12, prepared by SC 62A "Common aspects of electrical equipment used in medical practice", of IEC/TC 62 "Electrical equipment in medical practice", was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-1-12:2015.

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) 2015-11-22

– latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-12-31

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 Directives 93/42/EEC and 90/385/EEC, see informative Annexes ZZA and ZZB, which are integral parts of this document.

Endorsement notice

The text of the International Standard IEC 60601-1-12:2014 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 60038:2009	NOTE	Harmonized as EN 60038:2011 (modified).
IEC 60065	NOTE	Harmonized as EN 60065.
IEC 60335-1:2010	NOTE	Harmonized as EN 60335-1:2012 (modified).
IEC 60364	NOTE	Harmonized in HD 384 / HD 60364 series (partly modified).
IEC 60721-3-7:1995 + A1:1996	NOTE	Harmonized as EN 60721-3-7:1995 (not modified) + A1:1997 (not modified).
IEC 60950-1:2005	NOTE	Harmonized as EN 60950-1:2006 (modified).
IEC 61032:1997	NOTE	Harmonized as EN 61032:1998 (not modified).
ISO 10651-2:2004	NOTE	Harmonized as EN ISO 10651-2:2009 (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 1 When 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.

Publication	Year	Title	EN/HD	Year
IEC 60068-2-27	2008	Environmental testing - Part 2-27: Tests - Test Ea and guidance: Shock	EN 60068-2-27	2009
IEC 60068-2-31	2008	Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens	EN 60068-2-31	2008
IEC 60068-2-64	2008	Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance	EN 60068-2-64	2008
IEC 60529 - + A1	1989 - 1999	Degrees of protection provided by enclosures (IP Code)	EN 60529 + corrigendum May + A1	1991 1993 2000
IEC 60601-1 - + A1 -	2005 - 2012 -	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1 + corrigendum Mar. + A1 + A1/AC	2006 2010 2013 2014
IEC 60601-1-2	2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests	EN 60601-1-2	2014
IEC 60601-1-6 + A1	2010 2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6 + A1	2010 2015
IEC 60601-1-8 - + A1 -	2006 - 2012 -	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	EN 60601-1-8 + corrigendum Mar. + A1 + A1/AC	2007 2010 2013 2014

Publication	Year	Title	EN/HD	Year
IEC 60601-1-11	2015	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	EN 60601-1-11	2015
CISPR 11 (mod)	2009	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement	EN 55011	2009
ISO 7000	2014	Graphical symbols for use on equipment - Registered symbols	-	-
ISO 7010 + A1 + A2 + A3 + A4 + A5	2011 2012 2012 2012 2013 2014	Graphical symbols - Safety colours and safety signs - Registered safety signs	EN ISO 7010 + A1 + A2 + A3 + A4 + A5	2012 2014 2014 2014 2014 2015
ISO 15223-1	2012	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	EN ISO 15223-1	2012

Annex ZZA
(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.

Annex ZZB
(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 1 of EU Directive 90/385/EEC of 20 June 1990 relating to active implantable 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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