ELEKTRILISED MEDITSIINISEADMED. OSA 2-66: ERINÕUDED KUULDESEADMETE JA KUULDESEADMESÜSTEEMIDE ESMASELE OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE

Medical electrical equipment - Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 60601-2-66:2015 sisaldab Euroopa standardi EN 60601-2-66:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-2-66:2015 consists of the English text of the European standard EN 60601-2-66:2015.
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 27.11.2015.	Date of Availability of the European standard is 27.11.2015.
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 11.180.15, 17.140.50

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-66

November 2015

ICS 11.180.15; 17.140.50

Supersedes EN 60601-2-66:2013

English Version

Medical electrical equipment - Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems (IEC 60601-2-66:2015)

Appareils électromédicaux - Partie 2-66: Exigences particulières pour la sécurité de base et les performances essentielles des instruments d'audition et systèmes d'audition
(IEC 60601-2-66:2015)

Medizinische elektrische Geräte - Teil 2-66: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Hörgeräten und Hörgerätesystemen
(IEC 60601-2-66:2015)

This European Standard was approved by CENELEC on 2015-07-31. 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 60601-2-66:2015 E

European foreword

The text of document 29/851/FDIS, future edition 2 of IEC 60601-2-66, prepared by IEC/TC 29 "Electroacoustics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-66:2015.

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) 2016-05-27
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-07-31

This document supersedes EN 60601-2-66:2013.

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(s) see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 60601-2-66:2015 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 60118-4:2014	NOTE	Harmonized as EN 60118-4:2015 (not modified).
IEC 60318-5:2006	NOTE	Harmonized as EN 60318-5:2006 (not modified).
IEC 60601-1-4:1996	NOTE	Harmonized as EN 60601-1-4:1996 (not modified).
IEC 60601-1-9	NOTE	Harmonized as EN 60601-1-9.
IEC 60601-1-10	NOTE	Harmonized as EN 60601-1-10.
IEC 60645-1:2012	NOTE	Harmonized as EN 60645-1:2015 (not modified).
IEC 62489-1:2010	NOTE	Harmonized as EN 62489-1:2010 (not modified).
ISO 80000-8:2007	NOTE	Harmonized as EN ISO 80000-8:2007 (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.

Annex ZA of EN 60601-1:2006 applies except as follows:

Publication	Year	Title	EN/HD	Year
Replacement:				
IEC 60950-1 (mod)	2005	Information technology equipment - Safety - Part 1: General requirements	EN 60950-1 +AC	2006 2011
			+A11	2009
+A1 (mod)	2009		+A1	2010
			+A12	2011
+A2 (mod)	2013		+A2	2013
Addition:				
IEC 60118-0	2015	Electroacoustics - Hearing aids - Part 0: Measurement of the performance characteristics of hearing aids	EN 60118-0	2015
IEC 60118-13	-	Electroacoustics - Hearing aids - Part 13: Electromagnetic compatibility (EMC)	EN 60118-13	-
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1 + corr. March	2006 2010
+A1	2012		+A1 +A1/AC	2013 2014
			+A12	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
IEC 62304	-	Medical device software - Software life-cycle processes	EN 62304	-
IEC 62366	2007	Medical devices - Application of usability engineering to medical devices	EN 62366	2008

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 to provide a means of conforming to the Essential Requirements given in Annex I of the EU Directives 93/42/EEC as amended by 2007/47/EC.

General Guidance:

Once this standard will be cited in the Official Journal of the European Union under that Directive, compliance with the clauses of this standard given in Table ZZ.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements (ERs) of that Directive and associated EFTA regulations.

NOTE 1 This standard is intended to be applied in its entirety only. Selected clauses or subclauses may be not applicable due to the specific type of equipment under consideration. It is necessary to understand and apply Clauses 1 to 5. It is also recommended to understand and apply those clauses which contain general requirements related to a specific subclause. Elements of the standard that are not cited in Table ZZ.1 may be relevant for the appropriate fulfilment of certain essential requirements through indirect reference, and for safety and performance aspects of the device, that are not addressed through essential requirements.

NOTE 2 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance to the MDD (Directive 93/42/EEC amended by 2007/47/EC). This means that risks have to be reduced "as far as possible", "to a minimum", "to the lowest possible level", "minimized" or "removed", according to the wording of the corresponding essential requirement.

NOTE 3 With respect to Note 4 of 4.2.2 General requirement for risk management, the manufacturer's policy for determining **acceptable risk** must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the directive.

NOTE 4 References in the Clauses 3 to 17 or in the Annexes of this standard specify whether the normative references listed in Clause 2 as cited in Annex ZA are to be applied in whole or in part.

NOTE 5 This Annex ZZ is based on Normative References according to Annex ZA, replacing the references in the core text.

NOTE 6 According to the scope of this standard the coverage in Table ZZ.1 only applies to the design and construction of HEARING INSTRUMENTS or HEARING INSTRUMENT SYSTEMS. This European Standard lists in Table ZZ.1 only the essential requirements covered.

WARNING: Other requirements and other EU Directives and Regulations may be applicable to the product(s) falling within the scope of this standard.

Table ZZ.1 – Relationship between Essential Requirements of Directive 93/42/EEC amended by 2007/47/EC, and clauses and subclauses of this standard

No.	Essential Requirements	Coverage of EN 60601-2-66
I.	**GENERAL REQUIREMENTS**	
1	General Guidance note 2 and 3 shall be observed	
1	The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. This shall include:	The application of EN 60601-2-66 and the documents referenced in there (below referenced as “this document” or “this standard”) support a manufacturer to design HEARING INSTRUMENTS and HEARING INSTRUMENT SYSTEMS (below “devices”) in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, while accepting only risks associated with their intended use that constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. Details and exclusions supporting this general statement follow in order of the essential requirements below. Where the intended use of devices exceeds the scope of this document, the manufacturer may need to apply additional methods to achieve conformity to the essential requirements. Manufacturing aspects are not covered by this document! This statement applies to several essential requirements below but will not be repeated at each line, in order to provide for a better usability of this document.
	– reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and	The application of this document (201.7.1.1, 201.12.2 with reference to EN 62366) reduces, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used.

No.	Essential Requirements	Coverage of EN 60601-2-66
	– consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).	This document (201.7.9.1, 201.7.9.2.2) puts consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).
2	General Guidance note 2 and 3 shall be observed	
2	The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:	The requirements of this document for the design and construction of the devices conform to safety principles, taking account of the generally acknowledged state of the art at the time it has been released (2014). This document references EN ISO 14971, the application of which (4.3) does provide for the coverage of potential developments and new conclusions in hearing aid safety that became known after the release of this particular standard. The requirements of this document have been established by selecting the most appropriate solutions to the particular devices and their risks, by applying the following principles in the following order:
	– eliminate or reduce risks as far as possible (inherently safe design and construction),	
	– where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,	
	– inform users of the residual risks due to any shortcomings of the protection measures adopted.	
3	The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer.	The performance aspect (clinical evaluation) is not covered by this document unless basic safety is concerned. HEARING INSTRUMENTS do not have ESSENTIAL PERFORMANCE (201.4.3). If a manufacturer extends the intended use to safety critical functional claims, the resulting ESSENTIAL PERFORMANCE is not covered by application of this particular standard.