ELEKTRILISED MEDITSIINISEADMED. OSA 2-66: ERINÕUDED KUULDEAPARAATIDE JA KUULDESÜSTEEMIDE ESMASELE OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN IEC 60601-2-66:2020 sisaldab Euroopa standardi EN IEC 60601-2-66:2020 ingliskeelset teksti.	This Estonian standard EVS-EN IEC 60601-2-66:2020 consists of the English text of the European standard EN IEC 60601-2-66:2020.
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 03.04.2020.	Date of Availability of the European standard is 03.04.2020.
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 IEC 60601-2-66

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ICS 11.180.15; 17.140.50

Supersedes EN 60601-2-66:2015 and all of its amendments and corrigenda (if any)

English Version

Medical electrical equipment - Part 2-66: Particular requirements for the basic safety and essential performance of hearing aids and hearing aid systems (IEC 60601-2-66:2019)

Appareils électromédicaux - Partie 2-66: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de correction auditive et des systèmes de correction auditive (IEC 60601-2-66:2019)

Medizinische elektrische Geräte - Teil 2-66: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Hörgeräten und Hörgerätesystemen (IEC 60601-2-66:2019)

This European Standard was approved by CENELEC on 2020-02-19. 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.

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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.

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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 29/1023/FDIS, future edition 3 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 IEC 60601-2-66:2020.

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) 2020-11-19
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2023-02-19

This document supersedes EN 60601-2-66:2015 and all of its amendments and corrigenda (if any).

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.

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 60601-2-66:2019 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 60601-1-9	NOTE	Harmonized as EN 60601-1-9
IEC 60601-1-10	NOTE	Harmonized as EN 60601-1-10
IEC 60645-1:2017	NOTE	Harmonized as EN 60645-1:2017 (not modified)
IEC 61000-4-2	NOTE	Harmonized as EN 61000-4-2
IEC 61000-4-8	NOTE	Harmonized as EN 61000-4-8
IEC 62489-1:2010	NOTE	Harmonized as EN 62489-1:2010 (not modified)
IEC 62489-1:2010/A1:2014	NOTE	Harmonized as EN 62489-1:2010/A1:2015 (not modified)
IEC 62489-1:2010/A2:2017	NOTE	Harmonized as EN 62489-1:2010/A2:2018 (not modified)
IEC 62366-1:2015	NOTE	Harmonized as EN 62366-1:2015 (not modified)
CISPR 11	NOTE	Harmonized as EN 55011

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.

Clause 2 of the general standard applies except as follows:

Replacement:

Publication	Year	Title	EN/HD	Year
IEC 60950-1 (mod)	2005	Information technology equipment - Safety - Part 1: General requirements	EN 60950-1	2006
-	-		+ A11	2009
+ A1 (mod)	2009		+ A1	2010
-	-		+ A12	2011
+ A2 (mod)	2013		+ A2	2013
IEC 62368-1 (mod)	2014	Audio/video, information and communication technology equipment - Part 1: Safety requirements	EN 62368-1	2014
-	-		+ A11	2017

Addition:

Publication	Year	Title	EN/HD	Year
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	2019
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
+ A1	2012		+ A1	2013
-	-		+ A12	2014

Publication	Year	Title	EN/HD	Year
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	2015
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	2006
			+ A1	2015

Annex ZZ
(informative)

Coverage of Essential Requirements of EU Directives

This European standard has been prepared under a Commission's standardisation request M/023 and M432 concerning the development of European Standards related to medical devices 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 AIDS and HEARING AID 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

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	**Remarks/Notes**
1, second indent	201.7.9.1 201.7.9.2.1 201.7.9.2.2	This document (201.7.9.1, 201.7.9.2.1, 201.7.9.2.2) covers requirements related to instructions for use, including safety warnings and notices by considering 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).
5	201.7.2.17 201.7.9.2.2 201.15.3 201.15.3.7	Covered by requirements to design and packaging (201.7.2.17) to withstand transport and storage with regards of mechanical strength (201.15.3), resistance to environmental conditions (201.15.3.7) and the necessary instructions (201.7.9.2.2).
6	201.7.9.2.1 201.9.6	The reduction of unintentional exposure to excessive acoustic noise is covered in 201.9.6 regarding the design. 201.7.9.2.1 covers information and instructions for the user related to side effects.
7.1, first indent	201.11.1.1 201.13.1.2	Covered for risks of fire and high temperatures.
7.3	201.11.6.6 201.15.3.7	This document covers (201.15.3.7, 201.11.6.6) the design of devices in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures. Requirements for HEARING AIDS that are intended to be used in explosive and oxygenenriched atmospheres are not contained in this standard (see 201.11.2).
7.5, first sentence of first paragraph only	201.7.9.2.4	Covered for the risk of leakage from the battery in situ.
7.6	201.11.6.5	Covered in 201.11.6.5.
8.1, first sentence only	201.7.9.2.12 201.11.6.6 201.12.2	Design covered in 201.12.2, 201.11.6.6 and instruction covered in 201.7.9.2.12.
9.1	201.5.5 c) 201.6.2 201.7.9.2.5 201.7.9.2.9 201.8.1 201.8.2.1 201.8.4.2	

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	**Remarks/Notes**
9.2, first indent	201.9	Mechanical risks (e.g. 'entanglement') are covered by 201.9.
9.2, second indent	201.5.3 201.5.7 201.7.2.17 201.7.9.2.1 201.7.9.2.2 201.15.3.7	Covered in respect of environmental temperatures, humidity or variations in pressure: 201.5.3, 201.5.7, 201.7.2.17, 201.7.9.2.1, 201.7.9.2.2, 201.15.3.7 of this document provide design and test requirements with regards to climatic environmental conditions which are suitable to remove or minimize as far as possible these risks.
9.2, third indent	201.7.9.2.2 201.17	To fully cover this ER, risks must be removed or minimised as far as possible.
9.2, fourth indent	201.15.2	Covered for the serviceability of hearing aids subject to mechanical wear, electrical degradation or ageing.
9.3	201.11.1.1 201.13.1.2	Risks of fire and high temperatures covered in 201.11.1.1, 201.13.1.2. HEARING AIDS are normally not exposed to flammable substances or to substances which could cause combustion. The requirements for HEARING AIDS that are intended to be used in explosive and oxygenenriched atmospheres are not covered in this document.
12.5	201.17	To fully cover this ER, risks must be removed or minimised as far as possible.
12.6	201.8 201.13	Electrical risks covered in 201.8 for normal conditions and 201.13 in fault conditions.
12.7.1	201.15.3.1	Covered by the mechanical requirements in 201.15.3.1.
12.7.3	201.7 201.9.6 201.13.1.2	The reduction of unintentional exposure to excessive acoustic noise is covered in 201.9.6 regarding the design, in 201.7 regarding correct application 201.13.1.2 in case of faults.
12.7.4	201.8.1 201.8.2.1 201.8.7 201.16	Covered in respect of the following: Electrical Risks: 201.8.1 Fundamental rule of protection against electric shock 201.8.2.1 Connection to power sources 201.16 Limitation of voltage current or energy 201.8.7 Leakage current. Gas or hydraulic and pneumatic energy supplies not applicable to HEARING AIDS.
12.7.5	201.11.1	Covered by 201.11.1 Excessive temperatures

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	**Remarks/Notes**
12.8.1	201.9.6 201.12.4.4	Requirements of sufficient accurate indication of output is covered in 201.9.6. 201.12.4.4 covers possible sources of incorrect output.
12.8.2	201.9.6	The reduction of unintentional exposure to excessive acoustic noise is covered in 201.9.6
12.9	201.7.9.1 201.7.9.2.1 201.7.9.2.9	Requirements to specification of function of controls and indicators on the device or in the instructions for use are covered in 201.7.9.2.1 and 201.7.9.2.9.
13.1 – first and second paragraph	201.7.9.2 201.7.9.2.16	Covered in respect of the following: 201.7.9.2 Instructions for use. 201.7.9.2.16 Technical description, provided that the technical description is included in the instructions for use.
13.1 - first and third paragraph	201.7.2.2 201.7.2.17 201.7.9.2	Covered in respect of information on the packaging in 201.7.2.17. Covered in respect of information in the instruction for use in 201.7.9.2.
13.1 - first and fourth paragraph	201.7.9.2	Requirements for instruction for use covered in 201.7.9.2.
13.2	201.7.8.1 201.7.9.2.9	Description of symbols in the documentation covered in 201.7.9.2.9. Description of colours in the documentation covered in 201.7.8.1.
13.3 a)	201.7.2.2	To fully cover this ER, the name and address of the authorised representative must be provided, if applicable.
13.3 d)	201.7.2.2	To fully cover this ER the batch number (if provided) must be preceded by the symbol LOT.
13.3 i)	201.7.2.17	
13.3 j)	201.7.2	
13.3 l)	201.7.2.2	
13.4	201.7.9.1	Covered for the Instructions for Use.
13.5	201.7.2.2	Serial number required in 201.7.2.2.

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	**Remarks/Notes**
13.6 b)	201.7.9.3	Covered provided the technical description is included in the instructions for use.
13.6 d)	201.7.9.2.1 201.7.9.2.12	
13.6 k)	201.7.9.2.1	
13.6 l)	201.7.9.2.1	

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-66: Particular requirements for the basic safety and essential performance of hearing aids and hearing aid systems

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International Standard IEC 60601-2-66 has been prepared by IEC technical committee 29: Electroacoustics.

This third edition cancels and replaces the second edition published in 2015. It constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) revision of the definition about ESSENTIAL PERFORMANCE;
b) revision of the application of IEC 60601-1-2:2014 for electromagnetic disturbances;
c) correction of the used voltage for HEARING AIDS from 1,6 V to 4,5 V;
d) correction of the drop test level from 1,5 m to 1,0 m;
e) correction of the wording of IEC 60601-2-66:2015.