SLOVENSKI STANDARD
SIST EN IEC 60118-0:2024

01-julij-2024

Elektroakustika - Slušni aparati - 0. del: Meritve tehničnih karakteristik slušnih aparatov (IEC 60118-0:2022)

Electroacoustics - Hearing aids - Part 0: Measurement of the performance characteristics of hearing aids (IEC 60118-0:2022)

Akustik - Hörgeräte - Teil 0: Messung der Leistungsmerkmale von Hörgeräten (IEC 60118-0:2022)

Electroacoustique - Appareils de correction auditive - Partie 0: Mesure des caractéristiques fonctionnelles des appareils de correction auditive (IEC 60118-0:2022)

Ta slovenski standard je istoveten z: **EN IEC 60118-0:2024**

ICS:

11.180.15	Pripomočki za gluhe osebe in osebe z okvaro sluha	Aids for deaf and hearing impaired people
17.140.50	Elektroakustika	Electroacoustics

SIST EN IEC 60118-0:2024 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 60118-0

May 2024

ICS 17.140.50

Supersedes EN 60118-0:2015

English Version

Electroacoustics - Hearing aids - Part 0: Measurement of the performance characteristics of hearing aids (IEC 60118-0:2022)

Électroacoustique - Appareils de correction auditive - Partie 0: Mesure des caractéristiques fonctionnelles des appareils de correction auditive (IEC 60118-0:2022)

Akustik - Hörgeräte - Teil 0: Messung der Leistungsmerkmale von Hörgeräten (IEC 60118-0:2022)

This European Standard was approved by CENELEC on 2022-10-04. 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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

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

Ref. No. EN IEC 60118-0:2024 E

European foreword

The text of document 29/1126/FDIS, future edition 4 of IEC 60118-0, prepared by IEC/TC 29 "Electroacoustics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60118-0:2024.

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) 2024-11-10
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2027-05-10

This document supersedes EN 60118-0:2015 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 standardization request addressed to CENELEC by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

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

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice

The text of the International Standard IEC 60118-0:2022 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 standard indicated:

IEC 60068 (series)	NOTE	Approved as EN 60068 (series)
IEC 60118-7:2005	NOTE	Approved as EN 60118-7:2005 (not modified)
IEC 60118-8:2005	NOTE	Approved as EN 60118-8:2005 (not modified)
IEC 60118-15	NOTE	Approved as EN 60118-15
IEC 61094-8:2012	NOTE	Approved as EN 61094-8:2012 (not modified)

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.cencenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC 60118-12	-	Hearing aids – Part 12: Dimensions of electrical connector systems	EN 60118-12	1996
IEC 60318-4	2010	Electroacoustics – Simulators of human head and ear – Part 4: Occluded-ear simulator for the measurement of earphones coupled to the ear by means of ear inserts	EN 60318-4	2010
IEC 60318-5	-	Electroacoustics – Simulators of human head and ear – Part 5: 2 cm3 coupler for the measurement of hearing aids and earphones coupled to the ear by means of ear inserts	EN 60318-5	2006
IEC 60318-8	-	Electroacoustics – Simulators of human head and ear – Part 8: Acoustic coupler for high-frequency measurements of hearing aids and earphones coupled to the ear by means of ear inserts	EN 60318-8	2022
IEC 60268-2	1987	Sound system equipment – Part 2: Explanation of general terms and calculation methods	-	-
+ AMD 1	1991		-	-
IEC 60263	-	Scales and sizes for plotting frequency characteristics and polar diagrams	EN IEC 60263	2020
IEC 61094-4	-	Measurement microphones – Part 4: Specifications for working standard microphones	EN 61094-4	1995
ISO 3	1973	Preferred numbers – Series of preferred numbers		

Annex ZZ
(informative)

Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up.

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative 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 General Safety and Performance Requirements of that Regulation, and associated EFTA Regulations.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall be indicated in this Annex Z. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the European Regulation for medical devices (EU) 2017/745).

NOTE 1 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 with Regulation (EU) 2017/745. This means that risks have to be ‘reduced as far as possible’, ‘reduced to the lowest possible level’, ‘reduced as far as possible and appropriate’, ‘removed or reduced as far as possible’, ‘eliminated or reduced as far as possible’, ’removed or minimized as far as possible’, or ‘minimized’, according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer’s policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in Table ZZ.1, it means that it is not addressed by this European Standard.

Table ZZ.1 — Correspondence between this European standard and Annex I of Regulation (EU) 2017/745 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
1	Clauses 7, 8, 9, 10	Coverage is limited to electro-acoustic performance measurements and measurement of the safety relevant maximum acoustic output of hearing aids. It should be noted, the measurement results obtained by the methods specified in this document will express the performance under conditions of the measurement and can deviate substantially from the performance of the hearing aid under actual conditions of use.
10.1. (h)	Clause 10	Covers measurement procedures for the electro-acoustical parameters of hearing aids
14.2. (a)	Clause 10.4	Covers the measurement and specification of the safety relevant maximum output sound pressure level of a hearing aid; The risk of hearing damage, if measurement exceeds specified measurement uncertainty limits and/or tolerances, is mitigated by process control, such as training, regular maintenance and calibration of equipment.

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 product(s) falling within the scope of this standard.

IEC 60118-0

Edition 4.0 2022-08

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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INTERNATIONAL
ELECTROTECHNICAL
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COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 17.140.50

ISBN 978-2-8322-5591-9

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