ELEKTROAKUSTIKA. KUULDEAPARAADID. OSA 13: NÕUDED JA MEETODID MOBIILSETE TRAADITA DIGITAALSEADMETE ELEKTROMAGNETILISE HÄIRINGUKINDLUSE MÕÕTMISEKS

Electroacoustics - Hearing aids - Part 13: Requirements and methods of measurement for electromagnetic immunity to mobile digital wireless devices



EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

| See Eesti standard EVS-EN IEC 60118-13:2020 sisaldab Euroopa standardi EN IEC 60118-13:2020 ingliskeelset teksti. | This Estonian standard EVS-EN IEC 60118-13:2020 consists of the English text of the European standard EN IEC 60118-13:2020. |
|---|--|
| 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. |

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ICS 17.140.50, 33.100.20

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EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

EN IEC 60118-13

April 2020

ICS 17.140.50; 33.100.20

Supersedes EN 60118-13:2011 and all of its amendments and corrigenda (if any)

English Version

Electroacoustics - Hearing aids - Part 13: Requirements and methods of measurement for electromagnetic immunity to mobile digital wireless devices (IEC 60118-13:2019)

Électroacoustique - Appareils de correction auditive - Partie 13: Exigences et méthodes de mesure de l'immunité électromagnétique aux appareils numériques mobiles sans fil (IEC 60118-13:2019) Elektroakustik - Hörgeräte - Teil 13: Elektromagnetische Verträglichkeit (EMV), Störfestigkeit gegen digitale Mobilfunkgeräte (IEC 60118-13:2019)

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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 29/1024/FDIS, future edition 5 of IEC 60118-13, prepared by IEC/TC 29 "Electroacoustics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60118-13:2020.

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- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2023-02-19

This document supersedes EN 60118-13:2011 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 60118-13:2019 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 | NOTE | Harmonized as EN 60118-4 |
|----------------|------|-----------------------------|
| IEC 60118-7 | NOTE | Harmonized as EN 60118-7 |
| IEC 60118-15 | NOTE | Harmonized as EN 60118-15 |
| IEC 60601-1-2 | NOTE | Harmonized as EN 60601-1-2 |
| IEC 61000-4-2 | NOTE | Harmonized as EN 61000-4-2 |
| IEC 61000-4-8 | NOTE | Harmonized as EN 61000-4-8 |
| IEC 60601-2-66 | NOTE | Harmonized as EN 60601-2-66 |
| CISPR 11 | NOTE | Harmonized as EN 55011 |
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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.

| Publication | Year | <u>Title</u> | 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 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 61000-4-3 | | Electromagnetic compatibility (EMC) - | EN 61000-4-3 | 2006 |
| | | Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, | + A1 | 2008 |
| | | electromagnetic field immunity test | + A2 | 2010 |
| IEC 61000-4-20 | | Electromagnetic compatibility (EMC) - Part 4-20: Testing and measurement techniques - Emission and immunity testing in transverse electromagnetic (TEM) waveguides | | |
| | | | | 5 |

Annex ZZ

(informative)

Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [1993 OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request M/023 concerning the development of European Standards related to medical devices to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [1993 OJ L 160].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive and associated EFTA regulations.

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 Directive 93/42/EEC as 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 2 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 3 This Annex ZZ is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential 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 Directive 93/42/EEC [1993 OJ L 169]

| Essential Requirements of Directive 93/42/EEC | Clause(s)/sub-clause(s) of this EN | Remarks/Notes |
|---|---------------------------------------|---|
| 3 | 5, 6 | These clauses specify requirements and test methods to verify the immunity of the device to radiated electromagnetic fields from mobile phones. Design manufacturing and packaging are not covered. |
| 9.1, first sentence only | 5 | Covered for the use of a hearing aid in combination with a mobile phone with regards to radiated electromagnetic fields. |
| 9.2, second indent | 5 | Covered with regards to immunity to radiated electromagnetic fields from mobile phones. |

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.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

ELECTROACOUSTICS -HEARING AIDS -

Part 13: Requirements and methods of measurement for electromagnetic immunity to mobile digital wireless devices

FOREWORD

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International Standard IEC 60118-13 has been prepared by IEC technical committee 29: Electroacoustics.

This fifth edition cancels and replaces the fourth edition published in 2016 and constitutes a technical revision.

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

- a) it introduces a new measurement method and set of EMC requirements for hearing aids immunity to mobile digital wireless devices;
- b) generic EMC requirements for hearing aids are no longer included should be covered by other standards as appropriate.

The text of this International Standard is based on the following documents:

| FDIS | Report on voting |
|--------------|------------------|
| 29/1024/FDIS | 29/1031/RVD |

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

A list of all parts in the IEC 60118 series, published under the general title *Electroacoustics* – *Hearing aids*, can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- · replaced by a revised edition, or
- amended.

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