SLOVENSKI STANDARD
oSIST prEN IEC 60601-2-66:2026

01-marec-2026

Medicinska električna oprema - 2-66. del: Posebne zahteve za osnovno varnost in bistvene lastnosti slušnih pripomočkov in sistemov

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

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

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

Ta slovenski standard je istoveten z: **prEN IEC 60601-2-66:2026**

ICS:

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

oSIST prEN IEC 60601-2-66:2026 **en**

29/1227/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER:	
IEC 60601-2-66 ED4	
DATE OF CIRCULATION:	CLOSING DATE FOR VOTING:
2026-01-16	**2026-04-10**
SUPERSEDES DOCUMENTS:	
29/1203A/CD, 29/1208A/CC	

IEC TC 29 : ELECTROACOUSTICS	
SECRETARIAT:	SECRETARY:
Denmark	Ms Lise Aagesen
OF INTEREST TO THE FOLLOWING COMMITTEES:	HORIZONTAL FUNCTION(S):
ASPECTS CONCERNED:	
☒ SUBMITTED FOR CENELEC PARALLEL VOTING	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING
Attention IEC-CENELEC parallel voting The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting. The CENELEC members are invited to vote through the CENELEC online voting system.	

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Recipients of this document are invited to submit, with their comments, notification of any relevant "In Some Countries" clauses to be included should this proposal proceed. Recipients are reminded that the CDV stage is the final stage for submitting ISC clauses. (SEE AC/22/2007 OR NEW GUIDANCE DOC).

TITLE:

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

PROPOSED STABILITY DATE: 2028

NOTE FROM TC/SC OFFICERS:

At its meeting in September 2025 in New Delhi, TC 29 took the following decision, doc. 29/1219/DL refers:

DECISION 8

TC 29 decides to proceed with 3CD 60601-2-66 "Medical electrical equipment – Part 2-66: Particular requirements for the basic safety and essential performance of hearing aids and hearing aid systems" as a CDV with the following target dates:

CDV: 2026-01-31

FDIS: 2026-12-31

Publication: 2027-03-31.

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