SLOVENSKI STANDARD
oSIST prEN IEC 60601-2-36:2026

01-september-2026

Medicinska električna oprema - 2-36. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme za zunajtelesno litotripsijo

Medical electrical equipment - Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy

Medizinische elektrische Geräte - Teil 2-36: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Geräten zur extrakorporal induzierten Lithotripsie

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Appareils électromédicaux - Partie 2-36: Exigences particulières pour la sécurité de base et les performances essentielles des appareils pour lithotritie créée de façon extracorporelle

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Ta slovenski standard je istoveten z: **prEN IEC 60601-2-36:2026**

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general

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62D/2311/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 60601-2-36 ED3**	
DATE OF CIRCULATION: **2026-07-10**	CLOSING DATE FOR VOTING: **2026-10-02**
SUPERSEDES DOCUMENTS: **62D/2240/CD, 62D/2266A/CC**	

IEC SC 62D : PARTICULAR MEDICAL EQUIPMENT, SOFTWARE, AND SYSTEMS	
SECRETARIAT: United States of America	SECRETARY: Ms Ladan Bulookbashi
OF INTEREST TO THE FOLLOWING COMMITTEES: TC 87	HORIZONTAL FUNCTION(S):
ASPECTS CONCERNED: Electromagnetic Compatibility,Safety	
☒ 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.

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TITLE:

Medical electrical equipment - Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy

PROPOSED STABILITY DATE: 2030

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-36: Particular requirements for the basic safety and essential performance of therapy equipment for extracorporeally induced focused pressure pulses

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International standard IEC 60601-2-36 has been prepared by IEC subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems.

This third edition cancels and replaces the second edition of IEC 60601-2-36 published in 2014. This edition constitutes a technical revision to align structurally with IEC 60601-1:2005 and its Amendment 1:2012 and Amendment 2:2020.

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The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/xxxx/FDIS	62D/xxxx/RVD

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

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

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

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The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

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An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

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