SLOVENSKI STANDARD
SIST EN IEC 60601-2-91:2026

01-oktober-2026

Medicinska električna oprema - 2-91. del: Posebne zahteve za osnovno varnost in bistveno delovanje opreme za zdravljenje ran z netermično plazmo (IEC 60601-2-91:2026)

Medical electrical equipment - Part 2-91: Particular requirements for basic safety and essential performance of non-thermal plasma wound treatment equipment (IEC 60601-2-91:2026)

Besondere Festlegungen für die grundlegende Sicherheit und die wesentlichen Leistungsmerkmale von Geräten zur nichtthermischen Plasmawundbehandlung (IEC 60601-2-91:2026)

Exigences particulières pour la sécurité de base et les performances essentielles des appareils de traitement des plaies par plasma non thermique (IEC 60601-2-91:2026)

Ta slovenski standard je istoveten z: **EN IEC 60601-2-91:2026**

ICS:

11.040.99	Druga medicinska oprema	Other medical equipment

SIST EN IEC 60601-2-91:2026 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 60601-2-91

August 2026

ICS 11.040.99; 11.140

English Version

Medical electrical equipment - Part 2-91: Particular requirements for basic safety and essential performance of non-thermal plasma wound treatment equipment (IEC 60601-2-91:2026)

Appareils électromédicaux - Partie 2-91: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de traitement des plaies par plasma non thermique
(IEC 60601-2-91:2026)

Medizinische elektrische Geräte - Teil 2-91: Besondere Festlegungen für die grundlegende Sicherheit und die wesentlichen Leistungsmerkmale von Geräten zur nichtthermischen Plasmawundbehandlung
(IEC 60601-2-91:2026)

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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

Ref. No. EN IEC 60601-2-91:2026 E

European foreword

The text of document 62D/2297/FDIS, future edition 1 of IEC 60601-2-91, prepared by SC 62D "Particular medical equipment, software, and systems" of IEC/TC 62 "Medical equipment, software, and systems" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60601-2-91:2026.

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) 2027-08-31
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In the official version, for Bibliography, the following notes have to be added for the standard indicated:

IEC 60601-2-2:2017	NOTE	Approved as EN IEC 60601-2-2:2018 (not modified)
IEC 60601-2-2:2017/AMD1:2023	NOTE	Approved as EN IEC 60601-2-2:2018/A1:2024 (not modified)
IEC 60601-2-76:2018	NOTE	Approved as EN IEC 60601-2-76:2019 (not modified)
IEC 60601-1-3	NOTE	Approved as EN 60601-1-3
IEC 60601-1-10	NOTE	Approved as EN 60601-1-10
ISO 14971:2019	NOTE	Approved as EN ISO 14971:2019 (not modified) + A11:2021

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 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
-	-		+ A12	2014
+ A2	2020		+ A2	2021
-	-		+ A13	2024

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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Medical electrical equipment - Part 2-91: Particular requirements for basic safety and essential performance of non-thermal plasma wound treatment equipment

FOREWORD

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IEC 60601-2-91 has been prepared by subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

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

Draft	Report on voting
62D/2297/FDIS	62D/2314/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.