SLOVENSKI STANDARD
SIST EN IEC 60601-2-46:2024

01-november-2024

Medicinska električna oprema - 2-46. del: Posebne zahteve za osnovno varnost in bistvene lastnosti operacijskih miz (IEC 60601-2-46:2023)

Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables (IEC 60601-2-46:2023)

Medizinische elektrische Geräte - Teil 2-46: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Operationstischen (IEC 60601-2-46:2023)

Appareils électromédicaux - Partie 2-46: Exigences particulières pour la sécurité de base et les performances essentielles des tables d'opération (IEC 60601-2-46:2023)

Ta slovenski standard je istoveten z: **EN IEC 60601-2-46:2024**

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EUROPEAN STANDARD

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English Version

Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables (IEC 60601-2-46:2023)

Appareils électromédicaux - Partie 2-46: Exigences particulières pour la sécurité de base et les performances essentielles des tables d'opération (IEC 60601-2-46:2023)

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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 62D/1939/CDV, future edition 4 of IEC 60601-2-46, 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 60601-2-46:2024.

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)	2025-05-01
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2027-07-31

This document supersedes EN IEC 60601-2-46:2019 and all of its amendments and corrigenda (if any).

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Endorsement notice

The text of the International Standard IEC 60601-2-46:2023 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 60601-1-8:2006	NOTE	Approved as EN 60601-1-8:2007 (not modified) +A11:2017
IEC 60601-1-8:2006/A1:2012	NOTE	Approved as EN 60601-1-8:2007/A1:2013 (not modified)
IEC 60601-1-8:2006/A2:2020	NOTE	Approved as EN 60601-1-8:2007/A2:2021 (not modified)
IEC 60601-1-9:2007	NOTE	Approved as EN 60601-1-9:2008 (not modified)
IEC 60601-1-9:2007/A1:2013	NOTE	Approved as EN 60601-1-9:2008/A1:2013 (not modified)
IEC 60601-1-9:2007/A2:2020	NOTE	Approved as EN 60601-1-9:2008/A2:2020 (not modified)
IEC 60601-1-10:2007	NOTE	Approved as EN 60601-1-10:2008 (not modified)
IEC 60601-1-10:2007/A1:2013	NOTE	Approved as EN 60601-1-10:2008/A1:2015 (not modified)
IEC 60601-1-10:2007/A2:2020	NOTE	Approved as EN 60601-1-10:2008/A2:2021 (not modified)
IEC 60601-1-11:2015	NOTE	Approved as EN 60601-1-11:2015 (not modified)
IEC 60601-1-11:2015/A1:2020	NOTE	Approved as EN 60601-1-11:2015/A1:2021 (not modified)
IEC 60601-1-12:2014	NOTE	Approved as EN 60601-1-12:2015 (not modified)

IEC 60601-1-12:2014/A1:2020	NOTE	Approved as EN 60601-1-12:2015/A1:2020 (not modified)
IEC 60601-2-35:2020	NOTE	Approved as EN IEC 60601-2-35:2021 (not modified)
IEC 60601-2-52:2009/A1:2015	NOTE	Approved as EN 60601-2-52:2010/A1:2015 (not modified)
IEC 62366-1:2015	NOTE	Approved as EN 62366-1:2015 (not modified)
IEC 62366-1:2015/A1:2020	NOTE	Approved as EN 62366-1:2015/A1:2020 (not modified)
ISO 7494-1:2018	NOTE	Approved as EN ISO 7494-1:2018 (not modified)
ISO 20342-1:2022	NOTE	Approved as EN ISO 20342-1:2022 (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.

Annex ZA of EN 60601-1:2006[1]*, applies, except as follows:*

Replace:

Publication	Year	Title	EN/HD	Year
IEC 60601-1-3	2008	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment	EN 60601-1-3	2008
-	-		+ AC	2010
+ A1	2013		+ A1	2013
-	-		+ AC	2014
-	-		+ A11	2016
+ A2	2021		+ A2	2021
ISO 2878	2017	Rubber, vulcanized or thermoplastic - Antistatic and conductive products - Determination of electrical resistance	-	-

[1] As impacted by EN 60601-1:2006/AC:2010, EN 60601-1:2006/A1:2013, EN 60601-1:2006/A1:2013/AC:2014, EN 60601-1:2006/A12:2014, EN 60601-1:2006/A2:2021, EN 60601-1:2006/AC:2022-12 and EN 60601-1:2006/A13:2024.

Add:

Publication	Year	Title	EN/HD	Year
IEC 60601-2-2	2017	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	EN IEC 60601-2-2	2018
IEC 60601-2-43	2022	Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures	EN IEC 60601-2-43	2023
IEC 60601-2-54	2022	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	EN IEC 60601-2-54	2024

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-46: Particular requirements for the basic safety and essential performance of operating tables

Appareils électromédicaux –
Partie 2-46: Exigences particulières pour la sécurité de base et les performances essentielles des tables d'opération

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-46: Particular requirements for the basic safety and essential performance of operating tables

FOREWORD

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IEC 60601-2-46 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.

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

This edition includes the following significant technical change with respect to the previous edition: structural alignment with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.