



SLOVENSKI STANDARD
SIST EN IEC 80601-2-77:2021/A1:2024

01-februar-2024

Medicinska električna oprema - 2-77. del: Posebne zahteve za osnovno varnost in bistvene lastnosti robotsko podprte kirurške opreme - Dopolnilo A1 (IEC 80601-2-77:2019/AMD1:2023)

Medical electrical equipment - Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment (IEC 80601-2-77:2019/AMD1:2023)

Medizinische elektrische Geräte - Teil 2-77: Besondere Festlegungen an die Sicherheit, einschließlich der wesentlichen Leistungsmerkmale von durch Roboter unterstützte Chirurgiegeräte (IEC 80601-2-77:2019/AMD1:2023)

Appareils électromédicaux - Partie 2-77: Exigences particulières pour la sécurité de base et les performances essentielles des appareils chirurgicaux robotiquement assistés (IEC 80601-2-77:2019/AMD1:2023)

Ta slovenski standard je istoveten z: EN IEC 80601-2-77:2021/A1:2023

ICS:

11.040.30	Operacijski instrumenti in materiali	Surgical instruments and materials
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SIST EN IEC 80601-2-77:2021/A1:2024 en

EUROPEAN STANDARD

EN IEC 80601-2-77:2021/A1

NORME EUROPÉENNE

EUROPÄISCHE NORM

December 2023

ICS 11.040.01; 11.040.30

English Version

**Medical electrical equipment - Part 2-77: Particular requirements
for the basic safety and essential performance of robotically
assisted surgical equipment
(IEC 80601-2-77:2019/AMD1:2023)**

Appareils électromédicaux - Partie 2-77: Exigences
particulières pour la sécurité de base et les performances
essentiels des appareils chirurgicaux robotiquement
assistés
(IEC 80601-2-77:2019/AMD1:2023)

Medizinische elektrische Geräte - Teil 2-77: Besondere
Festlegungen an die Sicherheit, einschließlich der
wesentlichen Leistungsmerkmale von durch Roboter
unterstützte Chirurgiegeräte
(IEC 80601-2-77:2019/AMD1:2023)

This amendment A1 modifies the European Standard EN IEC 80601-2-77:2021; it was approved by CENELEC on 2023-12-20. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This amendment exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.



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

EN IEC 80601-2-77:2021/A1:2023 (E)

European foreword

The text of document 62D/2070/FDIS, future IEC 80601-2-77/AMD1, prepared by SC 62D "Electromedical equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 80601-2-77:2021/A1:2023.

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) 2024-09-20
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2026-12-20

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.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice

The text of the International Standard IEC 80601-2-77:2019/AMD1:2023 was approved by CENELEC as a European Standard without any modification.

Document Preview

[SIST EN IEC 80601-2-77:2021/A1:2024](https://standards.iteh.ai/catalog/standards/sist/8c0fa8df-2a70-463f-af99-95a9cc693624/sist-en-iec-80601-2-77-2021-a1-2023)

<https://standards.iteh.ai/catalog/standards/sist/8c0fa8df-2a70-463f-af99-95a9cc693624/sist-en-iec-80601-2-77-2021-a1-2023>

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.

The Annex ZA of EN IEC 80601-2-77:2021 applies with the following changes:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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Replace the following references:

IEC 60601-1-2	2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	EN 60601-1-2	2015
+ A1	2020		+ A1	2021
IEC 60601-1-6	2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6	2010
+ A1	2013		+ A1	2015
+ A2	2020		+ A2	2021
IEC 62366-1	2015	Medical devices - Part 1: Application of usability engineering to medical devices	EN 62366-1	2015
-	-		+ AC	2015
+ A1	2020		+ A1	2020

Add the following references:

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

