SLOVENSKI STANDARD
SIST EN IEC 60601-2-16:2025

01-april-2025

Medicinska električna oprema - 2-16. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme za hemodializo, hemodiafiltracijo in hemofiltracijo (IEC 60601-2-16:2025)

Medical electrical equipment - Part 2-16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment (IEC 60601-2-16:2025)

Medizinische elektrische Geräte - Teil 2-16: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Hämodialyse-, Hämodiafiltrations- und Hämofiltrationsgeräten (IEC 60601-2-16:2025)

Appareils électromédicaux - Partie 2-16: Exigences particulières pour la sécurité de base et les performances essentielles des appareils d'hémodialyse, d'hémodiafiltration et d'hémofiltration (IEC 60601-2-16:2025)

Ta slovenski standard je istoveten z: **EN IEC 60601-2-16:2025**

ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment

SIST EN IEC 60601-2-16:2025 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 60601-2-16

February 2025

ICS 11.040.20; 11.040.25

Supersedes EN IEC 60601-2-16:2019

English Version

Medical electrical equipment - Part 2-16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment (IEC 60601-2-16:2025)

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Medizinische elektrische Geräte - Teil 2-16: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Hämodialyse-, Hämodiafiltrations- und Hämofiltrationsgeräten (IEC 60601-2-16:2025)

This European Standard was approved by CENELEC on 2025-02-10. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard 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 European Standard 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

European foreword

The text of document 62D/2163/FDIS, future edition 6 of IEC 60601-2-16, 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 60601-2-16:2025.

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) 2026-02-28
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2028-02-29

This document supersedes EN IEC 60601-2-16:2019 and all of its amendments and corrigenda (if any).

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 60601-2-16:2025 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:

ISO 8637-2:2024	NOTE	Approved as EN ISO 8637-2:2024 (not modified)
ISO 23500-4:2024	NOTE	Approved as EN ISO 23500-4:2024 (not modified)
IEC 60601-2-39:2018	NOTE	Approved as EN IEC 60601-2-39:2019 (not modified)
ISO 23500-1:2024	NOTE	Approved as EN ISO 23500-1:2024 (not modified)
ISO 23500-5:2024	NOTE	Approved as EN ISO 23500-5:2024 (not modified)
IEC 80001-1:2021	NOTE	Approved as EN IEC 80001-1:2021 (not modified)
ISO 80369-1:2018	NOTE	Approved as EN ISO 80369-1:2018 (not modified)
ISO 11197:2019	NOTE	Approved as EN ISO 11197:2019 (not modified)
ISO 17664-1:2021	NOTE	Approved as EN ISO 17664-1:2021 (not modified)
ISO 15883 series	NOTE	Approved as EN ISO 15883 series
IEC 60601-2-24:2012	NOTE	Approved as EN 60601-2-24:2015 (not modified)
ISO 17664-2:2021	NOTE	Approved as EN ISO 17664-2:2023 (not modified)

ISO 14971:2019	NOTE	Approved as EN ISO 14971:2019 (not modified) +A11:2021
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 62366-1:2015	NOTE	Approved as EN 62366-1:2015 (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:

Add:

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
-	-		+ AC	2010
+ A1	2012		+ A1	2013
-	-		+ AC	2014
-	-		+ A12	2014
+ A2	2020		+ A2	2021
-	-		+ AC	2022
-	-		+ A13	2024
IEC 60601-1-10	2007	Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers	EN 60601-1-10	2008
+ A1	2013		+ A1	2015
+ A2	2020		+ A2	2021

[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.

Publication	Year	Title	EN/HD	Year
IEC 60601-1-11	2015	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	EN 60601-1-11	2015
+ A1	2020		+ A1	2021
IEC 61672-1	2013	Electroacoustics - Sound level meters - Part 1: Specifications	EN 61672-1	2013
ISO 3744	2010	Acoustics - Determination of sound power levels and sound energy levels of noise sources using sound pressure - Engineering methods for an essentially free field over a reflecting plane	EN ISO 3744	2010
ISO 23500-3	2024	Preparation and quality management of fluids for haemodialysis and related therapies – Part 3: Water for haemodialysis and related therapies	EN ISO 23500-3	2024

IEC 60601-2-16

Edition 6.0 2025-01

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

Medical electrical equipment –
Part 2-16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.20; 11.040.25

ISBN 978-2-8327-0088-4

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as “IEC Publication(s)”). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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IEC 60601-2-16 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 sixth edition cancels and replaces the fifth edition published in 2018. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) update of references to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, of references to IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, of references to IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, of references to IEC 60601-1-9:2007, IEC 60601-1-9:2007/AMD1:2013 and IEC 60601-1-9:2007/AMD2:2020, of references to IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020 and of references to IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020;

b) consideration of ESSENTIAL PERFORMANCE in SINGLE FAULT CONDITION regarding IEC 60601-1:2005/AMD1:2012/ISH1:2021;

c) including the information given in the document 62D/1771A/INF regarding 201.11.8;

d) including withdrawn IEC PAS 63023[17] as Annex CC;

e) including SECURITY (CYBERSECURITY) requirements;

f) consideration of HAEMODIALYSIS EQUIPMENT using pre-manufactured DIALYSIS FLUID bags;

g) improvements for labelling;

h) other minor technical improvements;

i) editorial improvements.

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

Draft	Report on voting
62D/2163/FDIS	62D/2184/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.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

In this document, 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 AND IEC 60601-1:2005/AMD2:2020, IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

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

– "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this document are by number only.

In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

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.

A list of all parts of the IEC 60601 and IEC 80601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

NOTE The attention of the users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committees that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

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