SLOVENSKI STANDARD
SIST EN IEC 80601-2-58:2024

01-november-2024

Medicinska električna oprema - 2-58. del: Posebne zahteve za osnovno varnost in bistvene lastnosti naprav za odstranjevanje leč in naprav za vitrektomijo pri očesni kirurgiji (IEC 80601-2-58:2024)

Medical electrical equipment - Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery (IEC 80601-2-58:2024)

Medizinische elektrische Geräte - Teil 2-58: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale für Geräte zur Linsenentfernung und Geräte zur Glaskörperentfernung in der Augenchirurgie (IEC 80601-2-58:2024

Appareils électromédicaux - Partie 2-58: Exigences particulières pour la sécurité de base et les performances essentielles des dispositifs de retrait du cristallin et des dispositifs de vitrectomie pour la chirurgie ophtalmique (IEC 80601-2-58:2024

Ta slovenski standard je istoveten z: **EN IEC 80601-2-58:2024**

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

SIST EN IEC 80601-2-58:2024 **en**

EUROPEAN STANDARD

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Medical electrical equipment - Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery (IEC 80601-2-58:2024)

Appareils électromédicaux - Partie 2-58: Exigences particulières pour la sécurité de base et les performances essentielles des dispositifs de retrait du cristallin et des dispositifs de vitrectomie pour la chirurgie ophtalmique (IEC 80601-2-58:2024)

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This European Standard was approved by CENELEC on 2024-07-31. 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.

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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

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European foreword

The text of document 62D/2096/FDIS, future edition 3 of IEC 80601-2-58, 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 80601-2-58:2024.

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 80601-2-58:2015 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.

This document has been prepared under a standardization request addressed to CENELEC by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

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 80601-2-58:2024 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 60601-1-3:2008	NOTE Approved as EN 60601-1-3:2008 (not modified) +A11:2016
IEC 60601-1-3:2008/A1:2013	NOTE Approved as EN 60601-1-3:2008/A1:2013 (not modified)
IEC 60601-1-3:2008/A2:2021	NOTE Approved as EN 60601-1-3:2008/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)
ISO 15004-2:2007	NOTE Approved as EN ISO 15004-2:2007 (not modified)
IEC 60825-1:2014	NOTE Approved as EN 60825-1:2014 (not modified) +A11:2021
IEC 61847:1998	NOTE Approved as EN 61847:1998 (not modified)
IEC 62368-1:2018	NOTE Approved as EN IEC 62368-1:2020 (not modified) +A11:2020

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 60601-2-2	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
+ AMD1	2023		+ A1	2024
IEC 60601-2-22	2019	Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment	EN IEC 60601-2-22	2020

[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
CISPR 11 (mod)	2015	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement	EN 55011	2016
+ A1	2016		+ A1	2017
-	-		+ A11	2020
+ A2	2019		+ A2	2021
ISO 11607-1	2019	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	EN ISO 11607-1	2020
-	-		+ A11	2022
ISO 11607-2	2019	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	EN ISO 11607-2	2020
-	-		+ A11	2022
ISO 17664	2017	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices	EN ISO 17664	2017[2]

[2] EN ISO 17664:2017 has been withdrawn and replaced with EN ISO 17664-1:2021.

IEC 80601-2-58

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery

Appareils électromédicaux –
Partie 2-58: Exigences particulières pour la sécurité de base et les performances essentielles des dispositifs de retrait du cristallin et des dispositifs de vitrectomie pour la chirurgie ophtalmique

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery

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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9) IEC draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at https://patents.iec.ch. IEC shall not be held responsible for identifying any or all such patent rights.

IEC 80601-2-58 has been prepared by subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems, in co-operation with ISO subcommittee SC 7: Ophthalmic optics and instruments, of ISO technical committee 172: Optics and photonics. It is an International Standard.

It is published as a double logo standard.

This third edition cancels and replaces the second edition published in 2014 and its Amendment 1:2016. This edition constitutes a technical revision.

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

a) the alignment of this particular standard based on the amendment of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020;

b) the update of collateral, particular and IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 references to align with amendments to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and other collateral standards;

c) the update of normative references;

d) the addition of a new requirement for particulate matter from APPLIED PARTS in 201.9.5.101;

e) the addition of the shadow light method in 201.12.1.101.7;

f) the clarification of test conditions for EMC requirements in 202.7.1.2;

g) the update of Table D.4 references to include specific IEC references to the symbols and deletion of Annex AA, 201.7.6.101;

h) the addition to Annex AA of 201.12.1.101.7;

i) the inclusion of a new annex to address the relevant general safety and performance requirements of European regulation (EU) 2017/745 [1][1] (Annex BB);

j) the removal of all references of the LIQUEFACTION FRAGMENTATION LENS REMOVAL method.

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

Draft	Report on voting
62D/2096/FDIS	62D/2110/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 PARTICULAR STANDARD 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).

[1] Numbers in square brackets refer to the Bibliography.