SLOVENSKI STANDARD
SIST EN 80601-2-58:2015/A1:2019

01-november-2019

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 - Dopolnilo A1 (IEC 80601-2-58:2014/A1:2016)

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 80601-2-58:2014/A1:2016)

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 80601-2-58:2014/A1:2016)

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 80601-2-58:2014/A1:2016)

Ta slovenski standard je istoveten z: **EN 80601-2-58:2015/A1:2019**

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

SIST EN 80601-2-58:2015/A1:2019 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 80601-2-58:2015/A1

August 2019

ICS 11.040.70

English Version

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 80601-2-58:2014/A1:2016)

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 80601-2-58:2014/A1:2016)

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This amendment A1 modifies the European Standard EN 80601-2-58:2015; it was approved by CENELEC on 2019-08-07. 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, Turkey 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/1364/FDIS, future IEC 80601-2-58:2014/A1, 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 80601-2-58:2015/A1:2019.

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)	2020-02-23
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2022-08-23

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 mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, included in EN 80601-2-58:2015.

Endorsement notice

The text of the International Standard IEC 80601-2-58:2014/A1:2016 was approved by CENELEC as a European Standard without any modification.

Replace:

IEC 60825-1	NOTE	Harmonized as EN 60825-1.
IEC 61847	NOTE	Harmonized as EN 61847.
IEC 60950-1	NOTE	Harmonized as EN 60950-1.
IEC 60065	NOTE	Harmonized as EN 60065.

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 When 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.cenelec.eu.

Publication	Year	Title	EN/HD	Year
In Annex ZA of EN 80601-2-58:2015, replace the existing references to the following publications as follows:				
IEC 60601-1-2	-	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	-
+ 1	2014		+ A1	2014
+ 1	2014		+ A1	2014
Addition:				
CISPR 11	-	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement	EN 55011	-
ISO 11607-1:2006/Amd1	2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	EN ISO 11607-1:2009/A1	2014
ISO 11607-2:2006/Amd1	2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes)	EN ISO 11607-2:2006/A1	2014

IEC 80601-2-58

Edition 2.0 2016-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 11.040.70

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FOREWORD

This amendment has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice, and subcommittee SC 7: Ophthalmic optics and instruments, of ISO technical committee 172: Optics and photonics.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/1364/FDIS	62D/1370/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 11 P members out of 11 having cast a vote.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION TO THE AMENDMENT

This amendment modifies the content of the second edition of IEC 80601-2-58 published in 2014. This Amendment constitutes a technical revision.

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

a) integration of updated definition of ESSENTIAL PERFORMANCE and updating the ESSENTIAL PERFORMANCE analysis;
b) undating collateral and general standard references to align with amendments to the general standard and other collateral standards;
c) addition of symbols to standard;
d) update of EMC requirements.

201.1.3 Collateral standards

Replace the existing title of this subclause by the following new title:

201.1.3 * Collateral standards

Replace the existing text of the second paragraph by the following:

IEC 60601-1-2 applies as modified in Clause 202. IEC 60601-1-3, IEC 60601-1-10, IEC 60601-1-11, and IEC 60601-1-12 do not apply.

201.1.4 Particular standards

Add, in the fourth paragraph of the subclause, "IEC" *before the existing references to "*60601-1-2*" and "*60601-1-3*".*

*Add, in the second sentence of the eight paragraph of the subclause, a comma immediately after "*However*".*

201.2 Normative references

Delete the second footnote of the standard.

Replace the existing reference to IEC 60601-1-2, by the following new reference:

IEC 60601-1-2, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests*

Add, before the existing reference to ISO 11607-1, the following new reference:

CISPR 11, *Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement*

*Add, in the following references, the reference to Amendment 1 "*AMD1:2014*":*

ISO 11607-1:2006/AMD1:2014, *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2:2006/AMD1:2014, *Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes*

201.3.205

Replace the existing source by the following new source and add the end of page footnote as follows:

[SOURCE: IEC 60825-1:2014, 3.44 [1][1]]

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

201.3.208
LENS REMOVAL DEVICE

Replace the existing definition by the following, without modifying the existing Note to entry:

ME EQUIPMENT OR ME SYSTEM designed to remove lens material which incorporates an IRRIGATION and ASPIRATION function, and a mechanism for LENS REMOVAL such as PHACOFRAGMENTATION, LIQUEFACTION, OR LASER FRAGMENTATION

201.7 ME EQUIPMENT identification, marking and documents

Add, after the instruction for subclause 201.7, the following new subcause: