

<b>STN</b>	<b>Zdravotnícke elektrické prístroje Časť 2-58: Osobitné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti prístrojov na odstraňovanie šošovky a prístrojov na vitrektómiu v očnej chirurgii Zmena A1</b>	<b>STN EN 80601-2-58/A1</b>  36 4800
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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

Táto norma obsahuje anglickú verziu európskej normy.  
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 12/19

STN EN 80601-2-58 z decembra 2015 sa bez zmeny A1 môže používať do 23. 8. 2022.

Obsahuje: EN 80601-2-58:2015/A1:2019, IEC 80601-2-58:2014/AMD1:2016

**130044**

EUROPEAN STANDARD

**EN 80601-2-58:2015/A1**

NORME EUROPÉENNE

EUROPÄISCHE NORM

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 ophthalmique (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 Augen Chirurgie (IEC 80601-2-58:2014/A1:2016)

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.

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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**

**EN 80601-2-58:2015/A1:2019 (E)****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

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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](http://www.cenelec.eu).

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



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  
essentielle des dispositifs de retrait du cristallin et des dispositifs de  
vitrectomie pour la chirurgie ophtalmique**



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IEC 80601-2-58

Edition 2.0 2016-10

# INTERNATIONAL STANDARD

# NORME INTERNATIONALE

AMENDMENT 1  
AMENDEMENT 1

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**Medical electrical equipment –  
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**Appareils électromédicaux –  
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essentiels des dispositifs de retrait du cristallin et des dispositifs de  
vitrectomie pour la chirurgie ophtalmique**

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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.

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## 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.

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### 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.



IEC 80601-2-58:2014/AMD1:2016  
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#### **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]<sup>1</sup>]

<sup>1</sup> Numbers in square brackets refer to the Bibliography.

**koniec náhľadu – text ďalej pokračuje v platenej verzii STN**