BS EN 80601-2-58:2015+A1:2019

BSI Standards Publication

# 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

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# National foreword

This British Standard is the UK implementation of EN 80601-2-58:2015+A1:2019. It is identical to IEC 80601-2-58:2014, incorporating amendment 1:2016. It supersedes BS EN 80601-2-58:2015, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/62/4, Electromedical equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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**Compliance with a British Standard cannot confer immunity from legal obligations.**

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 June 2015.

**Amendments/corrigenda issued since publication**

| Date | Text affected |
|---|---|
| 31 August 2019 | Implementation of IEC amendment 1:2016 with CENELEC endorsement A1:2019 |

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EUROPEAN STANDARD

NORME EUROPÉENNE

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# EN 80601-2-58:2015/A1

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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)

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)

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)

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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## European foreword

The text of document 62D/1151/FDIS, future edition 2 of IEC 80601-2-58 prepared by SC 62D "Electromedical equipment" of IEC/TC 62 "Electrical equipment in medical practice" and SC 7 "Ophthalmic optics and instruments" of ISO/TC 172 "Optics and photonics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 80601-2-58:2015.

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) | 2015-11-29 |
| • latest date by which the national standards conflicting with the document have to be withdrawn | (dow) | 2018-05-29 |

This document supersedes EN 80601-2-58:2009.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] 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.

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, which is an integral part of this document.

## Endorsement notice

The text of the International Standard IEC 80601-2-58:2014 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 standards indicated:

| | | |
|---|---|---|
| IEC 60065:2001 | NOTE | Harmonized as EN 60065:2002 [1)] (modified). |
| IEC 60825-1 | NOTE | Harmonized as EN 60825-1. |
| IEC 60950-1 | NOTE | Harmonized as EN 60950-1. |
| IEC 61847 | NOTE | Harmonized as EN 61847. |
| ISO 15004-2:2007 | NOTE | Harmonized as EN ISO 15004-2:2007 (not modified). |
| ISO 15752:2010 | NOTE | Harmonized as EN ISO 15752:2010 (not modified). |

[1)] Superseded by EN 60065:2014 (IEC 60065:2014): DOW = 2017-11-17.



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## Foreword to amendment A1

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. |



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# Annex ZA
(normative)

## Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 |
|---|---|---|---|---|
| ***Annex ZA of EN 60601-1:2006 applies except as follows:*** | | | | |
| ***Replacement:*** | | | | |
| IEC 60601-1-2 (mod) | - | 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 | - |
| IEC 60601-2-2 | - | 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 60601-2-2 | - |
| IEC 60601-2-22 | - | Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment | EN 60601-2-22 | - |
| 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 11607-22006/ Amd1 | 2014 | Packaging for terminally sterilized medical devices - Par 2: Validation requirements for forming, sealing and assembly processes | EN ISO 11607-2: 2006/A1 | 2014 |
| ISO 17664 | 2004 | Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices | EN ISO 17664 | 2004 |



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# Annex ZZ
(informative)

## Coverage of Essential Requirements of EU Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and within its scope the Standard covers all relevant essential requirements given in Annex I of EU Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

**WARNING**: Other requirements and other EU Directives can be applied to the products falling within the scope of this standard.



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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

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International standard IEC 80601-2-58 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.

It is published as a double logo standard.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, 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 THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, 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 standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, 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 standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
– “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 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

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The committee has decided that the contents of the base publication and its amendment 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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