



**BSI Standards Publication**

## **Medical electrical equipment**

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

## National foreword

This British Standard is the UK implementation of EN IEC 80601-2-58:2024. It is identical to IEC 80601-2-58:2024. It supersedes BS EN 80601-2-58:2015+A1:2019, which will be withdrawn on 31 July 2027.

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 committee manager.

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### Amendments/corrigenda issued since publication

| Date  | Text affected |
|-------|---------------|
| <hr/> |               |

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 80601-2-58:2024)

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)

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 80601-2-58:2024)

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.

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.

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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

## **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 (dop) 2025-05-01 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2027-07-31 document have to be withdrawn

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

*Annex ZA of EN 60601-1:2006<sup>1</sup>, applies, except as follows:*

*Add:*

| <u>Publication</u> | <u>Year</u> | <u>Title</u>                                                                                                                                                                                             | <u>EN/HD</u>          | <u>Year</u> |
|--------------------|-------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|-------------|
| IEC 60601-1        | 2005        | Medical electrical equipment - Part 1:<br>General requirements for basic safety and<br>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:<br>Particular requirements for the basic safety<br>and essential performance of high frequency<br>surgical equipment and high frequency<br>surgical accessories | EN IEC 60601-<br>2-2  | 2018        |
| + AMD1             | 2023        |                                                                                                                                                                                                          | + A1                  | 2024        |
| IEC 60601-2-22     | 2019        | Medical electrical equipment - Part 2-22:<br>Particular requirements for basic safety and<br>essential performance of surgical, cosmetic,<br>therapeutic and diagnostic laser equipment                  | EN IEC 60601-<br>2-22 | 2020        |

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<sup>1</sup> 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.

| <u>Publication</u> | <u>Year</u> | <u>Title</u>                                                                                                                             | <u>EN/HD</u>   | <u>Year</u>       |
|--------------------|-------------|------------------------------------------------------------------------------------------------------------------------------------------|----------------|-------------------|
| 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 <sup>2</sup> |

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<sup>2</sup> EN ISO 17664:2017 has been withdrawn and replaced with EN ISO 17664-1:2021.

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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

## 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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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]<sup>1</sup> (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](http://www.iec.ch/members_experts/refdocs). The main document types developed by IEC are described in greater detail at [www.iec.ch/publications](http://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).

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

References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard 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](https://webstore.iec.ch) in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

## INTRODUCTION

LENS REMOVAL DEVICES and VITRECTOMY DEVICES are used widely in ophthalmology to perform anterior-segment and posterior-segment surgery on the human eye. Commercial use of these MEDICAL ELECTRICAL EQUIPMENT devices began in the early 1970s. This document defines particular requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE of LENS REMOVAL DEVICES and VITRECTOMY DEVICES, comprising an equipment console, surgical HANDPIECES and ACCESSORIES connected to this ME EQUIPMENT.

In many parts of the world LENS REMOVAL DEVICES and VITRECTOMY DEVICES are used in combination by ophthalmic surgeons to perform combined anterior-segment (LENS REMOVAL) and posterior-segment (vitreoretinal) surgical PROCEDURES to maximize surgical outcomes. For this reason both LENS REMOVAL DEVICES and VITRECTOMY DEVICES are covered in this document.

As all particular standards in the IEC 60601-1 series are based on IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, the user of this document is reminded that RISK MANAGEMENT plays an important role in the use of this particular standard. Compliance with the requirements of this document should be recorded in the RISK MANAGEMENT FILE to ensure the HAZARDS associated with the product have been considered fully.

Refer to foreword of this document for list of significant technical changes with respect to the previous edition.

## 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

#### 201.1 Scope, object and related standards

Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

##### 201.1.1 \* Scope

*Replacement:*

This part of IEC 80601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of LENS REMOVAL DEVICES and VITRECTOMY DEVICES for ophthalmic surgery (as defined in 201.3.209 and 201.3.217) and associated ACCESSORIES that can be connected to this MEDICAL ELECTRICAL EQUIPMENT, hereafter referred to as ME EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document except in 7.2.13 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD2:2020 and 8.4.1 of IEC 60601-1:2005.

NOTE See also 4.2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

##### 201.1.2 Object

*Replacement:*

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for LENS REMOVAL DEVICES and VITRECTOMY DEVICES for ophthalmic surgery (as defined in 201.3.209 and 201.3.217) and associated ACCESSORIES that can be connected to the ME EQUIPMENT and shall be tested together or individually.

NOTE This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745 [1] as indicated in Annex BB.

##### 201.1.3 \* Collateral standards

*Addition:*

This document refers to those applicable collateral standards that are listed in Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, and Clause 201.2.

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply as modified in Clause 202. IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021[2], IEC 60601-1-9:2007, IEC 60601-1-9:2007/AMD1:2013 and IEC 60601-1-9:2007/AMD2:2020[3], IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020[4], IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020[5], and IEC 60601-1-12:2014 and IEC 60601-1-12:2014/AMD1:2020[6] do not apply.

#### 201.1.4 Particular standards

##### *Replacement:*

In the IEC 60601 series, particular standards specify BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for the particular ME EQUIPMENT and ME SYSTEMS. Particular standards may modify, replace or delete requirements contained in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and applicable collateral standards as appropriate for the particular ME EQUIPMENT and ME SYSTEMS under consideration. A requirement of a particular standard takes priority over IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and applicable collateral standards.

The numbering of clauses and subclauses of this document corresponds to that of the IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are specified by the use of the following words:

*"Replacement"* means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is replaced completely by the text of this document.

*"Addition"* means that the text of this document is additional to the requirements of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard.

*"Amendment"* means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables which are additional to those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered starting from 201.101. However, due to the fact that definitions in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered 3.1 through 3.154, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

Where there is no corresponding clause or subclause in this document, the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.