



**CSA C22.2 No. 80601-2-58:15**

**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, MOD)

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**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, MOD)



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# National Standard of Canada

CSA C22.2 No. 80601-2-58:15

**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, MOD)

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# **CSA C22.2 No. 80601-2-58:15**

## **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, MOD)**

### **CSA Preface**

This is the second edition of CAN/CSA-C22.2 No. 80601-2-58, *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*, which is an adoption, with Canadian deviations, of the identically titled IEC (International Electrotechnical Commission) Standard 80601-2-58 (second edition, 2014-09). It supersedes the previous edition published in 2010 as CAN/CSA-C22.2 No. 80601-2-58 (adopted IEC 80601-2-58:2008). It is one in a series of Standards issued by CSA Group under Part II of the *Canadian Electrical Code*.

For brevity, this Standard will be referred to as “CAN/CSA-C22.2 No. 80601-2-58” throughout.

This Standard is intended to be used in conjunction with CAN/CSA-C22.2 No. 60601-1:14, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance* (adopted IEC 60601-1:2005+A1:2012, with Canadian deviations).

This Standard is considered suitable for use for conformity assessment within the stated scope of the Standard.

This Standard was reviewed for Canadian adoption by the CSA Technical Committee on Consumer and Commercial Products, under the jurisdiction of the CSA Strategic Steering Committee on Requirements for Electrical Safety, and has been formally approved by the Technical Committee. Due to the medical content of this Standard, it was also approved by the CSA Technical Committee on Application of Electricity in Health Care under the jurisdiction of the CSA Strategic Steering Committee on Health Care Technology & Systems.

This Standard has been developed in compliance with Standards Council of Canada requirements for National Standards of Canada. It has been published as a National Standard of Canada by CSA Group.

**Interpretations:** The Strategic Steering Committee on Requirements for Electrical Safety has provided the following direction for the interpretations of standards under its jurisdiction: “The literal text shall be used in judging compliance of products with the safety requirements of this Standard. When the

literal text cannot be applied to the product, such as for new materials or construction, and when a relevant CSA committee interpretation has not already been published, CSA Group's procedures for interpretation shall be followed to determine the intended safety principle."

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This Standard is subject to review within five years from the date of publication, and suggestions for its improvement will be referred to the appropriate committee. To submit a proposal for change, please send the following information to [inquiries@csagroup.org](mailto:inquiries@csagroup.org) and include "Proposal for change" in the subject line:

- a) Standard designation (number);
- b) relevant clause, table, and/or figure number;
- c) wording of the proposed change; and
- d) rationale for the change.

# 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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## 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 the general standard<sup>1</sup> applies, except as follows:

##### 201.1.1 \* Scope

*Replacement:*

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of LENS REMOVAL DEVICES and VITRECTOMY DEVICES for ophthalmic surgery (as defined in 201.3.208 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 standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

##### 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 201.3.208 and 201.3.217) and associated ACCESSORIES that can be connected to the ME EQUIPMENT and are to be tested together or individually.

##### 201.1.3 Collateral standards

*Addition:*

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2:2007 applies as modified in Clause 202. All other published collateral standards in the IEC 60601-1 series apply as published.

##### 201.1.4 Particular standards

*Replacement:*

<sup>1</sup> The general standard is IEC 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*