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CSA C22.2 No. 61010-2-040:21
(IEC 61010-2-040:2020, MOD)
National Standard of Canada
Norme nationale du Canada

CSA C22.2 No. 61010-2-040:21
Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials
(IEC 61010-2-040:2020, MOD)

CSA C22.2 nº 61010-2-040:21
Exigences de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire — Partie 2-040 : Exigences particulières pour stérilisateurs et laveurs désinfecteurs utilisés pour traiter le matériel médical
(IEC 61010-2-040:2020, MOD)

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Title: *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials*

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Cette Norme Nationale du Canada est disponible en versions française et anglaise.

Although the intended primary application of this Standard is stated in its Scope, it is important to note that it remains the responsibility of the users to judge its suitability for their particular purpose.

National Standard of Canada

CSA C22.2 No. 61010-2-040:21

Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials

(IEC 61010-2-040:2020, MOD)

Prepared by
International Electrotechnical Commission

Reviewed by

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CSA Preface

This is the third edition of CSA C22.2 No. 61010-2-040, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials*, which is an adoption, with Canadian deviations, of the identically titled IEC (International Electrotechnical Commission) Standard 61010-2-040 (third edition, 2020-05). It supersedes the previous edition published in 2016 as CAN/CSA-C22.2 No. 61010-2-040 (adopted IEC 61010-2-040:2015). 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 "CSA C22.2 No. 61010-2-040" throughout.

This Standard is intended to be used in conjunction with CAN/CSA-C22.2 No. 61010-1:12, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements* (adopted IEC 61010-1:2010, with Canadian and US deviations); and Amendment 1:2018 to CAN/CSA-C22.2 No. 61010-1:12 (adopted IEC Amendment 1:2016, with Canadian and US 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 Subcommittee on Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, under the jurisdiction of the CSA Technical Committee on Consumer and Commercial Products and the CSA Strategic Steering Committee on Requirements for Electrical Safety, and has been formally approved by the Technical Committee.

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. The technical content of IEC and ISO publications is kept under constant review by IEC and ISO. To submit a proposal for change, please send the following information to 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.*

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SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE –

Part 2-040: Particular requirements for STERILIZERS and WASHER-DISINFECTORS used to treat medical materials

1 Scope and object

This clause of Part 1 is applicable except as follows:

1.1.1 Equipment included in scope

Replacement:

Replace the existing text with the following:

This part of IEC 61010 specifies safety requirements for electrical equipment intended for sterilization, washing, and disinfection of medical materials in the medical, veterinary, pharmaceutical and laboratory fields, when used under the environmental conditions of 1.4.

Examples of such equipment include the following:

a) STERILIZERS and disinfectors using steam and/or hot water as the sterilant;

b) STERILIZERS and disinfectors using toxic gas, toxic aerosol or toxic vapour as the sterilant;

c) STERILIZERS and disinfectors using hot air or hot inert gases as the sterilant; and

d) WASHER-DISINFECTORS.

1.1.2 Equipment excluded from scope

Addition:

Add the following note to item f):

NOTE IEC 60601-1:2005, 3.63, defines "medical electrical equipment" as follows (notes to entry are omitted):

Electrical equipment, having an applied part or transferring energy to or from the patient or detecting such energy transfer to or from the patient and which is:

a) provided with not more than one connection to a particular supply MAINS; and

b) intended by the manufacturer to be used:

1) in the diagnosis, treatment, or monitoring of a patient; or

2) for compensation or alleviation of disease, injury or disability.

Addition:

Add the following new second paragraph after the lettered list:

This document does not apply to the following types of equipment:

aa) equipment for use in hazardous atmospheres (see IEC 60079); however this document does apply to an atmosphere created inside equipment by a flammable sterilizing agent (see 13.2.101 and 13.2.102);

bb) laboratory equipment for the heating of materials for purposes other than sterilization or disinfection (see IEC 61010-2-010);