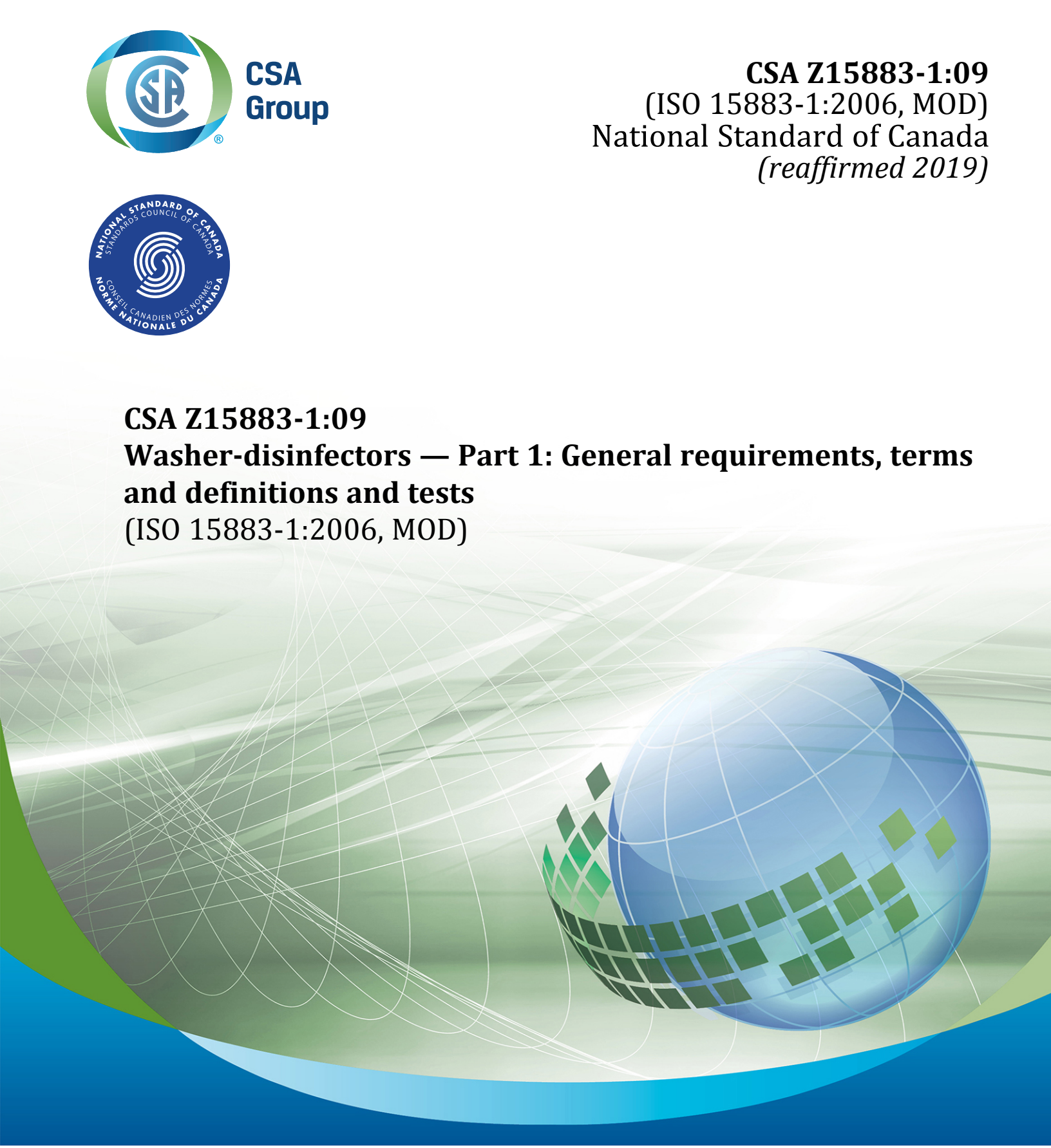
CSA Group

**CSA Z15883-1:09**
(ISO 15883-1:2006, MOD)
National Standard of Canada
*(reaffirmed 2019)*

# CSA Z15883-1:09
# Washer-disinfectors — Part 1: General requirements, terms and definitions and tests
(ISO 15883-1:2006, MOD)



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# *Update No. 1*
# *CAN/CSA-Z15883-1-09*
# *September 2009*

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**Title:** *Washer-disinfectors — Part 1: General requirements, terms and definitions and tests* — originally published March 2009

The following revisions have been formally approved and are marked by the symbol delta (Δ) in the margin on the attached replacement pages:

| | |
|---|---|
| **Revised** | Canadian deviation to Table B.1 |
| **New** | None |
| **Deleted** | None |

- Update your copy by inserting these revised pages.
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### 6.4.1 General

*[Add the following to the first paragraph]*

Refer to AAMI TIR34 for guidance on water testing and water quality for washer-disinfectors.

### 6.10.1 General

*[Add the following note]*

**Note 1A:** *The test methods and soils specified in ISO/TS 15883-5 are based on national practices in several ISO member countries other than Canada. Canadian users should employ qualified testing services when available through a contracted third party. As a supplement to this testing, or if qualified testing services are not available, commercially available indicators should be regularly used to verify cleaning efficacy.*

### 6.11.1 Procedure

*[Add the following note]*

**Note 1A:** *The tests specified in ISO/TS 14644-3 are based on national practices in several ISO member countries other than Canada. As such, these tests of air quality are not available in Canada.*

# **Annex A** (informative)
# Test programme

*[Add the following to the first paragraph below Figure A.1]*

The testing programme outlined in Table A.1 is a useful reference, but it should be adapted in consultation with the manufacturer or manufacturer-designate to align with this Standard (including the Canadian deviations).

# **Annex B** (informative)
# $A_0$ concept — Comparative lethality of moist heat processes

*[Add the following note below Table B.1]*

**Note 1A:** *The $A_0$ concept is not yet widely used in Canada. In general, the following equivalencies can help users to understand how $A_0$ values relate to existing decontamination and sterilization processes:*

*a) An $A_0$ = 60 (i.e.,* 1 min *at* 80 °C*) can be considered equivalent to thermal conditions that would render a device safe to handle or for contact with intact skin.*

*b) An $A_0$ = 600 (i.e.,* 1 min *at* 90 °C*) can be considered equivalent to thermal conditions that achieve pasteurization, i.e., rendering a device safe for contact with mucous membranes.*

Δ *c) An $A_0$ = 3000 (i.e.,* 10 min *at* 90 °C*) can be considered equivalent to thermal conditions for complete microbial kill. Devices exposed to these thermal conditions should not be used in procedures where sterility is required.*

# *Standards Update Service*

# *CSA Z15883-1:09*
# *March 2009*

**Title:** *Washer-disinfectors — Part 1: General requirements, terms and definitions and tests*

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# *National Standard of Canada*

## *CSA Z15883-1:09*

## ***Washer-disinfectors — Part 1: General requirements, terms and definitions and tests***

*(ISO 15883-1:2006, MOD)*

*Prepared by*
*International Organization for Standardization*

*Reviewed by*

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# CAN/CSA-Z15883-1-09
# Washer-disinfectors — Part 1: General requirements, terms and definitions and tests

## CSA Preface

This is the first edition of CAN/CSA-Z15883-1, *Washer-disinfectors — Part 1: General requirements, terms and definitions and tests*, which is an adoption, with Canadian deviations, of the identically titled ISO (International Organization for Standardization) Standard 15883-1 (first edition, 2006-04-15).

This Standard was reviewed for Canadian adoption by the CSA Technical Committee on Sterilization, under the jurisdiction of the Strategic Steering Committee on Health Care Technology, and has been formally approved by the Technical Committee. This Standard has been approved as a National Standard of Canada by the Standards Council of Canada.

*March 2009*



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# *Canadian deviations*

## Introduction

*[Add the following]*

This Standard includes requirements for tests to be performed after installation and periodically over the life of the washer-disinfector. Some of these tests require specialized knowledge and equipment that might not be available to Canadian users, either in-house or through third-party testing services. It is hoped that the publication of this Standard will lead to wider availability of services for periodic testing and maintenance of washer-disinfectors across the country. The use of commercially available indicators to demonstrate cleaning efficacy is recommended to supplement the testing required by this Standard.

The use of cleaning indicators alone will not ensure the achievement of defined outcomes. Other parameters that need to be considered include loading, equipment inspection, visual inspection of the devices post-cleaning, water temperature, water quality, and routine maintenance.

## 2 Normative references

*[Add the following]*

**AAMI (Association for the Advancement of Medical Instrumentation)**
AAMI TIR34:2007
*Water for the reprocessing of medical devices*

## 4 Performance requirements

### 4.2.1.1

*[Replace the second paragraph with the following]*

The test method for type testing and operational qualification testing (6.10.2) shall employ one of the nationally published tests, soils, and methods as described in ISO/TS 15883-5 (see also References [24] to [39]).

*[Add the following note]*

**Note 4A:** *The test methods and soils specified in ISO/TS 15883-5 are based on national practices in several ISO member countries other than Canada; however, some level of installation qualification testing should be made available by the manufacturer or manufacturer-designate. For routine testing, or for requalification testing that is not provided by the manufacturer/distributor, Canadian users should employ third-party testing services if available. As a supplement to this testing, or if qualified testing services are not available, commercially available indicators should be regularly used to verify cleaning efficacy.*

## 6 Testing for conformity

*[Add the following note]*

**Note 1A:** *Some of the tests described in Clause 6 require specialized equipment and expertise. Users should consult the manufacturer or distributor of the washer-disinfector to determine what tests are needed for requalification and who should perform the testing. Refer to Clause 8.3 g).*

### 6.4.1 General

*[Add the following to the first paragraph]*

Refer to AAMI TIR34 for guidance on water testing and water quality for washer-disinfectors.

### 6.10.1 General

*[Add the following note]*

**Note 1A:** *The test methods and soils specified in ISO/TS 15883-5 are based on national practices in several ISO member countries other than Canada. Canadian users should employ qualified testing services when available through a contracted third party. As a supplement to this testing, or if qualified testing services are not available, commercially available indicators should be regularly used to verify cleaning efficacy.*

### 6.11.1 Procedure

*[Add the following note]*

**Note 1A:** *The tests specified in ISO/TS 14644-3 are based on national practices in several ISO member countries other than Canada. As such, these tests of air quality are not available in Canada.*

# **Annex A** (informative)
# Test programme

*[Add the following to the first paragraph below Figure A.1]*

The testing programme outlined in Table A.1 is a useful reference, but it is should be adapted in consultation with the manufacturer or manufacturer-designate to align with this Standard (including the Canadian deviations).

# **Annex B** (informative)
# $A_0$ concept — Comparative lethality of moist heat processes

*[Add the following note below Table B.1]*

**Note 1A:** *The $A_0$ concept is not yet widely used in Canada. In general, the following equivalencies can help users to understand how $A_0$ values relate to existing decontamination and sterilization processes:*

*a) An $A_0$ = 60 (i.e.,* 1 min *at* 80 °C*) can be considered equivalent to thermal conditions that would render a device safe to handle or for contact with intact skin.*

*b) An $A_0$ = 600 (i.e.,* 1 min *at* 90 °C*) can be considered equivalent to thermal conditions that achieve pasteurization, i.e., rendering a device safe for contact with mucous membranes.*

*c) An $A_0$ = 6000 (i.e.,* 10 min *at* 90 °C*) can be considered equivalent to thermal conditions for complete microbial kill. Devices exposed to these thermal conditions should not be used in procedures where sterility is required.*

INTERNATIONAL STANDARD

**ISO 15883-1**

First edition
2006-04-15

# Washer-disinfectors —

## Part 1: General requirements, terms and definitions and tests

*Laveurs désinfecteurs —*

*Partie 1: Exigences générales, termes et définitions et essais*

Reference number
ISO 15883-1:2006(E)

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# Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 15883-1 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 102, *Sterilizers for medical purposes*, in collaboration with Technical Committee ISO/TC 198, *Sterilization of health care products*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

ISO 15883 consists of the following parts, under the general title *Washer-disinfectors*:

— *Part 1: General requirements, terms and definitions and tests*

— *Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.*

— *Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers*

— *Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes*

— *Part 5: Test soils and methods for demonstrating cleaning efficacy* [Technical Specification]

# Introduction

This part of ISO 15883 is the first of a series of standards specifying the performance of washer-disinfectors and specifies the general requirements for performance applicable to all washer-disinfectors. The requirements given in this part of ISO 15883 are applicable to all washer-disinfectors specified in subsequent parts of the ISO 15883 series, except insofar as they may be modified or added to by a subsequent part, in which case the requirements of that particular part will apply.

Fields of application within the scope of ISO 15883 series include laboratory, veterinary, dental and pharmaceutical applications and other specific applications, such as washer-disinfectors for bedsteads and transport carts and the disinfection of crockery and cutlery intended for use with immunologically compromised patients.

Washer-disinfectors should be used only for processing the type of loads specified by the manufacturer of the washer-disinfector.

In selecting the appropriate washer-disinfector, reference should be made both to this part of ISO 15883 and to the relevant subsequent parts of ISO 15883 series. It is the user's responsibility to ensure that the choice of type of washer-disinfector, operating cycle or quality of services or process chemicals is appropriate for any particular load.

Safety requirements for washer-disinfectors are given in IEC 61010-2-045.

This part of ISO 15883 has been prepared on the basis that each individual washer-disinfector will be subject to validation tests (commissioning and performance qualification on first installation) and that in use continued compliance will be established by periodic tests carried out by, or on behalf of, the user.

Verification of cleaning efficacy is a key aspect of establishing satisfactory performance of a washer-disinfector. The current state of knowledge has not permitted development of a single test method. As an interim measure reference has been made to test methods which are currently being applied in a number of different countries. The specification for these test methods including their test soils can be found in ISO/TS 15883-5. It remains the intention of the Technical Committee of TC 198 to develop a single test method.

In respect of the potential adverse effects on the quality of water intended for human consumption caused by the washer-disinfector:

a) it should be noted that, until verifiable European criteria are adopted, existing national regulations concerning the use and/or the characteristics of the washer-disinfector remain in force;

b) the ISO 15883 series of standards provides no information as to whether the washer-disinfector may be used without restrictions in any of the member states of the EU or EFTA.

 

# Washer-disinfectors —

# Part 1:
# General requirements, terms and definitions and tests

## 1 Scope

This part of ISO 15883 specifies general performance requirements for washer-disinfectors (WD) and their accessories that are intended to be used for cleaning and disinfection of re-usable medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice. It specifies performance requirements for cleaning and disinfection as well as for the accessories which can be required to achieve the necessary performance. The methods and instrumentation required for validation, routine control and monitoring and re-validation, periodically and after essential repairs, are also specified.

The requirements for washer-disinfectors intended to process specific loads are specified in subsequent parts of this standard. For washer-disinfectors intended to process loads of two or more different types the requirements of all relevant parts of this standard apply.

This part of ISO 15883 does not specify requirements intended for machines for use for laundry or general catering purposes.

This part of ISO 15883 does not include requirements for machines which are intended to sterilize the load, or which are designated as “sterilizers”, these are specified in other standards e.g. EN 285.

The specified performance requirements of this standard may not ensure the inactivation or removal of the causative agent(s) (prion protein) of transmissible spongiform encephalopathies.

NOTE If it is considered that prion protein can be present, particular care is needed in the choice of disinfectants and cleaning agents to ensure that the chemicals used do not react with the prion protein in a manner that may inhibit its removal or inactivation.

This part of ISO 15883 may be used by prospective purchasers and manufacturers as the basis of agreement on the specification of a WD. The test methods for demonstration of compliance with the requirements of this part of ISO 15883 may also be employed by users to demonstrate continued compliance of the installed WD throughout its working life. Guidance on a routine test programme is given in Annex A.

## 2 Normative references

The following referenced documents are indispensable for the application 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.

ISO 228-1, *Pipe threads where pressure-tight joints are not made on the threads — Part 1: Dimensions, tolerances and designation*

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*