

CAN/CSA-ISO 11138-1:17
(ISO 11138-1:2017, IDT)
National Standard of Canada

CAN/CSA-ISO 11138-1:17
Sterilization of health care products —
Biological indicators — Part 1: General requirements
(ISO 11138-1:2017, IDT)



CSA Group
Groupe CSA



Standards Council of Canada
Conseil canadien des normes

Legal Notice for Standards

Canadian Standards Association (operating as “CSA Group”) develops standards through a consensus standards development process approved by the Standards Council of Canada. This process brings together volunteers representing varied viewpoints and interests to achieve consensus and develop a standard. Although CSA Group administers the process and establishes rules to promote fairness in achieving consensus, it does not independently test, evaluate, or verify the content of standards.

Disclaimer and exclusion of liability

This document is provided without any representations, warranties, or conditions of any kind, express or implied, including, without limitation, implied warranties or conditions concerning this document’s fitness for a particular purpose or use, its merchantability, or its non-infringement of any third party’s intellectual property rights. CSA Group does not warrant the accuracy, completeness, or currency of any of the information published in this document. CSA Group makes no representations or warranties regarding this document’s compliance with any applicable statute, rule, or regulation.

IN NO EVENT SHALL CSA GROUP, ITS VOLUNTEERS, MEMBERS, SUBSIDIARIES, OR AFFILIATED COMPANIES, OR THEIR EMPLOYEES, DIRECTORS, OR OFFICERS, BE LIABLE FOR ANY DIRECT, INDIRECT, OR INCIDENTAL DAMAGES, INJURY, LOSS, COSTS, OR EXPENSES, HOWSOEVER CAUSED, INCLUDING BUT NOT LIMITED TO SPECIAL OR CONSEQUENTIAL DAMAGES, LOST REVENUE, BUSINESS INTERRUPTION, LOST OR DAMAGED DATA, OR ANY OTHER COMMERCIAL OR ECONOMIC LOSS, WHETHER BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE), OR ANY OTHER THEORY OF LIABILITY, ARISING OUT OF OR RESULTING FROM ACCESS TO OR POSSESSION OR USE OF THIS DOCUMENT, EVEN IF CSA GROUP HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, INJURY, LOSS, COSTS, OR EXPENSES.

In publishing and making this document available, CSA Group is not undertaking to render professional or other services for or on behalf of any person or entity or to perform any duty owed by any person or entity to another person or entity. The information in this document is directed to those who have the appropriate degree of experience to use and apply its contents, and CSA Group accepts no responsibility whatsoever arising in any way from any and all use of or reliance on the information contained in this document.

CSA Group is a private not-for-profit company that publishes voluntary standards and related documents. CSA Group has no power, nor does it undertake, to enforce compliance with the contents of the standards or other documents it publishes.

Intellectual property rights and ownership

As between CSA Group and the users of this document (whether it be in printed or electronic form), CSA Group is the owner, or the authorized licensee, of all works contained herein that are protected by copyright, all trade-marks (except as otherwise noted to the contrary), and all inventions and trade secrets that may be contained in this document, whether or not such inventions and trade secrets are protected by patents and applications for patents. Without limitation, the unauthorized use, modification, copying, or disclosure of this document may violate laws that protect CSA Group’s and/or others’ intellectual property and may give rise to a right in CSA Group and/or others to seek legal redress for such use, modification, copying, or disclosure. To the extent permitted by licence or by law, CSA Group reserves all intellectual property rights in this document.

Patent rights

Attention is drawn to the possibility that some of the elements of this standard may be the subject of patent rights. CSA Group shall not be held responsible for identifying any or all such patent rights. Users of this standard are expressly advised that determination of the validity of any such patent rights is entirely their own responsibility.

Authorized use of this document

This document is being provided by CSA Group for informational and non-commercial use only. The user of this document is authorized to do only the following:

If this document is in electronic form:

- load this document onto a computer for the sole purpose of reviewing it;
- search and browse this document; and
- print this document if it is in PDF format.

Limited copies of this document in print or paper form may be distributed only to persons who are authorized by CSA Group to have such copies, and only if this Legal Notice appears on each such copy.

In addition, users may not and may not permit others to

- alter this document in any way or remove this Legal Notice from the attached standard;
- sell this document without authorization from CSA Group; or
- make an electronic copy of this document.

If you do not agree with any of the terms and conditions contained in this Legal Notice, you may not load or use this document or make any copies of the contents hereof, and if you do make such copies, you are required to destroy them immediately. Use of this document constitutes your acceptance of the terms and conditions of this Legal Notice.



This is a preview. [Click here to purchase the full publication.](#)

Standards Update Service

CAN/CSA-ISO 11138-1:17 *August 2017*

Title: *Sterilization of health care products — Biological indicators — Part 1: General requirements*

To register for e-mail notification about any updates to this publication

- go to shop.csa.ca
- click on **CSA Update Service**

The **List ID** that you will need to register for updates to this publication is **2425796**.

If you require assistance, please e-mail techsupport@csagroup.org or call 416-747-2233.

Visit CSA Group's policy on privacy at www.csagroup.org/legal to find out how we protect your personal information.

Canadian Standards Association (operating as “CSA Group”), under whose auspices this National Standard has been produced, was chartered in 1919 and accredited by the Standards Council of Canada to the National Standards system in 1973. It is a not-for-profit, nonstatutory, voluntary membership association engaged in standards development and certification activities.

CSA Group standards reflect a national consensus of producers and users — including manufacturers, consumers, retailers, unions and professional organizations, and governmental agencies. The standards are used widely by industry and commerce and often adopted by municipal, provincial, and federal governments in their regulations, particularly in the fields of health, safety, building and construction, and the environment.

Individuals, companies, and associations across Canada indicate their support for CSA Group’s standards development by volunteering their time and skills to Committee work and supporting CSA Group’s objectives through sustaining memberships. The more than 7000 committee volunteers and the 2000 sustaining memberships together form CSA Group’s total membership from which its Directors are chosen. Sustaining memberships represent a major source of income for CSA Group’s standards development activities.

CSA Group offers certification and testing services in support of and as an extension to its standards development activities. To ensure the integrity of its certification process, CSA Group regularly and continually audits and inspects products that bear the CSA Group Mark.

In addition to its head office and laboratory complex in Toronto, CSA Group has regional branch offices in major centres across Canada and inspection and testing agencies in eight countries. Since 1919, CSA Group has developed the necessary expertise to meet its corporate mission: CSA Group is an independent service organization whose mission is to provide an open and effective forum for activities facilitating the exchange of goods and services through the use of standards, certification and related services to meet national and international needs.

For further information on CSA Group services, write to
CSA Group
178 Rexdale Boulevard
Toronto, Ontario, M9W 1R3
Canada

A National Standard of Canada is a standard developed by an SCC-accredited Standards Development Organization (SDO), and approved by the Standards Council of Canada (SCC), in accordance with SCC’s: *Requirements and Guidance — Accreditation for Standards Development Organizations*, and *Requirements and Guidance — Approval of National Standards of Canada Designation*. More information on National Standard requirements can be found at www.scc.ca.

An SCC-approved standard reflects the consensus of a number of experts whose collective interests provide, to the greatest practicable extent, a balance of representation of affected stakeholders. National Standards of Canada are intended to make a significant and timely contribution to the Canadian interest.

SCC is a Crown corporation within the portfolio of Industry Canada. With the goal of enhancing Canada’s economic competitiveness and social well-being, SCC leads and facilitates the development and use of national and international standards. SCC also coordinates Canadian participation in standards development, and identifies strategies to advance Canadian standardization efforts. Accreditation services are provided by SCC to various customers, including product certifiers, testing laboratories, and standards development organizations. A list of SCC programs and accredited bodies is publicly available at www.scc.ca.

Users should always obtain the latest edition of a National Standard of Canada from the standards development organization responsible for its publication, as these documents are subject to periodic review.

Standards Council of Canada
600-55 Metcalfe Street
Ottawa, Ontario, K1P 6L5
Canada



Standards Council of Canada
Conseil canadien des normes

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.

TMA trade-mark of the Canadian Standards Association, operating as “CSA Group”

This is a preview. Click here to purchase the full publication.

National Standard of Canada

CAN/CSA-ISO 11138-1:17 Sterilization of health care products — Biological indicators — Part 1: General requirements (ISO 11138-1:2017, IDT)

Prepared by
International Organization for Standardization



Reviewed by



®A trademark of the Canadian Standards Association,
operating as "CSA Group"

Approved by



Standards Council of Canada
Conseil canadien des normes

*Published in August 2017 by CSA Group
A not-for-profit private sector organization
178 Rexdale Boulevard, Toronto, Ontario, Canada M9W 1R3*

*To purchase standards and related publications, visit our Online Store at shop.csa.ca
or call toll-free 1-800-463-6727 or 416-747-4044.*

*ICS 11.080.01
ISBN 978-1-4883-1174-1*

*© 2017 CSA Group
All rights reserved. No part of this publication may be reproduced in any form whatsoever
without the prior permission of the publisher.*

[This is a preview. Click here to purchase the full publication.](#)

CAN/CSA-ISO 11138-1:17

Sterilization of health care products — Biological indicators — Part 1: General requirements (ISO 11138-1:2017, IDT)

CSA Preface

This is the second edition of CAN/CSA-ISO 11138-1, *Sterilization of health care products — Biological indicators — Part 1: General requirements*, which is an adoption without modification of the identically titled ISO (International Organization for Standardization) Standard 11138-1 (third edition, 2017-03). It supersedes the previous edition published in 2007 as CAN/CSA-Z11138-1 (adopted ISO 11138-1:2006).

For brevity, this Standard will be referred to as “CAN/CSA-ISO 11138-1” throughout.

This Standard was reviewed for Canadian adoption by the SCC Mirror Committee to ISO/TC 198, under the jurisdiction of the CSA Technical Committee on Medical Device Reprocessing and the CSA Strategic Steering Committee on Health Care Technology & Systems, 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.

© 2017 CSA Group

All rights reserved. No part of this publication may be reproduced in any form whatsoever without the prior permission of the publisher. ISO material is reprinted with permission. Where the words “this International Standard” appear in the text, they should be interpreted as “this National Standard of Canada”.

Inquiries regarding this National Standard of Canada should be addressed to

CSA Group

178 Rexdale Boulevard, Toronto, Ontario, Canada M9W 1R3

1-800-463-6727 • 416-747-4000

<http://csa.ca>

To purchase standards and related publications, visit our Online Store at shop.csa.ca or call toll-free 1-800-463-6727 or 416-747-4044.

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 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.*

CSA Technical Committee on Medical Device Reprocessing

I. Pequegnat	STERIS Canada Inc., Mississauga, Ontario <i>Category: Producer Interest</i>	<i>Chair</i>
G. Schultz	Winnipeg Regional Health Authority, Winnipeg, Manitoba <i>Category: User Interest</i>	<i>Vice-Chair</i>
N. Aelick	University of Alberta Hospital, Edmonton, Alberta	<i>Associate</i>
T. Bennardo	Sault Area Hospital, Sault Ste. Marie, Ontario <i>Category: General Interest</i> <i>Representing Medical Device Reprocessing Association of Ontario (MDRAO)</i>	
B. Bolding	MDR Consultant, Burnaby, British Columbia <i>Category: User Interest</i>	
L. Buist	Interior Health Authority, Kelowna, British Columbia <i>Category: User Interest</i>	
S. Cleaver	3M Canada Company, London, Ontario <i>Category: Producer Interest</i>	
L. Coutoulas	Southlake Regional Health Centre, Newmarket, Ontario <i>Category: User Interest</i>	
S. Dufresne	TSO ₃ Inc., Québec, Québec <i>Category: Producer Interest</i>	
K. Flynn	ACART, Toronto, Ontario	<i>Associate</i>