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Group**

**Z314.14-15**

# **Selection and use of packaging (sterile barrier systems) in healthcare settings**

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**Z314.14-15**  
***Selection and use of packaging  
(sterile barrier systems) in  
healthcare settings***



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# Contents

Technical Committee on Sterilization	3
Subcommittee on Packaging	7
Preface	10
<b>0 Introduction</b>	<b>11</b>
<b>1 Scope</b>	<b>11</b>
<b>2 Reference publications</b>	<b>13</b>
<b>3 Definitions</b>	<b>15</b>
<b>4 General requirements for all packaging systems</b>	<b>17</b>
4.1 General	17
4.2 Evaluation, purchase, and inspection	18
4.3 Product design	18
4.4 Assembly	19
4.5 Labelling or labelling information	19
4.6 Packaging system performance testing	20
4.7 Sterile barrier system stability	21
<b>5 Pouches and rolls</b>	<b>21</b>
5.1 Evaluating for purchase	21
5.2 Using pouches	22
5.3 Selection and package assembly	22
5.4 Testing	23
5.4.1 General	23
5.4.2 Verification of the closure seal process	23
5.4.3 Installation qualification of heat sealer	23
5.4.4 Operational qualification (OQ)	24
5.4.5 Performance qualification (PQ)	24
<b>6 Wrappers</b>	<b>25</b>
6.1 Barrier properties of single- and multiple-use wrapper	25
6.1.1 Microbiological barrier	25
6.1.2 Maintenance of package integrity (shelf life)	25
6.1.3 Liquid barrier	25
6.2 Evaluation for purchase	26
6.3 Using wrappers	27
6.4 Wrapper selection and package assembly	27
6.4.1 General	27
6.4.2 Wrapping techniques/methods	28
6.4.3 Closures/sealing	28
6.4.4 Labelling	28
6.5 Verification of the wrapping process (folding and closing of sterilization wraps)	29

6.5.1	Installation qualification (IQ)	29
6.5.2	Operational qualification (OQ)	29
6.5.3	Performance qualification	30
<b>7</b>	<b>Sterilization trays and container systems</b>	<b>31</b>
7.1	General	31
7.2	Evaluation for purchase	31
7.2.1	General	31
7.2.2	Inspection of newly purchased or acquired sterilization trays and container systems	33
7.3	Testing	34
7.3.1	Pre-purchase	34
7.3.2	Common test procedures for all sterilization trays and container systems	35
7.3.3	Testing requirements specific to dynamic-air-removal (pre-vacuum) and gravity-displacement steam sterilizers	37
7.3.4	Testing requirements for chemical sterilizers	37
7.4	Using sterilization trays and container systems	37
7.4.1	Disassembly	37
7.4.2	Decontamination	37
7.4.3	Inspection	38
7.4.4	Preparation and assembly	39
7.4.5	Use of absorbent materials	41
7.4.6	Accessories	41
7.4.7	Pouches and wraps	41
7.4.8	Security of lids	42
7.4.9	Chemical indicators	42
7.4.10	Additional requirements for sterilization container systems	42
7.5	Quality assurance	43
7.5.1	General	43
7.5.2	Maintenance of sterilization trays and container systems	43

---

Annex A (informative)	— Guidance for the purchase of sterilization container systems	47
Annex B (normative)	— Information to be supplied by the manufacturer	54
Annex C (informative)	— Properties of sterilization wrappers	57

# Technical Committee on Sterilization

<b>I. Pequegnat</b>	STERIS Canada Inc, Mississauga, Ontario <i>Category: Producer Interest</i>	<i>Chair</i>
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<b>D. Moore</b>	Regional Infection Control Network Mississauga- Halton, Brampton, Ontario	<i>Associate</i>

<b>R. Nightingale</b>	K-Bro Linen Systems Inc, Toronto, Ontario <i>Category: User Interest</i>	
<b>L. O'Neil</b>	Public Health Agency of Canada, Ottawa, Ontario <i>Category: Government and/or Regulatory Authority</i>	
<b>R.D. Parker</b>	Stryker Corporation, Kalamazoo, Michigan, USA	<i>Associate</i>
<b>M. Patenaude</b>	Johnson & Johnson Medical Companies, Gatineau, Québec <i>Category: Producer Interest</i>	
<b>A. Pelletier</b>	Institut National de Santé Publique du Québec, Montréal, Québec <i>Category: Government and/or Regulatory Authority</i>	
<b>D. Pinsonneault</b>	Jewish General Hospital, Montréal, Québec <i>Category: User Interest</i>	
<b>A. Poirier</b>	Horizon Health Network, Fredericton, New Brunswick	<i>Associate</i>
<b>P. Quinn</b>	Saskatoon Health Region, Saskatoon, Saskatchewan <i>Category: User Interest</i>	
<b>A.M. Rancourt</b>	McGill University Health Centre, Montréal, Québec <i>Category: User Interest</i>	
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<b>J. Storrord</b>	Government of New Brunswick Department of Health, Fredericton, New Brunswick <i>Category: Government and/or Regulatory Authority</i>	

<b>M. Steele-Rodway</b>	Eastern Health Medical Device Reprocessing Serv, Mount Pearl, Newfoundland and Labrador <i>Category: User Interest</i>	
<b>K.G. Stitz</b>	MEDEC, Toronto, Ontario	<i>Associate</i>
<b>A. Sun</b>	SciCan Ltd., Toronto, Ontario	<i>Associate</i>
<b>D. Trudeau</b>	Providence Health Care, Vancouver, British Columbia <i>Category: User Interest</i>	
<b>C. Williamson</b>	Alberta Health Services, Edmonton, Alberta	<i>Associate</i>
<b>S.M. Wilson</b>	Alberta Health Services, Edmonton, Alberta	<i>Associate</i>
<b>C. Cortisoz</b>	CSA Group, Toronto, Ontario	<i>Project Manager</i>

# ***Subcommittee on Packaging***

<b>P. Quinn</b>	Saskatoon Health Region, Saskatoon, Saskatchewan	<i>Chair</i>
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<b>B. Bolding</b>	Consultant, Burnaby, British Columbia	
<b>D. Bosnjak</b>	Hamilton Health Sciences, Hamilton, Ontario	
<b>L. Buist</b>	Interior Health Authority, Kelowna, British Columbia	
<b>B.J. Bushman</b>	Standard Textile Co. Ltd, Cincinnati, Ohio, USA	
<b>L. Coutoulas</b>	Southlake Regional Health Centre, Newmarket, Ontario	
<b>P.M. Haney</b>	Keir Surgical Ltd., Vancouver, British Columbia	
<b>L. Jakeman</b>	L Jakeman Consulting, West Porters Lake, Nova Scotia	
<b>D.W. Johnson</b>	Halyard Health, Alpharetta, Georgia, USA	
<b>M. Kanlic</b>	St Joseph's Healthcare - Charlton Campus, Hamilton, Ontario	
<b>R. Khotar</b>	Providence Health Care, Vancouver, British Columbia	
<b>C. Landers</b>	Weeneebayko Area Health Authority, Moose Factory, Ontario	

---

<b>G. Lankin</b>	Lac-Mac Limited, London, Ontario
<b>N. Mazurat</b>	University of Manitoba College of Dentistry, Winnipeg, Manitoba
<b>M. Middaugh</b>	Cardinal Health, Waukegan, Illinois, USA
<b>L. Murphy</b>	L. Murphy Consulting, Furry Creek, British Columbia
<b>K.P. Murray</b>	Medline Canada Corporation, Oakville, Ontario
<b>P. Nichol</b>	Medline Industries, Inc, Waukegan, Illinois, USA
<b>R. Nightingale</b>	K-Bro Linen Systems Inc, Toronto, Ontario
<b>B. O'Neill</b>	London Hospital Linen Service Inc., London, Ontario
<b>R.D. Parker</b>	Stryker Corporation, Kalamazoo, Michigan, USA
<b>M. Patenaude</b>	Johnson & Johnson Medical Companies, Gatineau, Québec
<b>I. Pequegnat</b>	STERIS Canada Inc, Mississauga, Ontario
<b>A.M. Rancourt</b>	McGill University Health Centre, Montréal, Québec
<b>J. Rasmussen</b>	William Osler Health Centre Brampton Memorial Hospital Campus, Brampton, Ontario
<b>A. Schnitker</b>	Miele Limited, Vaughan, Ontario

---

<b>M.H. Scholla</b>	DuPont Protection Technologies, Wilmington, Delaware, USA	
<b>G. Schultz</b>	Winnipeg Regional Health Authority, Winnipeg, Manitoba	
<b>M.N. Smith</b>	Getinge Sourcing LLC, Rochester, New York, USA	
<b>J.M. Spear</b>	Aesculap, Westminster, Maryland, USA	
<b>S. Stacey</b>	Trudell Medical Marketing Ltd., London, Ontario	
<b>M. Steele-Rodway</b>	Eastern Health Medical Device Reprocessing Serv, Mount Pearl, Newfoundland and Labrador	
<b>M.B. Walsh</b>	Medline Industries Inc, Mundelein, Illinois, USA	
<b>C. Williamson</b>	Alberta Health Services, Edmonton, Alberta	
<b>M. Zambrano</b>	Trillium Health Partners Mississauga Hospital, Mississauga, Ontario	
<b>C. Cortisoz</b>	CSA Group, Toronto, Ontario	<i>Project Manager</i>

# Preface

This is the fifth edition of CSA Z314.14, *Selection and use of packaging (sterile barrier systems) in healthcare settings*. It supersedes the previous editions published in 2010, 2004, and 1993 under the title, *Selection and use of sterilization containers*. It is one of the CSA Z314 series of Standards addressing quality systems, decontamination, disinfection, packaging, sterilization, and storage.

This Standard specifies requirements for the effective use of sterile barrier systems, including wrappers, and includes selection criteria for healthcare settings to use when purchasing these medical devices. This Standard has been revised to work in tandem with applicable requirements of CSA Z314.0, *Medical device reprocessing – General requirements*, and other standards in the CSA Z314 series.

CSA group would like to acknowledge the contributions of Andrée Pelletier, Johanne Dionne, Diane Pinsonnault, and Anne Marie Rancourt towards the development of this Standard.

This Standard was prepared by the Subcommittee on Packaging, under the jurisdiction of the Technical Committee on Sterilization and the Strategic Steering Committee on Healthcare Technology, and has been formally approved by the Technical Committee.

## Notes:

- 1) *Use of the singular does not exclude the plural (and vice versa) when the sense allows.*
- 2) *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 of the Standard to judge its suitability for their particular purpose.*
- 3) *This Standard was developed by consensus, which is defined by CSA Policy governing standardization — Code of good practice for standardization as “substantial agreement. Consensus implies much more than a simple majority, but not necessarily unanimity”. It is consistent with this definition that a member may be included in the Technical Committee list and yet not be in full agreement with all clauses of this Standard.*
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  - a) *define the problem, making reference to the specific clause, and, where appropriate, include an illustrative sketch;*
  - b) *provide an explanation of circumstances surrounding the actual field condition; and*
  - c) *where possible, phrase the request in such a way that a specific “yes” or “no” answer will address the issue.*

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

## Z314.14-15

# ***Selection and use of packaging (sterile barrier systems) in healthcare settings***

## **0 Introduction**

Medical devices are used in every medical procedure. Patients and healthcare professionals expect these medical devices to be safe. The safety of medical devices begins with the manufacturer and is supported by a system of national standards and government regulations that includes medical device licensing, construction and performance standards, and problem reporting systems. These systems serve as a guide for healthcare facilities and users to ensure proper care and handling is achieved every time a medical device is used.

Within this structure there are, departments, clinics, and offices located on and off site that reprocess medical devices. These areas play an essential role and face unique challenges. Unlike the medical device manufacturer, medical device reprocessing personnel work with a wide array of medical devices manufactured by different companies, these medical devices are received in varying states of cleanliness and repair. It is the responsibility of the medical device reprocessing department (MDRD) to develop standard operating procedures that provide for each step of the cleaning, inspection, and functionality testing, followed by disinfection or sterilization for each medical device. These standard operating procedures are developed using the device manufacturer's validated written instruction for reprocessing a reusable medical device. The goal is to provide medical devices that perform as intended by the manufacturer and are safe for reuse.

Packaging is a vital step in reprocessing. The user requires knowledge of the quality and type of packaging required to maintain the sterility of medical devices. Packaging is available in many types and this Standard will address the types, quality and wrapping techniques.

This Standard is one of a series of standards to be used in conjunction with CSA Z314.0, *Medical device reprocessing – General requirements*, which provides a framework to establish, document, and maintain requirements for the reprocessing of medical devices as part of a quality management system. This Standard is intended to provide comprehensive requirements for the safe and reliable packaging of reusable medical devices.

## **1 Scope**

### **1.1**

This Standard defines essential elements for the evaluation, selection, inspection, and proper use of preformed sterile barrier systems, sterile barrier systems, and packaging systems. The selection criteria include minimum performance requirements to help healthcare settings choose products that are appropriate for their intended use.

## 1.2

This Standard applies to the following

- a) reusable sterilization container systems including trays and cassettes intended for use in sterilization processes that do not rely on wrapping;
- b) sterilization wraps including
  - i) reusable textile sterilization wrap; and
  - ii) disposable sterilization wrap; and
- c) sealable sterilization pouches and rolls.

In addition this Standard addresses items intended to facilitate aseptic presentation such as protective organizing cases or trays that require additional wrapping or an additional method of containment for sterilization and maintenance of sterility.

## 1.3

This Standard sets forth requirements in the following areas:

- a) policies and procedures related to the use of packaging;
- b) general characteristics, selection, and purchasing of packaging;
- c) evaluation of the design, performance, and labelling of packaging;
- d) matching of packaging to appropriate sterilization methods and cycles;
- e) testing prior to use;
  - i) preparation, and assembly of packaging including wrapping methods;
  - ii) infection prevention and control; and
  - iii) aseptic presentation and use; and
- f) quality assurance.

## 1.4

This Standard does not provide requirements for

- a) ongoing sterility assurance programs in healthcare settings;
- b) textile gowns and packs;
- c) laundering and maintenance of reusable sterilization gowns and wraps;
- d) sterilizer loading and unloading; and
- e) use of packaging materials after opening, for other purposes (e.g. sterile fields, transport of contaminated items).

**Note:** CSA Z314.0 provides requirements for quality management systems. CSA Z314.3 and CSA Z314.23 provide requirements for steam sterilization and chemical sterilization in healthcare settings. CSA Z314.10.1 provides requirements for the selection and use of sterilization gowns and drapes. CSA Z314.10.2 provides requirements for laundering of reusable surgical textiles. CSA Z314.15 provided requirements for, storage, handling, and transportation of single use and reusable medical devices.

## 1.5

In this Standard, “shall” is used to express a requirement, i.e., a provision that the user is obliged to satisfy in order to comply with the standard; “should” is used to express a recommendation or that which is advised but not required; and “may” is used to express an option or that which is permissible within the limits of the Standard.

Notes accompanying clauses do not include requirements or alternative requirements; the purpose of a note accompanying a clause is to separate from the text explanatory or informative material.

Notes to tables and figures are considered part of the table or figure and may be written as requirements.

Annexes are designated normative (mandatory) or informative (non-mandatory) to define their application.

## 2 Reference publications

This Standard refers to the following publications, and where such reference is made, it shall be to the edition listed below:

### **CSA Group**

Z314.0-13

*Medical device reprocessing — General requirements*

Z314.3-14

*Effective sterilization in health care settings by the steam process*

Z314.8-14

*Decontamination of reusable medical devices*

Z314.10.1-15

*Selection and use of gowns and drapes, intended for use in healthcare settings*

Z314.10.2-15

*Laundering, maintenance, and preparation of multiple-use gowns, drapes, and wrappers in health care settings*

CAN/CSA-Z314.22-04 (R2009)

*Management of loaned, shared, and leased medical devices*

Z314.23-12

*Chemical sterilization of reusable medical devices in health care facilities*

CAN/CSA-Z14161-11

*Sterilization of health care products — Biological indicators — Guidance for the selection, use, and interpretation of results*

CAN/CSA-Z15882-09 (R2014)

*Sterilization of health care products—Chemical indicators—Guidance for selection, use and interpretation of results*

CAN/CSA-Z17664-06 (R2011)

*Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

### **AATCC (American Association of Textile Chemists and Colorists)**

Test Method 42

*Water Resistance: Impact Penetration Test (Developed in 1945 by AATCC Committee RA63)*