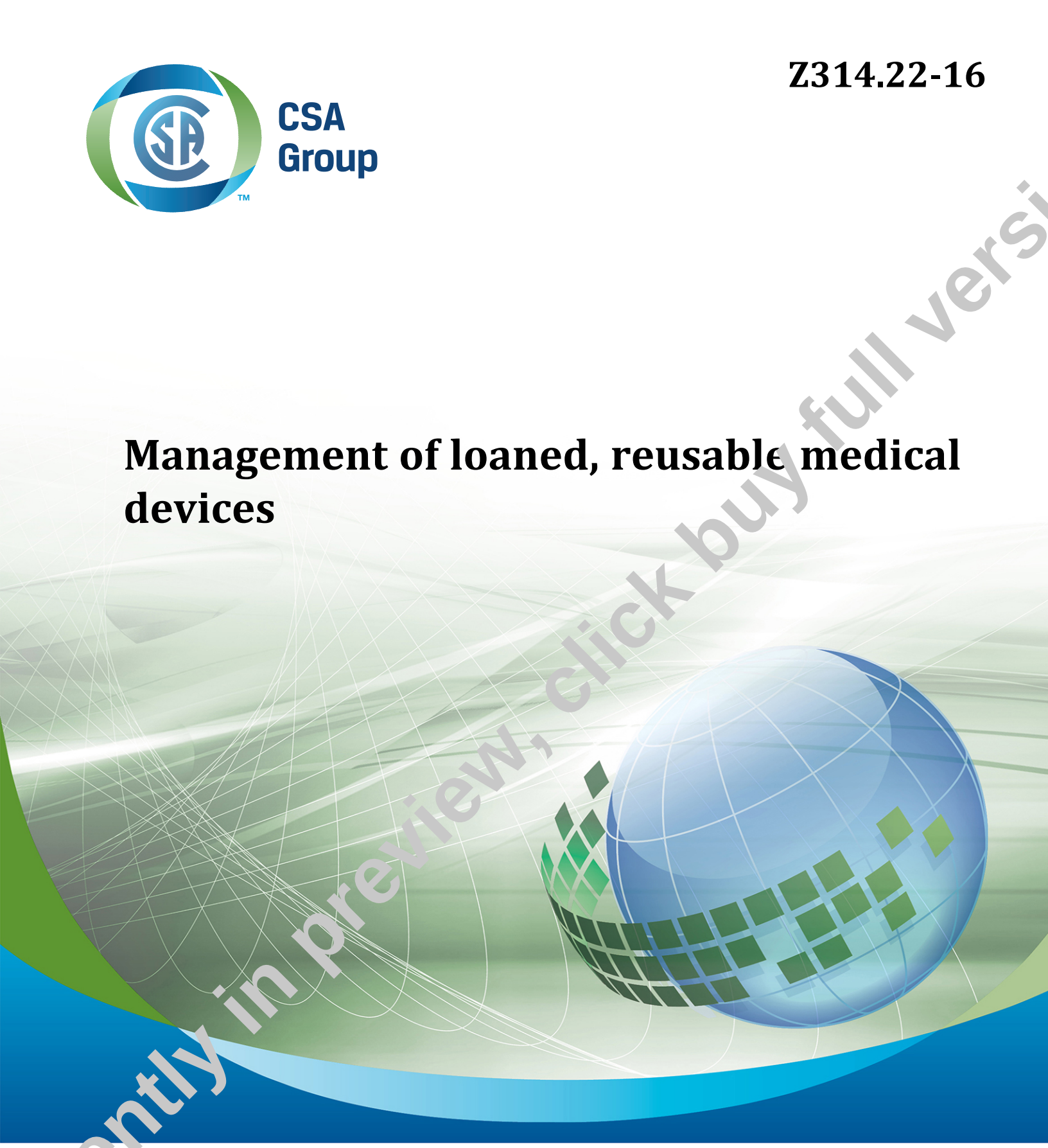
CSA Group

Z314.22-16

Management of loaned, reusable medical devices



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Preface

This is the third edition of CSA Z314.22, *Management of loaned, reusable medical devices*. It supersedes the previous editions, published in 2010 and 2004. It is intended to be used with the CSA Z314 series of Standards pertaining to the reprocessing of 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 acknowledges that the development of this Standard was made possible, in part, by the financial support of CADTH.

This Standard was prepared by the Subcommittee on Loaned, Shared, or Leased Medical Devices, under the jurisdiction of the Technical Committee on Sterilization and the Strategic Steering Committee on Health Care Technology and Systems, 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.*

4) *To submit a request for interpretation of this Standard, please send the following information to* ***inquiries@csagroup.org*** *and include "Request for interpretation" in the subject line:*

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.*

Committee interpretations are processed in accordance with the CSA Directives and guidelines governing standardization *and are available on the* Current Standards Activities *page at* ***standardsactivities.csa.ca****.*

5) *This Standard is subject to review five years from the date of publication. 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.*

Z314.22-16
Management of loaned, reusable medical devices

0 Introduction

Health care settings use loaned, reusable medical devices for a number of reasons. Apart from the potential cost savings of not keeping expensive medical devices in inventory, loaned, reusable medical devices allow health care settings to save on maintenance costs as well as to keep up with changing technology.

Nevertheless, these devices can create difficulties for a health care setting if they arrive at the facility without notice, are incomplete, unclean, or too late for reprocessing. Manufacturers and distributors can likewise be affected if devices are returned contaminated or incomplete.

As a way of addressing these problems, this Standard specifies common requirements for health care settings, manufacturers, distributors, and other parties involved with loaned, reusable medical devices. The goal of this Standard is to help protect patients, health care professionals, manufacturers, and distributors from the hazards and costs associated with contaminated medical devices, damaged or missing parts, scheduling issues, and malfunctions. This Standard is one of a series of standards to be used in conjunction with CSA Z314.0, which provides a framework to establish, document, and maintain requirements for the reprocessing of medical devices as part of a quality management system.

1 Scope

1.1

This Standard

a) specifies requirements for critical and semi-critical loaned, reusable medical devices; and
b) applies to all health care settings and vendors that use, send, receive, transport, or reprocess loaned, reusable medical devices.

1.2

This Standard specifies requirements for

a) policies and standard operating procedures (SOPs) related to loaned, reusable medical devices;
b) logistics and timing;
c) accountabilities and responsibilities;
d) transportation; and
e) required documentation.

Note: *Examples of the types of transactions covered by this Standard include*

a) *health care setting to health care setting; and*
b) *vendor to health care setting and health care setting to vendor.*

1.3

This Standard does not address:

a) decontamination of reusable medical devices (see CSA Z314.8);

b) sterilization of medical devices (see CSA Z314.3 and CSA Z314.23);
c) packaging of medical devices (see CSA Z314.14);
d) storage of medical devices (see CSA Z314.15);
e) single-use medical devices that accompany loaned, reusable medical devices; and
f) non-critical equipment (e.g., light source) accompanying critical and semi critical devices.

Note: *The health care setting should ensure that equipment accompanying critical and semi critical devices go through the proper channels.*

1.4

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, including all amendments published thereto.

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

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

Z314.15-15
Storage, transportation and distribution of single use and reusable medical devices

Z314.23-16
Chemical sterilization of reusable medical devices in health care facilities

CAN/CSA-Z17664-06 (R2011)
Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices

