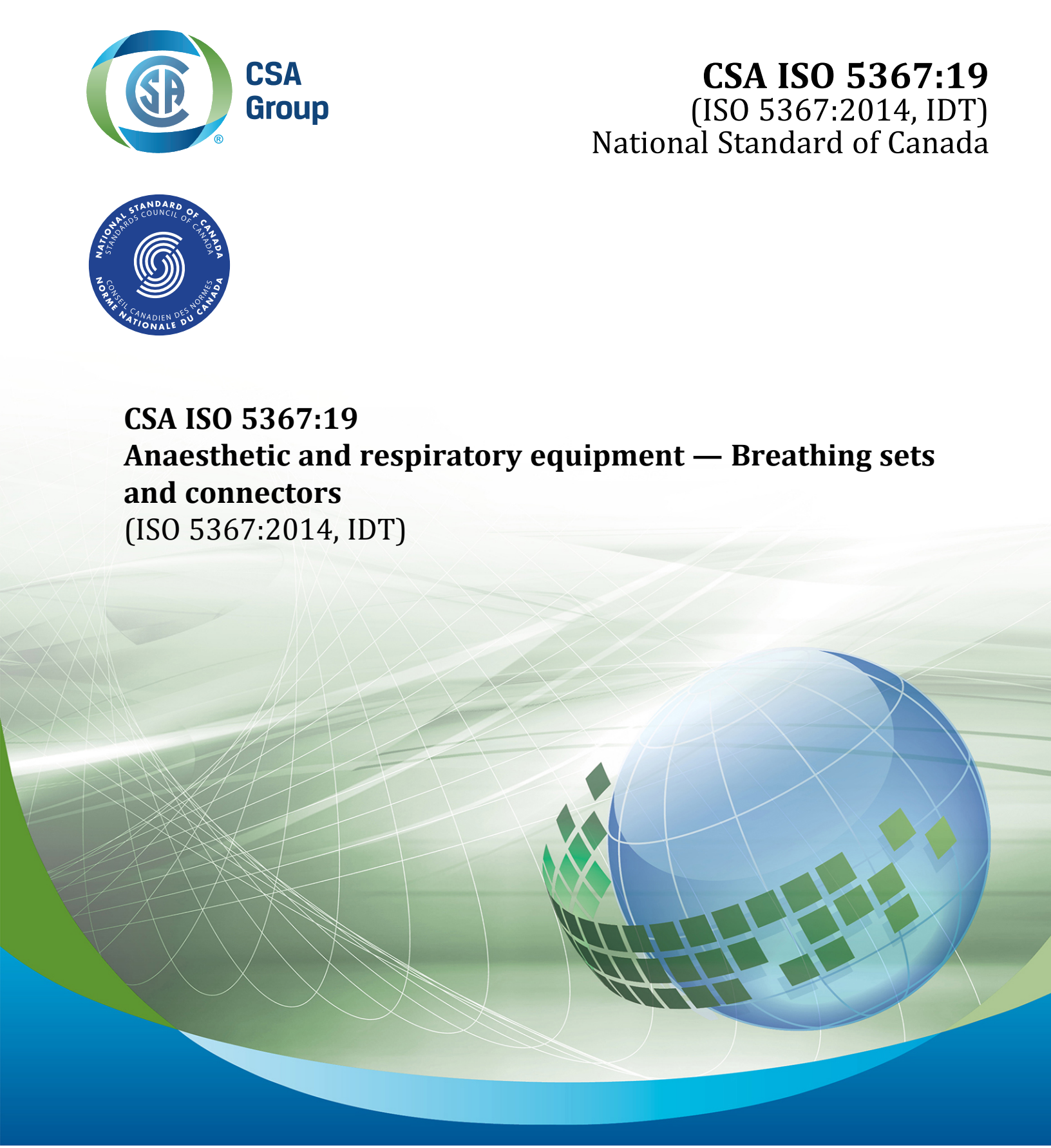
CSA Group

CSA ISO 5367:19
(ISO 5367:2014, IDT)
National Standard of Canada

CSA ISO 5367:19
Anaesthetic and respiratory equipment — Breathing sets and connectors
(ISO 5367:2014, IDT)



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.

Standards Update Service

CSA ISO 5367:19
March 2019

Title: *Anaesthetic and respiratory equipment — Breathing sets and connectors*

To register for e-mail notification about any updates to this publication
- go to **store.csagroup.org**
- click on **CSA Update Service**

The **List ID** that you will need to register for updates to this publication is **2427133**.

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 a Standards Council of Canada (SCC) accredited Standards Development Organization, in compliance with requirements and guidance set out by SCC. More information on National Standards of Canada can be found at www.scc.ca.

SCC is a Crown corporation within the portfolio of Innovation, Science and Economic Development (ISED) 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.

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

CSA Group

Standards Council of Canada
Conseil canadien des normes

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

National Standard of Canada

CSA ISO 5367:19

Anaesthetic and respiratory equipment — Breathing sets and connectors

(ISO 5367:2014, IDT)

Prepared by
International Organization for Standardization

Reviewed by

CSA Group

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

Published in March 2019 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 **store.csagroup.org***
or call toll-free 1-800-463-6727 or 416-747-4044.

ICS 11.040.10
ISBN 978-1-4883-2143-6

CSA ISO 5367:19
Anaesthetic and respiratory equipment — Breathing sets and connectors
(ISO 5367:2014, IDT)

CSA Preface

This is the second edition of CSA ISO 5367-19, *Anaesthetic and respiratory equipment — Breathing sets and connectors*, which is an adoption without modification of the identically titled ISO (International Organization for Standardization) Standard 5367 (fifth edition, 2014-10-15). It supersedes the previous edition published in 2014 as CAN/CSA-ISO 5367, *Breathing tubes intended for use with anaesthetic apparatus and ventilators* (adopted ISO 5367:2000).

For brevity, this Standard will be referred to as "CSA ISO 5367 "throughout.

This Standard was reviewed for Canadian adoption by the CSA Technical Committee on Perioperative Safety, under the jurisdiction of the CSA Strategic Steering Committee on Health Care Technology & Systems, 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.

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
https://www.csagroup.org

*To purchase standards and related publications, visit our Online Store at **https://store.csagroup.org/** 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. 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.*

INTERNATIONAL STANDARD

ISO 5367

Fifth edition
2014-10-15

Anaesthetic and respiratory equipment — Breathing sets and connectors

Matériel d'anesthésie et de réanimation respiratoire — Systèmes respiratoires et raccords

Reference number
ISO 5367:2014(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related equipment*.

This fifth edition cancels and replaces the fourth edition (ISO 5367:2000), which has been technically revised.

The following major changes were made:

— title and scope;

— additional normative references;

— additional terms and definitions;

— additional general requirements, including risk management, usability, clinical and biophysical research;

— requirements for coaxial tubing, revised leakage limits, and testing for flow resistance and compliance;

— revised limits for prevention of electrostatic charges;

— revised requirements for marking of packaging, including the use of symbols, disclosure of intended patient category, flow resistance and compliance;

— added an annex for rationale;

— added an annex for hazard identification for risk assessment;

— revised test method annexes for resistance to flow, security of attachments, leakage and compliance;

— added an annex for compliance with the EU Directives.

Introduction

This International Standard contains requirements for **breathing sets, breathing tubes,** and connectors that are intended to function as accessories to anaesthetic and respiratory equipment. **Breathing sets** and **breathing tubes** are characterized by certain design requirements such as a means of connection and leakage limits. Disclosure requirements for **compliance** and flow resistance values allow the user to make an informed choice when connecting these accessories to a **breathing system**. These design requirements are intended to allow operation within the limits of performance of the **anaesthetic breathing systems** and **ventilator breathing systems** with which the accessories are intended to operate.

This International Standard includes requirements for both single-use and reusable **breathing sets** and **breathing tubes**. Re-usable **breathing sets and breathing tubes** are intended to comply with the requirements of this International Standard for the recommended service life.

Certain tests are performed under constant pressure to simplify the test methodology. It is recognized that this does not reflect clinical use, where pressure is intermittent and peak pressures occur for short periods. The limits in the test methods take this into account. While such test methods do not address product variability, the limits required also take this into account.

Terms defined in this International Standard are set in **bold type**.

Throughout this International Standard, text for which a rationale is provided in Annex A is indicated by an asterisk (*).

Throughout this International Standard, all pressures are denoted in SI units of hPa with corresponding cmH_2O equivalent values rounded to the nearest whole cmH_2O.

NOTE The unit cmH_2O is not an SI notation and is not used in ISO documents; rounded cmH_2O values are given for information only to allow comparison to medical literature and related **breathing system** standards.

Anaesthetic and respiratory equipment — Breathing sets and connectors

1 Scope

*This International Standard specifies basic requirements for **breathing sets and breathing tubes** intended to be used with **anaesthetic breathing systems**, **ventilator breathing systems**, humidifiers or nebulizers. It applies to **breathing sets** and **breathing tubes** and **patient end adaptors** supplied already assembled and to those supplied as components and assembled in accordance with the manufacturer's instructions.

This International Standard is applicable to **breathing sets** which include special components (e.g. water traps) between the **patient end** and **machine end** which are supplied already assembled.

This International Standard is not applicable to **breathing sets** and **breathing tubes** for special purposes.

EXAMPLE 1 Ventilators having special **compliance**, pressure or breathing frequency requirements.

EXAMPLE 2 High Frequency Oscillatory Ventilation, (HFOV) or High Frequency Jet Ventilation (HFJV).

EXAMPLE 3 **Breathing sets** and **breathing tubes** with special connectors for neonatal ventilation.

Provision is made for coaxial and related bifurcated, double-lumen, or multiple-lumen **breathing sets** and **breathing tubes** suitable for use with **patient end adaptors**.

NOTE 1 Examples of various types of **breathing sets** with **patient end adaptors** are depicted in Annex A.

Requirements for exhalation valves, exhaust valves, **adjustable pressure-limiting (APL) valves,** heat and moisture exchangers (HMEs), breathing filters, and reservoir bags, if provided, are not covered by this International Standard.

NOTE 2 ISO 80601-2-12, ISO 80601-2-13, ISO 9360-1[3], ISO 23328-2[4], and ISO 5362[1] cover these.

NOTE 3 Certain aspects of heated-wire **breathing tubes** are discussed in ISO 8185[2].

2 Normative references

*The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE See Annex A for information on the use of dated and undated normative references.

ISO 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 14971, *Medical devices — Application of risk management to medical devices*