

ISO/TC 121/SC 2

Secretariat: ANSI

Voting begins on:
2015-10-29

Voting terminates on:
2015-12-29

Tracheal tubes designed for laser surgery — Requirements for marking and accompanying information

Tubes trachéaux destinés aux opérations laser — Exigences relatives au marquage et aux informations d'accompagnement

iTeh STANDARD PREVIEW
(standards.iteh.ai)
Full standard:
<https://standards.iteh.ai/catalog/standards/sist/05c881a-107d-4736-8343-a80a031b4bd3/iso-14408-2016>

Please see the administrative notes on page iii

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.



Reference number
ISO/FDIS 14408:2015(E)

ISO/CEN PARALLEL PROCESSING

This final draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement. The final draft was established on the basis of comments received during a parallel enquiry on the draft.

This final draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel two-month approval vote in ISO and formal vote in CEN.

Positive votes shall not be accompanied by comments.

Negative votes shall be accompanied by the relevant technical reasons.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
Full standard:
<https://standards.iteh.ai/catalog/standards/sist/05e4c13d-107d-4736-8343-a80a031b4bd3/iso-14408-2016>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2015, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Marking and labelling	2
4.1 Use of symbols	2
4.2 Marking	2
4.3 Labelling of packs	3
4.4 Labelling of shelf or multi-unit containers	3
5 Information to be supplied by the manufacturer	4
5.1 Instructions for preparation and use of laser-resistant tracheal tube and tracheal tube treatments	4
5.2 Indications for use	4
5.3 Warnings and precautions about the use of the tube	4
5.4 Graph showing test results for laser resistance	4
Annex ZA (informative) Relationship between this document and the Essential Requirements of EU Directive 93/42/EEC	7
Bibliography	9

iTeh STANDARD PREVIEW
 (standards.iteh.ai)
 Full standard:
<https://standards.iteh.ai/catalog/standards/sist/5564c13d-107d-4736-8343-a80a031b4bd3/iso-14408-2015>

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 third edition cancels and replaces the second edition (ISO 14408:2005), which has been technically revised.

Major changes include an update on the normative references to ISO 11990-1, *Lasers and laser-related equipment — Determination of laser resistance of tracheal tubes — Part 1 Tracheal tube shaft* and ISO 11990-2, *Lasers and laser-related equipment — Determination of laser resistance of tracheal tubes — Part 2: Tracheal tube cuffs*.

The attention of Member Bodies is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended, or revised ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

Introduction

This International Standard is intended to provide requirements for marking, labelling, and information supplied for tracheal tubes which are designed for resistance to ignition by a laser and which have been tested for laser resistance in accordance with ISO 11990-1 and ISO 11990-2 including a standard format for reporting results obtained when tested in accordance with ISO 11990-1 and ISO 11990-2. It is intended that, by limiting the requirements to disclosure of information determined in accordance with standard test methods, the manufacturer will be allowed maximum use of alternatives in design and materials.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Full standard:
<https://standards.iteh.ai/catalog/standards/sist/05e4c13d-107d-4736-8343-a80a031b4bd3/iso-14408-2016>

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Full standard:
<https://standards.iteh.ai/catalog/standards/sist/05e4c13d-107d-4736-8343-a80a031b4bd3/iso-14408-2016>

Tracheal tubes designed for laser surgery — Requirements for marking and accompanying information

1 Scope

This International Standard specifies marking, labelling, and information to be supplied by the manufacturer for cuffed and uncuffed tracheal tubes and related materials designed to resist ignition by a laser

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.

ISO 7000¹⁾, *Graphical symbols for use on equipment — Registered symbols*

ISO 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 11990-1, *Lasers and laser-related equipment — Determination of laser resistance of tracheal tubes — Part 1: Tracheal tube shaft*

ISO 11990-2, *Lasers and laser-related equipment — Determination of laser resistance of tracheal tubes — Part 2: Tracheal tube cuffs*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

tracheal tube

tube designed for insertion through the larynx into the trachea to convey gases and vapours to and from the trachea

[SOURCE: ISO 4135:2001]

3.2

cuff

inflatable balloon permanently attached around the tracheal tube near the patient end to provide an effective seal between the tube and the trachea

[SOURCE: ISO 4135:2001, modified]

3.3

laser-resistant tracheal tube

tracheal tube specifically designed by the manufacturer for use during laser surgery of the airway

Note 1 to entry: This includes devices sold preassembled or in kit form.

1) The graphical symbols in ISO 7000 are also available on line in the ISO web store. For more information, consult http://www.iso.org/iso/publications_and_e-products/databases.htm.

3.4

laser-resistant tracheal tube treatment

covering and/or surface treatment that adapts or modifies non-laser-resistant tracheal tubes for use in laser surgery of the airway

3.5

upper anatomical airway

upper airway

airway above the laryngotracheal junction

3.6

laser-resistant portion

portion of the tracheal tube intended by the manufacturer to be laser-resistant

4 Marking and labelling

4.1 Use of symbols

The requirements given in 4.2, 4.3, and 4.4 may be met by the use of the appropriate symbols in accordance with ISO 7000 or ISO 15223-1.

4.2 Marking

4.2.1 Marking of tracheal tubes, connectors, packages, inserts and information to be supplied by the manufacturer should comply with EN 1041.

4.2.2 The following shall be permanently marked on or affixed to the tracheal tube or tracheal tube treatment:

- a) the name and/or trademark of the manufacturer or supplier;
- b) the nominal inside diameter in millimetres designated by the manufacturer for the tracheal tube;
- c) model identification, if necessary to distinguish between similar products from the same manufacturer;
- d) for cuffed tracheal tubes, a reference to any preparation designated by the manufacturer as essential for protection of the cuff from ignition (e.g. "inflate the cuff with saline or water before use").

4.2.3 Additional marks may be provided (optional) to assist in positioning the tracheal tube within the trachea.

4.2.4 Any component of a laser-resistant tracheal tube treatment that is affixed to, or protects the treatment covering or material until it is applied to the tracheal tube, shall be marked with a reference to any preparatory steps designated by the manufacturer as essential to the laser resistance of the tube (e.g. "saturate covering with saline solution").

4.2.5 If the laser-resistant portion is not visually obvious, this shall be marked.

4.2.6 If any marks are applied to the laser-resistant area of the tracheal tube, the test to determine laser-resistance values required for the graph in 5.4 shall be carried out directly upon these markings.

4.2.7 All markings shall be of sufficient size and contrast to be legible.

4.2.8 All markings shall be non-toxic and tissue-compatible. Marking materials shall resist deterioration by anaesthetic agents. The markings shall be durable and remain legible during use of the tube. If the

tracheal tube is intended for reuse, the materials shall resist deterioration by the recommended agents and procedures used to clean and disinfect or sterilize the device.

4.3 Labelling of packs

The following information shall be on the laser-resistant tracheal tube or laser-resistant tracheal tube treatment pack:

- a) a description of contents, including wording to indicate that the tracheal tube is intended for use in laser surgery;
- b) the name and/or trademark of the manufacturer or supplier;
- c) the product code or catalogue number;
- d) the largest outside diameter after preparations for use;
- e) the nominal internal diameter in millimetres designated by the manufacturer for the tracheal tube;
- f) the means to ensure traceability such as type, batch or serial number or year of manufacture or symbols 5.1.5 from ISO 15223-1:2012/ISO 7000-2492, 5.1.6 from ISO 15223-1:2012/ISO 7000-2493 or 5.1.7 from ISO 15223-1:2012/ISO 2498 or 5.1.3 from ISO 15223-1:2012/ISO 7000-2497;
- g) the word "STERILE" or "NON-STERILE", as appropriate or symbols 5.2.1 from ISO 15223-1:2012/ISO 7000-2499 (or as appropriate for sterilization method) or 5.2.7 from ISO 15223-1/ISO 7000-2609;
- h) for tracheal tubes not intended for reuse, the words "SINGLE USE" or equivalent or symbol 5.4.2 from ISO 15223-1/ISO 7000;
- i) for cuffed tracheal tubes, the cuff resting diameter, expressed in millimetres;
- j) any storage instructions, including a statement of known conditions of storage likely to result in rapid deterioration of the materials (e.g. high temperature, ultraviolet light or fluorescent lighting) or appropriate symbols in ISO 15223-1:2012, 5.3; or appropriate symbols in ISO 15223-1:2012, 5.3 or appropriate symbols in ISO 15223-1:2012, 5.3 symbol 5.1.4 from ISO 15223-1:2012/ISO 7000-2607;
- k) an instruction to refer to information describing laser resistance, including type(s) and nominal wavelength(s), considered by the manufacturer as appropriate for use and contraindications.
- l) an indication of the presence of natural rubber (latex), if present in the device with the word "LATEX", or symbol 5.4.5 from ISO 15223-1:2012/ISO 7000-2725

4.4 Labelling of shelf or multi-unit containers

The following information shall be on shelf or multi-unit containers:

- a) the descriptive name of the device (trademark, etc.);
- b) the name and/or trademark and address of
 - the manufacturer or supplier, and
 - where the manufacturer does not have an address within the locale, an authorized representative within the locale
 to which the responsible organization can refer;
- c) the product code or catalogue number;
- d) the nominal outside diameter of the tube;