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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

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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).

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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.

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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.

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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 7000[1)], *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?= .

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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

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