Irish Standard
I.S. EN ISO 14408:2016

Tracheal tubes designed for laser surgery - Requirements for marking and accompanying information (ISO 14408:2016)

I.S. EN ISO 14408:2016

Incorporating amendments/corrigenda/National Annexes issued since publication:

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This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):

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Údarás um Chaighdeáin Náisiúnta na hÉireann

National Foreword

I.S. EN ISO 14408:2016 is the adopted Irish version of the European Document EN ISO 14408:2016, Tracheal tubes designed for laser surgery - Requirements for marking and accompanying information (ISO 14408:2016)

This document does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with this document does not of itself confer immunity from legal obligations.

In line with international standards practice the decimal point is shown as a comma (,) throughout this document.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14408

March 2016

ICS 11.040.10

Supersedes EN ISO 14408:2009

English Version

Tracheal tubes designed for laser surgery - Requirements for marking and accompanying information (ISO 14408:2016)

Tubes trachéaux destinés aux opérations laser - Exigences relatives au marquage et aux informations d'accompagnement (ISO 14408:2016)

Trachealtuben für die Laserchirurgie - Anforderungen an die Kennzeichnung und die begleitenden Informationen (ISO 14408:2016)

This European Standard was approved by CEN on 30 January 2016.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

European foreword

This document (EN ISO 14408:2016) has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” in collaboration with Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment”, the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2016, and conflicting national standards shall be withdrawn at the latest by March 2019.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 14408:2009.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 14408:2016 has been approved by CEN as EN ISO 14408:2016 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of Directive 93/42/EEC on Medical Devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard confers, within the limits of the scope of this standard, a presumption of conformity with the relevant Essential Requirements of that Directive.

NOTE 1 Where a reference from a clause of this European Standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC / Directive 90/385/EEC, as amended by 2007/47/EC. This means that risks have to be reduced "as far as possible", "to a minimum", "to the lowest possible level", "minimized" or "removed", according to the wording of the corresponding essential requirement.

NOTE 2 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/notes
4.3 g) 4.4 g)	8.7	Partly covered. Marked sterile if appropriate.
5.2.2 5.5.4, 5.9, 5.5.1	9.1	Partly covered, limited to information relating to use with laser surgery equipment.
4.2.2 b) 4.2.3 4.3 d), e), j) 4.4 d), e)	9.2 (first and second indent)	Partly covered to address only the risk of injury in connection with their physical features by specifying sizing and marking conventions for the ID/OD of the tracheal tube, optional positioning marks, marking for the OD of the cuff.
4.2.3	10.2	Partly addressed with optional marks to aid in intubation positioning.
4	13.1	Partly covered by mandating limited marking and labelling and instructions on the tube, unit and packing labels, and instructions for use.
4.1	13.2	Partly covered. Symbols are mandated to conform to ISO 7000 or - EN ISO 15223-1
4.2.2 a) 4.3 b)	13.3 a)	Name and or trademark of manufacturer or supplier mandated on the device and on individual pack.

4.4 b)		Authorized representative mandated
4.3 a) 4.4 a)	13.3 b)	
4.3 g) 4.4 g)	13.3 c)	Only identifies that the device is sterile (if applicable).
4.3 f) 4.4 f)	13.3 d)	Very limited only to the choice of either a batch number or serial number or year of manufacture on the individual pack; batch number on the shelf/multi-pack.
4.3 k) 4.4 i)	13.3 e)	
4.3 h) 4.4 h)	13.3 f)	
4.2.2 d) 4.3 j) 4.4 k) 5.1.1	13.3 i)	Limited to information regarding laser resistance and related special set-up instructions
4.3 l) 4.4 l) 5.4	13.3 i)	Limited to information charts regarding laser resistance.
4.3 l) 4.4 l) 5.4	13.3 j)	Limited to information charts regarding laser resistance.
5.3	13.3 k)	
4	13.6 a)	Mandated markings, labelling and instructions, limited to those listed above.
5.4	13.6 b)	Limited to information charts regarding laser resistance.
5.1.2	13.6 h), first sentence	Partly covered to mandated instructions for cleaning and disinfection or sterilization.
5.1.1	13.6 i)	Limited to details for preparation for use related to laser resistance.
5.3	13.4 l)	Party covered to precautions relating to contact with lasers.

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this document.

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INTERNATIONAL STANDARD

ISO 14408

Third edition
2016-02-15

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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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 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.

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?= .