SLOVENSKI STANDARD
SIST EN ISO 14408:2016

01-maj-2016

Nadomešča:
SIST EN ISO 14408:2009

Sapnični (endotrahealni) tubusi za lasersko kirurgijo - Zahteve za označevanje in spremne podatke (ISO 14408:2016)

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

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

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

Ta slovenski standard je istoveten z: **EN ISO 14408:2016**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

SIST EN ISO 14408:2016 **en**

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.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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 United Kingdom.

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

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Ref. No. EN ISO 14408:2016 E

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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.

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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