SLOVENSKI STANDARD
SIST EN ISO 14408:2009

01-julij-2009

Nadomeġļ a:
SIST EN ISO 14408:2005

Sapniļ ni (endotrahealni) tubusi za lasersko kirurgijo - Zahteve za oznaļ evanje in spremne podatke (ISO 14408:2005)

Tracheal tubes designed for laser surgery - Requirements for marking and accompanying information (ISO 14408:2005)

Trachealtuben für die Laserchirurgie - Anforderungen an die Kennzeichnung und die begleitenden Informationen (ISO 14408:2005)

Tubes trachéaux destinés aux opérations laser - Exigences relatives au marquage et aux informations d'accompagnement (ISO 14408:2005)

Ta slovenski standard je istoveten z: **EN ISO 14408:2009**

ICS:

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

SIST EN ISO 14408:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14408

April 2009

ICS 11.040.10

Supersedes EN ISO 14408:2005

English Version

Tracheal tubes designed for laser surgery - Requirements for marking and accompanying information (ISO 14408:2005)

Tubes trachéaux destinés aux opérations laser - Exigences relatives au marquage et aux informations d'accompagnement (ISO 14408:2005)

Trachealtuben für die Laserchirurgie - Anforderungen an die Kennzeichnung und die begleitenden Informationen (ISO 14408:2005)

This European Standard was approved by CEN on 21 March 2009.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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

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Foreword

The text of ISO 14408:2005 has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 14408:2009 by 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 October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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 14408:2005.

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 EC Directive.

For relationship with EC Directive, 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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 14408:2005 has been approved by CEN as a EN ISO 14408:2009 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 the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 – Correspondence between this European Standard and EU Directives

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4.1	13.2	
4.2	13.1	
4.2.8	13.3 m)	
4.3	13.3	
4.3 a)	13.3 b), 13.4	
4.3 b)	13.3 a)	
4.3 c)	13.3 d)	
4.3 d)	13.3 b)	
4.3 e)	13.3 b)	
4.3 f)	13.3 d)	
4.3 g)	8.7, 13.3 c)	
4.3 h)	13.3 f)	
4.3 i)	13.3 b)	
4.3 j)	13.3 i)	
4.3 k)	13.3 e)	
4.3 l)	13.3 j)	
4.4 a)	13.3 b)	
4.4 b)	13.3 b)	
4.4 c)	13.3 d)	
4.4 d)	13.3 b)	
4.4 e)	13.3 b)	
4.4 f)	13.3 d)	
4.4 g)	8.7, 13.3 c)	
4.4 h)	13.3 f)	
4.4 i)	13.3 e)	
4.4 k)	13.3 i)	
4.4 l)	1.3, 13.6 c)	

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
5.1.1	13.6 d)	
5.1.2	13.6 h)	
5.2	13.1, 13.6 c)	
5.3	13.1, 13.6 b)	
5.4	13.1, 13.3 j)	
1 through 5	13.1	
-	13.3 (a):	This relevant Essential Requirement is not fully addressed in this Standard
-	13.3 (f)	This relevant Essential Requirement is not fully addressed in this Standard
-	13.6 (h) (2nd paragraph)	This relevant Essential Requirement is not fully addressed in this Standard
-	13.6 (h) (3rd paragraph)	This relevant Essential Requirement is not fully addressed in this Standard
-	13.6 (q)	This relevant Essential Requirement is not addressed in this Standard

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 14408

Second edition
2005-06-01

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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