Laserkirurgias kasutatavad trahheotoomiavoolikud. Nõuded märgistusele ja kaasnevale informatsioonile

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 14408:2009 sisaldab Euroopa standardi EN ISO 14408:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 14408:2009 consists of the English text of the European standard EN ISO 14408:2009.
Standard on kinnitatud Eesti Standardikeskuse 29.05.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 29.05.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 15.04.2009.	Date of Availability of the European standard text 15.04.2009.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.10

Võtmesõnad: accident prevention, apparatus, designations, determination, fire conditions

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14408

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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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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.

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 including a standard format for reporting results obtained when tested in accordance with ISO 11990. 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 referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11990, *Optics and optical instruments — Lasers and laser-related equipment — Determination of laser resistance of tracheal tube shafts*