SLOVENSKI STANDARD
SIST EN ISO 5366-1:2005

01-januar-2005

Nadomeġļa:
SIST EN 1282-1:2000

Anestezijska in dihalna oprema ï Traheostomske cevke ï 1. del: Cevke in priključ ki za odrasle (ISO 5366-1:2000)

Anaesthetic and respiratory equipment - Tracheostomy tubes - Part 1: Tubes and connectors for use in adults (ISO 5366-1:2000)

Anästhesie- und Beatmungsgeräte - Tracheotomietuben - Teil 1: Tuben und Verbindungsstücke zur Anwendung bei Erwachsenen (ISO 5366-1:2000)

Matériel d'anesthésie et de réanimation respiratoire - Tube de trachéostomie - Partie 1: Tubes et raccords pour adultes (ISO 5366-1:2000)

Ta slovenski standard je istoveten z: **EN ISO 5366-1:2004**

ICS:

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

SIST EN ISO 5366-1:2005 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 5366-1

July 2004

ICS 11.040.10

Supersedes EN 1282-1:1996

English version

Anaesthetic and respiratory equipment - Tracheostomy tubes - Part 1: Tubes and connectors for use in adults (ISO 5366-1:2000)

Matériel d'anesthésie et de réanimation respiratoire - Tube de trachéostomie - Partie 1: Tubes et raccords pour adultes (ISO 5366-1:2000)

Anästhesie- und Beatmungsgeräte - Tracheotomietuben - Teil 1: Tuben und Verbindungsstücke zur Anwendugn bei Erwachsenen (ISO 5366-1:2000, korrigiert und neu gedruckt im Jahre 2001)

This European Standard was approved by CEN on 21 June 2004.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

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

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN ISO 5366-1:2004: E

Foreword

The text of ISO 5366-1:2000 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 5366-1:2004 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 January 2005, and conflicting national standards shall be withdrawn at the latest by January 2005.

This document supersedes EN 1282-1:1996.

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 ZB, 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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 5366-1:2000 has been approved by CEN as EN ISO 5366-1:2004 without any modifications.

NOTE Normative references to International Standards are listed in Annex ZA (normative).

Annex ZA
(normative)

Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

Publication	Year	Title	EN	Year
ISO 594-1	1986	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements	EN 20594-1	1993
ISO 4135	2001	Anaesthetic and respiratory equipment - Vocabulary	EN ISO 4135	2001
ISO 10993-1	1997	Biological evaluation of medical devices - Part 1: Evaluation and testing	EN ISO 10993-1	1997

Annex ZB

(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.

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 normative clauses of this standard given in Table ZB.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.

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

TABLE ZB.1 - Correspondence between this European Standard and EU Directives

Clause/subclause of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
1	N/A	
2	N/A	
3	N/A	
4	1, 2 a), 3	
5	1, 2 a), 3, 7.1 a), 7.1 b), 7.2	
6	1, 2, 3, 9.2 a)	
6.1	4, 9.1, 9.3	
6.1.1	7.5	
6.1.4	7.5	
6.2	4	
6.3	9.1, 9.3	
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6.4.2	4	
6.5.2.1	2 b)	
6.5.3	9.1	
6.7	4	
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7.2.2	5, 8.1, 8.3	
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8.2.1 b)	13.3 b), 2 c)	
8.2.1 c)	13.3 a)	
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8.3.2 b)	13.3 b)	
8.3.2 d)	13.3 b)	
8.3.2 e)	13.3 b)	
8.3.2 f)	13.3 b)	
8.3.2 g)	13.3 a)	
8.3.2 h)	13.3 d), 13.5	
8.3.2 i)	8.6, 13.6 h)	
8.3.2 j)	8.1, 8.3, 8.7, 13.2, 13.3 b), c)	
8.3.2 k)	13.3 b)	
8.3.2 l)	2 c), 13.3 b)	
8.3.3	13.3 e)	
8.3.3 a)	13.3 b), 13.4	
8.3.3 b)	13.3 b)	
8.3.3 c)	13.3 b)	
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8.3.3 h)	13.3 b), d) – f), 13.5	
Annex C	4, 7.1 b), 7.3, 9.2 a)	
C.1.2	13.6 h)	
C.1.3	9.3	
N/A = not applicable		

INTERNATIONAL STANDARD

ISO 5366-1

Fourth edition
2000-12-15

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2001-09-01

Anaesthetic and respiratory equipment — Tracheostomy tubes —

Part 1: Tubes and connectors for use in adults

Matériel d'anesthésie et de réanimation respiratoire — Tubes de trachéostomie —

Partie 1: Tubes et raccords pour adultes

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