



# SLOVENSKI STANDARD SIST EN ISO 5366-1:2009

01-julij-2009

BUXca Yý U  
SIST EN ISO 5366-1:2005

5 bYghYn]g\_U]b`X] UbUcdfYa U!`HfU Ycglca g\_YWj\_Y!`%`XY.`7 Yj\_Y]b`df[\_`1 \_]  
nUcXfUg`YfIGC`)`\*\*!%&\$\$L

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 - Tubes de trachéostomie - Partie 1: Tubes et raccords pour adultes (ISO 5366-1:2000)

Ta slovenski standard je istoveten z: EN ISO 5366-1:2009

**ICS:**

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

SIST EN ISO 5366-1:2009 en

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

SIST EN ISO 5366-1:2009

<https://standards.iteh.ai/catalog/standards/sist/abf7b1f6-aec3-4e31-bdbd-b833c03114a7/sist-en-iso-5366-1-2009>

EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN ISO 5366-1**

April 2009

ICS 11.040.10

Supersedes EN ISO 5366-1:2004

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 - Tubes  
de trachéostomie - Partie 1: Tubes et raccords pour adultes  
(ISO 5366-1:2000)

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

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.

<https://standards.iteh.ai/catalog/standards/sist/ab17b116-acc3-4e31-bdbd-b833c03114a7/sist-en-iso-5366-1-2009>



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

**Management Centre: Avenue Marnix 17, B-1000 Brussels**

<b>Contents</b>	<b>Page</b>
<b>Foreword</b> .....	<b>3</b>
<b>Annex ZA (Informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC</b> .....	<b>4</b>

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[SIST EN ISO 5366-1:2009](https://standards.iteh.ai/catalog/standards/sist/abf7b1f6-aec3-4e31-bdbd-b833c03114a7/sist-en-iso-5366-1-2009)  
<https://standards.iteh.ai/catalog/standards/sist/abf7b1f6-aec3-4e31-bdbd-b833c03114a7/sist-en-iso-5366-1-2009>

## 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 5366-1:2009 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 5366-1:2004.

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.

<https://standards.iteh.ai/catalog/standards/sist/abf7b1f6-aec3-4e31-bdbd-b833c03114a7/sist-en-iso-5366-1-2009>

### Endorsement notice

The text of ISO 5366-1:2000 has been approved by CEN as a EN ISO 5366-1:2009 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
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	
6.4.1	4	
6.4.2	4	
6.5.2.1	2 b)	
6.5.3	9.1	
6.7	4	
7.1	8.1, 8.3, 8.4	
7.2.2	5, 8.1, 8.3	
8.1	13.2, 13.3 g) – m), 13.4	
8.2	13.1	
8.2.1 a)	13.3 b)	
8.2.1 b)	13.3 b), 2 c)	
8.2.1 c)	13.3 a)	
8.3	13.1, 13.3 e)	
8.3.1	13.2	
8.3.2 a)	13.3 b), 13.4	
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)	

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
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)	
8.3.3 d)	13.3 a)	
8.3.3 e)	13.3 d), 13.5	
8.3.3 f)	8.6, 13.6 h)	
8.3.3 g)	8.1, 8.3, 8.7, 13.2, 13.3 b), c)	
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	
-	1 (2nd paragraph, 1st dash) (2nd paragraph, 2nd dash)	These parts of this Essential Requirement are not addressed in this Standard
-	6a) <a href="https://standards.iteh.ai/catalog/standards/sist/abf7b1f6-aec3-4e31-b833c03114a7/sist-en-iso-5366-1-2009">SIST EN ISO 5366-1:2009</a>	This part of this Essential Requirement is not addressed in this Standard
-	7.1 (3rd dash)	This part of this Essential Requirement is not addressed in this Standard
-	7.5 (1st paragraph)	This part of this Essential Requirement is not fully addressed in this European Standard
-	7.5 (2nd paragraph)	This part of this Essential Requirement is not fully addressed in this European Standard
-	13.3 (a):	This relevant Essential Requirement is not fully addressed in this European Standard
-	13.3 (f)	This relevant Essential Requirement is not fully addressed in this European Standard

## EN ISO 5366-1:2009 (E)

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
-	13.6 (h)(2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
-	13.6 (h)(3rd paragraph)	This relevant Essential Requirement is not addressed in this European Standard
-	13.6 (q)	This relevant Essential Requirement is not addressed in this European Standard
N/A = not applicable		

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

## iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN ISO 5366-1:2009](https://standards.iteh.ai/catalog/standards/sist/abf7b1f6-aec3-4e31-bdbd-b833c03114a7/sist-en-iso-5366-1-2009)

<https://standards.iteh.ai/catalog/standards/sist/abf7b1f6-aec3-4e31-bdbd-b833c03114a7/sist-en-iso-5366-1-2009>



# INTERNATIONAL STANDARD

**ISO**  
**5366-1**

Fourth edition  
2000-12-15

Corrected and reprinted  
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*

[SIST EN ISO 5366-1:2009](https://standards.iteh.ai/catalog/standards/sist/abf7b1f6-aec3-4e31-bdbd-b833c03114a7/sist-en-iso-5366-1-2009)

<https://standards.iteh.ai/catalog/standards/sist/abf7b1f6-aec3-4e31-bdbd-b833c03114a7/sist-en-iso-5366-1-2009>



Reference number  
ISO 5366-1:2000(E)

© ISO 2000

**PDF disclaimer**

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

## iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN ISO 5366-1:2009](https://standards.iteh.ai/catalog/standards/sist/abf7b1f6-aec3-4e31-bdbd-b833c03114a7/sist-en-iso-5366-1-2009)

<https://standards.iteh.ai/catalog/standards/sist/abf7b1f6-aec3-4e31-bdbd-b833c03114a7/sist-en-iso-5366-1-2009>

© ISO 2000

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.ch](mailto:copyright@iso.ch)  
Web [www.iso.ch](http://www.iso.ch)

Printed in Switzerland

**Contents**

	Page
1 Scope .....	1
2 Normative references .....	1
3 Terms and definitions .....	1
4 Size designation and dimensions .....	4
5 Materials .....	6
6 Design and finish .....	6
7 Requirements for tracheostomy tubes supplied sterile .....	7
8 Marking and labelling .....	8

**Annexes**

A Test method for the security of attachment of connector and neck-plate to tracheostomy tube.....	10
A.1 Principle .....	10
A.2 Apparatus .....	10
A.3 Procedure .....	10
A.4 Expression of results .....	10
B Test method for determining the resting diameter of the cuff .....	11
B.1 Principle .....	11
B.2 Apparatus .....	11
B.3 Procedure .....	11
B.4 Expression of results .....	11
C Guidance on materials and design .....	12
C.1 Materials .....	12
C.2 Design .....	12
Bibliography.....	13

iTech STANDARD PREVIEW  
(standards.itech.ai)

SIST EN ISO 5366-1:2009  
<https://standards.itech.ai/catalog/standards/sist/abf7b1f6-aec3-4e31-bdbd-b833c03114a7/sist-en-iso-5366-1-2009>