SLOVENSKI STANDARD
SIST EN ISO 5361:2016

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Nadomešča:
SIST EN ISO 5361:2013
SIST EN ISO 5361:2013/AC:2013

Anestezijska in dihalna oprema - Sapnični (endotrahealni) tubusi in priključki (ISO 5361:2016)

Anaesthetic and respiratory equipment - Tracheal tubes and connectors (ISO 5361:2016)

Anästhesieund Beatmungsgeräte - Trachealtuben und Verbindungsstücke (ISO 5361:2016)

Matériel d'anesthésie et de réanimation respiratoire - Sondes trachéales et raccords (ISO 5361:2016)

Ta slovenski standard je istoveten z: **EN ISO 5361:2016**

ICS:

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

SIST EN ISO 5361:2016 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 5361

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English Version

Anaesthetic and respiratory equipment - Tracheal tubes and connectors (ISO 5361:2016)

Matériel d'anesthésie et de réanimation respiratoire - Sondes trachéales et raccords (ISO 5361:2016)

Anästhesie- und Beatmungsgeräte - Trachealtuben und Verbindungsstücke (ISO 5361:2016)

This European Standard was approved by CEN on 15 July 2016.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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European foreword

This document (EN ISO 5361:2016) 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of an identical text or by endorsement, at the latest by March 2017, and conflicting national standards shall be withdrawn at the latest by September 2019.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 5361:2012.

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.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard “within the meaning of Annex ZA", the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When the ISO or IEC standard is referred to in the ISO text standard, this must be understood as a normative reference to the parallel EN standard or dated ISO standard, as outlined below, including the foreword and the Annexes ZZ.

NOTE The way in which these references documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table – Correlations between normative references and dated EN and ISO/IEC standards

Normative references as listed in Clause 2	Equivalent dated standard	
	EN	ISO/IEC
ISO 594-1	EN 20594-1:1993 + AC:1993 + A1:1997	ISO 594-1:1986
ISO 5356-1	EN ISO 5356-1:2015	ISO 5356-1:2015
ISO 7000[1]		ISO 7000:2014
ISO 10993-1	EN ISO 10993-1:2009	ISO 10993-1:2009
ISO 11135	EN ISO 11135:20104	ISO 11135:2014

ISO 11137-1	EN ISO 11137-1:2015	ISO 11137-1:2006 + AMD 1:2013
ISO 11607-1	EN ISO 11607-1:2009 + A1:2014	ISO 11607-1:2006 + AMD 1:2014
ISO 14155	EN ISO 14155:2011	ISO 14155:2011 + CORR 1:2011
ISO 14971	EN ISO 14971:2012	ISO 14971:2007
ISO 15223-1	EN 15223-1:—[1]	ISO 15223-1:2015[1]
ISO 15223-2	—	ISO 15223-2:2010
EN 556-1:2001	EN 556-1:2001	—
EN 1041	EN 1041:2008 + A1:2013	—
ASTM F640-2007	—	—
ASTM D3002-2007	—	—
1 The graphical symbols in ISO 7000 are also available on line in the ISO web store. For more information, consult http://www.iso.org/iso/publications_and_e-products/databases.htm?=.		

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 5361:2016 has been approved by CEN as EN ISO 5361:2016 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 Commission's standardization request [M/023 concerning the development of European Standards related to medical devices] / [M/295 concerning the development of European Standards related to medical devices] / [reference number and title of any other standardization request as relevant] to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 160].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative 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.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/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 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 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 International Standard and Annex I of Directive 93/42/EEC [OJ L 169]<Tbl_large_span></Tbl_large_span>

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
7.1 (2nd indent) 7.1 (3rd indent)	5.3 4.1.6	7.1 (second indent) Partly Covered. There are no requirements for materials apart for e requirements to perform a risk assessment.
7.2	5.3.1 7.1 7.2	7.1 and 7.2 covers the integrity of the packaging only for devices supplied sterile.
7.3	5.3.1 5.3.3	5.3.1 and 5.3.1 First part covered; does not cover devices intended to

		administer medicinal products.
7.5 (second paragraph)	5.3.4 8.3.1 m)	
8.1	7.2	Covered only for packaging of sterile devices.
8.3	7.2	Partly addressed by 7.2 which mandates the requirements of ISO 11607-1 that the packaging is suitable to prevent contamination during transportation and use.
8.4	7.1	7.1 mandates that sterile devices satisfy 4.1 of EN 556-1.
8.7	8.3.1 h)	Partly covered. Marked sterile if appropriate.
9.1	5.2.2	Generally covered by mandating construction and testing of the interface connector.
9.2 (first and second indent)	5.1 5.2 Tables 1a), 1b), and 1c) 5.5 5.7 6 8.3.2 b)	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, curvature of the tube, marking for the OD of the cuff, and pressure limits for cuff performance testing.
10.1 (first sentence)	8.2.1.1 d)	Partly covered to address length measurement and marking in cm.
10.2	8.2.1.1 d) 8.2.1.2	Partly addressed. Length marking positions are mandated to provide ergonomic angular visibility during intubation. Glottic depth marks aid in intubation positioning.
10.3	8.2.1.1 d), and e)	Length marking is mandated using SI units (cm).
12.7.4	5.2.2.5 5.6.5	Tracheal tube gas connectors are mandated to comply with ISO 5356-1 for 15 mm connectors. Tracheal tube cuff inflation

		connectors are mandated to comply with ISO 594-1 for Luers.
13.1	8	Covered by mandating marking and labelling and instructions on the tube, connector, unit label, and instructions for use. 4.2.1
13.3 b)	7.2 8.3.1 b) 8.3.1 c) 8.3.1 d) 8.3.1 h)	Only identifies that the device is sterile (if applicable). Marking of 8.3.1 b), c) and d) on the unit pack will further address this requirement.
13.3 c)	8.3.1 h)	
13.3 d)	8.3.1 g)	Batch code preceded by the word “LOT” mandated for EU countries.
13.3 e)	8.3.1 g)	‘Use by date’ is only addressed via a ‘strong’ recommendation; The EU regulation makes it mandatory.
13.3 f)	8.3.1 i)	For full coverage of this ER, the NOTE in 8.1.1 l) is mandatory.
13.3 j)	4.2.1 NOTE	4.2.1 Safety note draws attention to consideration of disclosure of specific labelling and instructions for intended use that may deviate from the currently accepted medical practice. This NOTE is mandatory to cover this ER.
13.3 m)	8.3.1 h) NOTE	This NOTE is mandatory to cover this ER.
13.5	8.4	Limited to detachable connectors, which are marked with the designated tracheal tube size.
13.6, a)	8	Covers the following details referred to in section 13.3 13.3a), b), c), f), and j). For 13.3 m) to be covered the recommendation in 8.3.1 h) is mandatory.

13.6, b)	8	Covered in full
13.6, c)	5.2.2.5 8.3.1 b)	8.3.1 b) requires the description of the contents. Per 5.2.2.5 the connector is mandated to be a 15mm male connector.
13.6 h), first and second paragraphs	8.3.1 l)	Mandated instructions for cleaning and disinfection or sterilization. Risks associated with the reuse of devices marked for single use are covered partly by the risk management file and use of the informative Annex F Hazard identification for risk assessment
13.6 i)	8.3.2 a)	Details for preparation for use are mandated for disclosure.
13.6 q)	8.3.2 c)	The date of issue of the latest revision of instructions for use is mandated.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

NOTE Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance to the Medical Devices Directive 93/42/EEC. 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.

INTERNATIONAL STANDARD

ISO 5361

Third edition
2016-09-01

Anaesthetic and respiratory equipment — Tracheal tubes and connectors

Matériel d'anesthésie et de réanimation respiratoire — Sondes trachéales et raccords

Reference number
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related equipment*.

This third edition cancels and replaces the second edition (ISO 5361:2012), which has been technically revised.

Throughout this International Standard, terms defined in Clause 3 or in ISO 4135 appear in **bold** type.

Throughout this International Standard, text for which a rationale is provided in Annex A is indicated by an asterisk (*).

Introduction

This International Standard provides the essential performance and safety requirements for the design of **tracheal tubes** and **tracheal tube connectors**. **Tracheal tubes** are intended to be inserted through the larynx into the trachea to provide a patent airway in patients during spontaneous, assisted or controlled ventilation for short or prolonged durations to convey gases and vapours to and from the trachea.

In addition, **tracheal tubes** with **cuffs** are intended to seal and protect the trachea from aspiration.

A variety of **cuff** designs are available to meet particular clinical requirements. **Cuff** performance requirements with associated test methods remain unchanged from the second edition.

Requirements for paediatric **tracheal tubes,** with and without **cuffs**, have been updated from the second edition to include revised length marks and new provisions for **glottic depth marks** have been added in this edition because these are commercially available and in common use.

Tracheal tubes are also intended to conform as closely as possible to human anatomy when in position.

Clinical considerations have also dictated the specified length of **tracheal tubes** because long **tracheal tubes**, sometimes of relatively narrow diameter, may be required and, therefore, should be readily available. Provision has also been included for pre-cut **tracheal tubes**.

Kink resistance requirements with associated test methods remain unchanged from the second edition to measure the ability of the shaft of the **tracheal tube** to resist collapse and increased breathing resistance when bent or curved.

Radiopacity requirements and test methods remain unchanged from the second edition to characterize the visibility of **tracheal tubes** in X-rays used to determine proper placement of the tube. The requirements of this International Standard were developed using the hazard identification for **risk assessment** in Annex F.