SLOVENSKI STANDARD
SIST EN ISO 5361:2013

01-januar-2013

Nadomešča:
SIST EN 1782:2000+A1:2009

Anestezijska in dihalna oprema - Sapnični (endotrahealni) tubusi in priključki (ISO 5361:2012)

Anaesthetic and respiratory equipment - Tracheal tubes and connectors (ISO 5361:2012)

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Matériel d'anesthésie et de réanimation respiratoire - Sondes trachéales et raccords (ISO 5361:2012)

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Ta slovenski standard je istoveten z: EN ISO 5361:2012

ICS:

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

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2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 5361

October 2012

ICS 11.040.10

English Version

Anaesthetic and respiratory equipment - Tracheal tubes and connectors (ISO 5361:2012)

Matériel d'anesthésie et de réanimation respiratoire - Sondes trachéales et raccords (ISO 5361:2012)

Anästhesie- und Beatmungsgeräte - Trachealtuben und Verbindungsstücke (ISO 5361:2012)

This European Standard was approved by CEN on 15 September 2012.

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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-CENELEC Management Centre has the same status as the official versions.

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Foreword

This document (EN ISO 5361:2012) 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of an identical text or by endorsement, at the latest by April 2013, and conflicting national standards shall be withdrawn at the latest by October 2015.

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 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.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organisations 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.

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The text of ISO 5361:2012 has been approved by CEN as a EN ISO 5361:2012 without any modification.

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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 to conforming to Essential Requirements of Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Union 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 ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive.

NOTE 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 European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/notes
5.3 4.1.6	7.1 (2nd indent) 7.1 (3rd indent)	In the EU, competent authorities always require applicable ERs.
5.3.1 7.1 7.2	7.2	7.1 and 7.2 covers the integrity of the packaging only for devices supplied sterile.
4.1.1 4.1.2 5.3	7.3	4.1.1, 4.1.2, and 5.3 mandates a risk assessment be carried out which does not exclude risks associated with materials and the substances with which they may come into contact. Does not cover devices intended to administer medicinal products.
5.3.4 8.3.1 m)	7.5	Partly addressed by 5.3.4 and 8.3.1 m), calls specifically for a warning if phthalates are incorporated. However, justification for the use of phthalates for use with children or pregnant or nursing women is not covered.
7.2	8.1	7.2 mandates the requirements of ISO 11607-1 to ensure that the packaging is suitable to prevent contamination during transportation and use.
7.2	8.3	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.
7.1	8.4	7.1 mandates that sterile devices satisfy 4.1 of EN 556-1.

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Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/notes
7.1	8.5	7.1 mandates that sterile devices satisfy 4.1 of EN 556-1.
8.3.1 h)	8.7	Partly covered. Marked sterile if appropriate.
5.2.2 5.5.4, 5.9, 5.5.1	9.1	Generally covered by mandating construction and testing of the interface connector, resistance to tube collapse and kinking, and cuff leakage.
5.1 5.2 Tables 1a), 1b), and 1c) 5.5 5.7 6 8.3.2 b)	9.2 (first and second indent)	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.
8.2.1.1 d), e), and f)	10.1 (first sentence)	Partly covered to address length measurement and marking in cm. Limits of accuracy are specified in the standard and not disclosed by the manufacturer.
8.2.1.1 d), e), and f)	10.2	Length marking positions are mandated to provide ergonomic angular visibility during intubation.
8.2.1.1 d), e), and f)	10.3	Length marking is mandated using SI units (cm).
5.2.2.5 5.6.5	12.7.4	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.
8 4.2.1 NOTE	13.1	Covered by mandating marking and labelling and instructions on the tube, connector, unit label, and instructions for use. 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.
8.1	13.2	Symbols are mandated in 8.1 to conform to EN 1041 and ISO 7000 or EN 980 or ISO 15223-1 and ISO 15223-2.
8.2.1.1 a) 8.3.1 f)	13.3 a)	Manufacturer identification mandated on the device and on individual pack or any insert. Authorised representative mandated on the individual pack or any insert.
7.2 8.3.1 h)	13.3 b)	Only identifies that the device is sterile (if applicable).
8.3.1 h)	13.3 c)	

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Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/notes
8.3.1 g)	13.3 d)	Batch code preceded by the word “LOT” mandated for EU countries.
8.3.1 g)	13.3 e)	‘Use by date’ is only addressed via a ‘strong’ recommendation; The EU regulation makes it mandatory.
8.3.1 i)	13.3 f)	
4.2.1 NOTE	13.3 j)	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.
8.3.1 h) NOTE	13.3 m)	This NOTE is mandatory to cover this ER.
8.4	13.5	Limited to detachable connectors, which are marked with the designated tracheal tube size.
8	13.6, a), b), c)	Mandated markings, labelling and instructions.
8.3.1 l)	13.6 h), first and second paragraphs	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
8.3.2 a)	13.6 i)	Details for preparation for use are mandated for disclosure.
8.3.2 c)	13.6 q)	The date of issue of the latest revision of instructions for use is mandated.

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

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INTERNATIONAL STANDARD

ISO 5361

Second edition
2012-10-01

Anaesthetic and respiratory equipment — Tracheal tubes and connectors

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

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

This second edition cancels and replaces the first edition (ISO 5361:1999), which has been technically revised.

The requirements of ISO 5361-4, ***Tracheal tubes*** — *Part 4: Cole type*, have been included in this second edition because **Cole type tracheal tubes** are specialized tubes, and as such, are now included in the scope of this International Standard.

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

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

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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 convey gases and vapours to and from the trachea.

Tracheal tubes with **cuffs** are intended to seal and protect the trachea from aspiration of secretions and to provide an unobstructed airway in patients during spontaneous, assisted, or controlled ventilation for short or prolonged durations.

A variety of **cuff** designs are available to meet particular clinical requirements. **Cuff** performance requirements with associated test methods have been added to this second edition.

Requirements for paediatric **tracheal tubes** with **cuffs** have been added 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 have also been added to 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.

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Radiopacity requirements and test methods have been added to this 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.

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Anaesthetic and respiratory equipment — Tracheal tubes and connectors

1 *Scope

This International Standard provides essential performance and safety requirements for **oro-tracheal and naso-tracheal tubes** and **tracheal tube connectors. Tracheal tubes** with walls reinforced with metal or nylon, **tracheal tubes** with **shoulders**, tapered **tracheal tubes**, **tracheal tubes** with means for suctioning or monitoring or delivery of drugs or other gases, and the many other types of **tracheal tubes** devised for specialized applications are included in this International Standard, as many specialized **tracheal tubes** are now commonly used, and all share similar essential requirements as defined in this International Standard.

Tracheobronchial (endobronchial) tubes, tracheostomy tubes and supralaryngeal airways are excluded from the scope of this International Standard.

Tracheal tubes intended for use with flammable anaesthetic gases or agents, lasers or electrosurgical equipment are outside the scope of this International Standard.

NOTE ISO/TR 11991, ISO 11990-1, ISO 11990-2, and ISO 14408 cover this[1][2][3][4].

2 Normative references

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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.

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ISO 594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

ISO 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 7000, *Graphical symbols for use on equipment – Index and synopsis*[1)]

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11135-1, *Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11607-1, *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 14155, *Clinical investigation of medical devices for human subjects – Good clinical practice*

ISO 14971, *Medical Devices - Application of risk management to medical devices*

ISO 15223-1, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*

ISO 15223-2, *Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied – Part 2: Symbol development, selection and validation*

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?=.

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