Anaesthetic and respiratory equipment - Tracheostomy tubes and connectors (ISO 5366:2016)

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NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 5366:2016 sisaldab Euroopa standardi EN ISO 5366:2016 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 5366:2016 consists of the English text of the European standard EN ISO 5366:2016.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 26.10.2016.	Date of Availability of the European standard is 26.10.2016.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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Anaesthetic and respiratory equipment - Tracheostomy tubes and connectors (ISO 5366:2016)

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Anästhesie- und Beatmungsgeräte - Tracheotomietuben und Verbindungsstücke (ISO 5366:2016)

This European Standard was approved by CEN on 20 August 2016.

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 5366:2016) 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of an identical text or by endorsement, at the latest by April 2017, and conflicting national standards shall be withdrawn at the latest by April 2017.

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 5366-1:2009.

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 5366:2016 has been approved by CEN as EN ISO 5366:2016 without any modification.

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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 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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

This first edition of ISO 5366 cancels and replaces ISO 5366-1 and ISO 5366-3, which have been technically revised.

Introduction

This International Standard provides the essential requirements for the design of cuffed and uncuffed TRACHEOSTOMY TUBES and connectors. These devices are intended to be inserted through a stoma in the trachea to convey gases and vapours to and from the trachea. Cuffed devices are designed to seal and protect the trachea from aspiration and to provide an unobstructed airway in patients during spontaneous, assisted or controlled ventilation for short or prolonged durations. Specialized tubes with walls reinforced with metal or nylon, tubes with shoulders, tapering tubes, tubes with provision for suctioning or monitoring or delivery of drugs or other gases and the many other types of TRACHEOSTOMY TUBES devised for specialized applications are included in this specification, as many specialized TRACHEOSTOMY TUBES are now commonly used, and all share similar essential requirements defined in this International Standard.

The method of describing tube dimensions and configuration has been devised in order to assist clinicians in the selection of the most suitable tube for a particular patient's anatomy. Size is designated by the internal dimension, which is important because of its relationship to resistance to gas flow. Because stoma and tracheal sizes are also important factors when selecting a TRACHEOSTOMY TUBE, it is considered essential that the outside dimension for each size of tube is also made known to the user.

Cuffed TRACHEOSTOMY TUBES can be characterized by a combination of the tube inside and outside dimensions and by the diameter of the CUFF.

A variety of CUFF designs are available to meet particular clinical requirements. This International Standard encompasses requirements for both paediatric and adult TRACHEOSTOMY TUBES. They share many common requirements that can be standardized and which are important for patient safety. An infant or child differs from an adult, not only in size, but also with regard to airway anatomy and respiratory physiology; thus, airway equipment for paediatric patients differs from that for adults, both in size and in basic design. This International Standard does not require the connector to be permanently attached to the tube, as this can be impractical with infants and small children. Other acceptable methods of connecting these components are available, and this International Standard makes provision for them. This International Standard does not limit the range of tube designs needed to match the variations in paediatric anatomy, lesions and space limitations encountered.

Kink resistance requirements with associated test methods have also been added to this International Standard to measure the ability of the shaft of the TRACHEOSTOMY TUBE to resist collapse and increased breathing resistance when bent or curved.

Requirements for TRACHEOSTOMY TUBES that are common to other airway and related devices have been removed from this International Standard as these are now included in ISO 18190, which is cross referenced where appropriate.

Throughout this International Standard, the following print types are used:

— requirements and definitions: roman type;

— *test specifications: italic type*;

— informative material appearing outside of tables, such as notes, examples and references: smaller type. The Normative text of tables is also in smaller type;

— TERMS DEFINED IN CLAUSE 3: SMALL CAPS.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

Anaesthetic and respiratory equipment — Tracheostomy tubes and connectors

1 *Scope

This International Standard specifies requirements for adult and paediatric TRACHEOSTOMY TUBES and connectors. Such tubes are primarily designed for patients who require anaesthesia, artificial ventilation or other respiratory support.

This International Standard is also applicable to specialized TRACHEOSTOMY TUBES that share common attributes, for example, those without a connector at the MACHINE END intended for spontaneously breathing patients and those with reinforced walls or tubes made of metal or tubes with shoulders, tapering tubes, tubes with provision for suctioning or monitoring or delivery of drugs or other gases.

Flammability of TRACHEOSTOMY TUBES is a well recognized hazard (for example, when electrosurgical units or lasers are used with flammable anaesthetic agents in oxidant-enriched atmospheres) that is addressed by appropriate clinical management and is outside the scope of this International Standard.

NOTE ISO/TR 11991 gives guidance on avoidance of airway fires.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 4135, *Anaesthetic and respiratory equipment — Vocabulary*

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

ISO 18190:2016, *Anaesthetic and respiratory equipment — General requirements for airways and related equipment*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

ASTM F2052, *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*

ASTM F2503, *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135 and the following apply.

NOTE See Figure 1 for illustrations of typical TRACHEOSTOMY TUBES and associated nomenclature.

3.1
ANGLE OF BEVEL
angle between the plane of the BEVEL (3.2) and the longitudinal axis of a TRACHEOSTOMY TUBE (3.13)

3.2
BEVEL
slanted portion at the PATIENT END (3.12) of a TRACHEOSTOMY TUBE (3.13)