

SLOVENSKI STANDARD **SIST EN ISO 16628:2022**

01-september-2022

Anestezijska in dihalna oprema - Traheobronhialne cevi (ISO 16628:2022)

Anaesthetic and respiratory equipment - Tracheobronchial tubes (ISO 16628:2022)

Anästhesie- und Beatmungsgeräte - Tracheobronchialtuben (ISO 16628:2022)

Matériel d'anesthésie et de réanimation respiratoire - Sondes trachéobronchiques (ISO 16628:2022)

Ta slovenski standard je istoveten z: EN ISO 16628:2022

ICS:

11.040.10

reanimacijska oprema

Anestezijska, respiratorna in Anaesthetic, respiratory and reanimation equipment

SIST EN ISO 16628:2022

en

SIST EN ISO 16628:2022

iTeh STANDARD PREVIEW (standards.iteh.ai)

SIST EN ISO 16628:2022 .ai/catalog/standards/sist/2ab079d6-2f0b-46b7-8eb EUROPEAN STANDARD NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 16628

July 2022

ICS 11.040.10

English Version

Anaesthetic and respiratory equipment - Tracheobronchial tubes (ISO 16628:2022)

Matériel d'anesthésie et de réanimation respiratoire -Sondes trachéobronchiques (ISO 16628:2022) Anästhesie- und Beatmungsgeräte -Tracheobronchialtuben (ISO 16628:2022)

This European Standard was approved by CEN on 11 June 2022.

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

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

https://standards.iteh.ai/catalog/standards/sist/2ab079d6-2f0b-46b7-8eb9-f8ea0f01b646/sist-en-iso-16628-2022



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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

EN ISO 16628:2022 (E)

Contents	Page	e
Furonean foreword		3

iTeh STANDARD PREVIEW (standards.iteh.ai)

SIST EN ISO 16628:2022 https://standards.iteh.ai/catalog/standards/sist/2ab079d6-2f0b-46b7-8eb9-

EN ISO 16628:2022 (E)

European foreword

This document (EN ISO 16628:2022) 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 January 2023, and conflicting national standards shall be withdrawn at the latest by January 2023.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 16628:2022 has been approved by CEN as EN ISO 16628:2022 without any modification.

https://standards.iteh.ai/catalog/standards/sist/2ab079d6-2f0b-46b7-8eb9-f8ea0f01b646/sist-en-iso-16628-2022

SIST EN ISO 16628:2022

iTeh STANDARD PREVIEW (standards.iteh.ai)

SIST EN ISO 16628:2022 .ai/catalog/standards/sist/2ab079d6-2f0b-46b7-8eb **SIST EN ISO 16628:2022**

INTERNATIONAL STANDARD

ISO 16628

Second edition 2022-06

Anaesthetic and respiratory equipment — Tracheobronchial tubes

Matériel d'anesthésie et de réanimation respiratoire — Sondes trachéobronchiques

iTeh STANDARD PREVIEW (standards.iteh.ai)

<u>SIST EN ISO 16628:2022</u> https://standards.iteh.ai/catalog/standards/sist/2ab079d6-2f0b-46b7-8eb9 f8ea0f01b646/sist-en-iso-16628-2022



Reference number ISO 16628:2022(E)

ISO 16628:2022(E)

iTeh STANDARD PREVIEW (standards.iteh.ai)

SIST EN ISO 16628:2022 https://standards.iteh.ai/catalog/standards/sist/2ab079d6-2f0b-46b7-8eb9-



COPYRIGHT PROTECTED DOCUMENT

© ISO 2022

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office CP 401 • Ch. de Blandonnet 8 CH-1214 Vernier, Geneva Phone: +41 22 749 01 11 Email: copyright@iso.org Website: www.iso.org

Published in Switzerland

Coı	ntents	Page
Fore	eword	iv
Intr	oduction	v
1	Scope	1
2	Normative references	1
3	Terms and definitions	
4	General requirements	
4	4.1 General	
	4.2 Safety	
5	Materials	
	5.1 General	
	5.2 Biological safety testing	
6	Design requirements	3
	6.1 General	
	6.2 Designated size	
	6.3 Dimensions	3
	6.4 Connectors	3
	6.5 <i>Cuffs</i>	3
	6.6 <i>Cuff</i> inflation system	
	6.7 Bronchial segment	4
7	Requirements for tracheobronchial tubes supplied sterile	
8	Packaging (Stantuarus.item.ai)	5
9	Information supplied by the manufacturer	6
	9.1 General SIST EN ISO 16628:2022	
	9.2 http Marking ards iteh ai/catalog/standards/sist/2ab079d6-2f0b-46b7-8eb9-	
	9.2.1 Durability and legibility 1-01-150-16628-2022	
	9.2.2 Marking on the <i>tracheobronchial tube</i>	
	9.3 Colour coding	
	9.4 Marking on the individual packaging or insert	
Ann	ex A (informative) Rationale	8
Ann	ex B (normative) Test method to determine the outside diameter of the broadenessegment	
A	S .	
	tex C (normative) Test method to determine the effective inside diameters	
Rihl	ingranhy	13

ISO 16628:2022(E)

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 of the voluntary nature of standards, 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related equipment*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 16628:2008), which has been technically revised.

The main changes are as follows:

- alignment with the general standard for airway devices, ISO 18190;
- inclusion of requirements in addition to marking and sizing;
- updating of references.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Tracheobronchial tubes are double lumen tracheal tubes that enable isolation of the airways of one lung from the other. This allows protection of one lung if there is bleeding or a leak in the airways of the other. They facilitate selective ventilation of each lung. One lumen ends in the trachea, with a tracheal cuff above the opening. The other lumen is designed to lie either in the right or the left main bronchus with a cuff sealing that bronchus. The cuff of a right-sided tube is usually shaped to permit ventilation of the right upper lobe.

The first edition of ISO 16628 only specified requirements for the marking and sizing of *tracheobronchial tubes*.

Throughout this document the following print types are used:

- requirements and definitions: roman 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 <u>Clause 3</u>: italics.

iTeh STANDARD PREVIEW (standards.iteh.ai)

SIST EN ISO 16628:2022 https://standards.iteh.ai/catalog/standards/sist/2ab079d6-2f0b-46b7-8eb9-