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

SIST EN ISO 16628:2022 **en**

EUROPEAN STANDARD

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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)

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

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

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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of an identical text or by endorsement, at the latest by January 2023, and conflicting national standards shall be withdrawn at the latest by January 2023.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.

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Endorsement notice

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

INTERNATIONAL STANDARD

ISO 16628

Second edition
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Anaesthetic and respiratory equipment — Tracheobronchial tubes

Matériel d'anesthésie et de réanimation respiratoire — Sondes trachéobronchiques

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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

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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).

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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 Clause 3: italics.*