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Anaesthetic and respiratory equipment — Tracheobronchial tubes

*Matériel d'anesthésie et de réanimation respiratoire — Sondes
trachéobronchiques*



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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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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.

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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.*