SLOVENSKI STANDARD
oSIST prEN ISO 8836:2026

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Anestezijska in dihalna oprema - Aspiracijski katetri za čiščenje dihalnih poti (ISO/DIS 8836:2026)

Anaesthetic and respiratory equipment - Suction catheters for use in the respiratory tract (ISO/DIS 8836:2026)

Beatmungs- und Anästhesiegeräte - Absaugkatheter zur Verwendung im Atemtrakt (ISO/DIS 8836:2026)

Matériel d'anesthésie et de réanimation respiratoire - Sondes d'aspiration pour les voies respiratoires (ISO/DIS 8836:2026)

Ta slovenski standard je istoveten z: **prEN ISO 8836**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters

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Anaesthetic and respiratory equipment — Suction catheters for use in the respiratory tract

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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 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, *Airway devices and related equipment*.

This sixth edition cancels and replaces the fifth edition (ISO 8836:2019), which has been technically revised. The main changes compared to the previous edition are as follows:

— The second edition of ISO 18190 (ISO 18190:2025) is now referenced, with removal of requirements that are now found in that document (evaluation of bicompatibility in accordance with ISO 18562-1).

— Terms defined in ISO 14971 have been removed from this document.

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

This document is concerned with the basic requirements and method of size designation of both *open* and *closed suction catheters* made of flexible materials.

The method of describing tube dimensions and configuration has been devised in order to assist clinicians in the selection of the most suitable *suction catheter* for a particular patient. The size designation is important when selecting a catheter because of its relationship to the ease with which the catheter can be passed through a *tracheal* EN ISO 5361 [1] or *tracheostomy tube*ISO 5366 [2].

Throughout this document the following print types are used:

— Requirements and definitions: roman type;

— *Conformance checks and 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;

— *defined terms: italics*.

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 — Suction catheters for use in the respiratory tract

1 Scope

This document specifies dimensions and requirements for both *open* and *closed suction catheters* made of flexible materials and intended for use in suctioning of the respiratory tract through an airway device.

Suction catheters intended for use with flammable anaesthetic gases or agents, lasers or electrosurgical equipment are not covered by this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

ISO 5361:2023, *Anaesthetic and respiratory equipment — Tracheal tubes and connectors*

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

ISO 5367:2023, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

ISO 18190:2025, *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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135, ISO 14971, ISO 18190 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
***closed suction catheter**
suction catheter (3.11) enclosed within a *protective sleeve* (3.8) that allows its use within the airway without opening the *ventilator breathing system (VBS)* (3.17) directly to atmosphere ISO 4135:2022 [3] 3.10.3.2

3.2
***closed suction catheter manifold**
part of the *closed suction catheter* (3.1) that provides a connection to an airway device ISO 4135:2022 [3] 3.10.3.3

3.3
connector
fitting to join together two or more componentsISO 4135:2022 [3] 3.1.4.5