



**SLOVENSKI STANDARD**  
**oSIST prEN ISO 8836:2026**  
**01-maj-2026**

---

**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 and catheters

**oSIST prEN ISO 8836:2026**

**en,fr,de**

# Sample Document

get full document from [standards.iteh.ai](https://standards.iteh.ai)



# DRAFT International Standard

## ISO/DIS 8836

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

ICS: 11.040.10; 11.040.25

ISO/TC 121/SC 2

Secretariat: **ANSI**

Voting begins on:  
**2026-03-03**

Voting terminates on:  
**2026-05-26**

Sample Document

get full document from [standards.iteh.ai](https://standards.iteh.ai)

This document is circulated as received from the committee secretariat.

**ISO/CEN PARALLEL PROCESSING**

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENTS AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

© ISO 2026

Reference number  
ISO/DIS 8836:2026(en)

# Sample Document

get full document from [standards.iteh.ai](https://standards.iteh.ai)



## **COPYRIGHT PROTECTED DOCUMENT**

© ISO 2026

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](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

Published in Switzerland

## ISO/DIS 8836:2026(en)

## Contents

	Page
Foreword.....	iv
Introduction.....	v
<b>1 Scope.....</b>	<b>1</b>
<b>2 Normative references.....</b>	<b>1</b>
<b>3 Terms and definitions.....</b>	<b>1</b>
<b>4 General requirements.....</b>	<b>3</b>
<b>5 Materials.....</b>	<b>3</b>
<b>6 Design requirements.....</b>	<b>3</b>
6.1 General.....	3
6.2 *Size designations and dimensions.....	3
6.3 <i>Suction catheter tip</i> .....	4
6.4 *Suction catheter connector.....	5
6.5 Additional requirements for <i>closed suction catheters</i> .....	6
6.5.1 General design.....	6
6.5.2 <i>Closed suction catheter manifold and connectors</i> .....	7
6.5.3 <i>Protective sleeve</i> .....	8
6.5.4 * <i>Suction control device</i> .....	8
6.5.5 Flushing system.....	9
6.5.6 T-piece port.....	9
6.6 Performance requirements.....	9
6.6.1 Security of construction.....	9
6.6.2 <i>Shaft performance</i> .....	10
6.6.3 Suction control device performance.....	10
6.6.4 *Leakage.....	10
6.6.5 *Resistance to flow.....	10
<b>7 Requirements for <i>suction catheters</i> supplied sterile.....</b>	<b>10</b>
<b>8 Packaging.....</b>	<b>11</b>
<b>9 Information supplied by the manufacturer.....</b>	<b>11</b>
9.1 General.....	11
9.2 Marking.....	11
9.3 Instructions for use.....	12
<b>Annex A (informative) Rationale.....</b>	<b>13</b>
<b>Annex B (normative) Test method for security of attachment.....</b>	<b>16</b>
<b>Annex C (normative) Measurement of residual vacuum.....</b>	<b>17</b>
<b>Annex D (normative) *Method of testing leakage.....</b>	<b>20</b>
<b>Annex E (informative) Hazard identification for risk assessment.....</b>	<b>21</b>
<b>Bibliography.....</b>	<b>23</b>

## ISO/DIS 8836:2026(en)

### 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](http://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](http://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](http://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](http://www.iso.org/members.html).

## ISO/DIS 8836:2026(en)

### 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](#).

# Sample Document

get full document from [standards.iteh.ai](https://standards.iteh.ai)

# Sample Document

get full document from [standards.iteh.ai](https://standards.iteh.ai)

# 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 components ISO 4135:2022 [3] 3.1.4.5