SLOVENSKI STANDARD
SIST EN ISO 5367:2023

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Nadomešča:
SIST EN ISO 5367:2015

Anestezijska in dihalna oprema - Dihalni seti in priključki (ISO 5367:2023)

Anaesthetic and respiratory equipment - Breathing sets and connectors (ISO 5367:2023)

Anästhesie- und Beatmungsgeräte - Atemsets und Verbindungsstücke (ISO 5367:2023)

Matériel d'anesthésie et de réanimation respiratoire - Ensembles respiratoires et raccords (ISO 5367:2023)

Ta slovenski standard je istoveten z: **EN ISO 5367:2023**

ICS:

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

SIST EN ISO 5367:2023 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 5367

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English Version

Anaesthetic and respiratory equipment - Breathing sets and connectors (ISO 5367:2023)

Matériel d'anesthésie et de réanimation respiratoire - Ensembles respiratoires et raccords (ISO 5367:2023)

Anästhesie- und Beatmungsgeräte - Atemsets und Verbindungsstücke (ISO 5367:2023)

This European Standard was approved by CEN on 3 March 2023.

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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 5367:2023) 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of an identical text or by endorsement, at the latest by January 2024, and conflicting national standards shall be withdrawn at the latest by January 2024.

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.

This document supersedes EN ISO 5367:2014.

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, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 5367:2023 has been approved by CEN as EN ISO 5367:2023 without any modification.

INTERNATIONAL STANDARD

ISO 5367

Sixth edition
2023-07

Anaesthetic and respiratory equipment — Breathing sets and connectors

Matériel d'anesthésie et de réanimation respiratoire — Ensembles respiratoires et raccords

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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, *Airway devices 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 sixth edition cancels and replaces the fifth edition (ISO 5367:2014), which has been technically revised.

The main changes are as follows:

— the layout now follows the format of ISO 18190:2016;

— the general requirements such as risk management, usability, clinical investigation and some common marking requirements have been removed as they are now in ISO 18190 and cross-referenced in the appropriate clauses of this document.

— the list of normative references, many of which are cited in ISO 18190 has been updated.

— requirements for hose systems for neonatal applications were added (e.g. the 11,5 mm conical connector according to ISO 5356-1).

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 contains requirements for *breathing sets*, *breathing tubes* and connectors that are intended to function as accessories to anaesthetic and respiratory equipment. *Breathing sets* and *breathing tubes* are characterized by certain design requirements such as a means of connection and leakage limits. Disclosure requirements for conformance and flow resistance values allow the user to make an informed choice when connecting these accessories to a breathing system. These design requirements are intended to allow operation within the limits of performance of the *anaesthetic breathing systems* and *ventilator breathing systems* with which the accessories are intended to operate.

This document includes requirements for both single-use and reusable *breathing sets* and *breathing tubes*. Reusable *breathing sets* and *breathing tubes* are intended to conform to the requirements of this document for the recommended service life.

NOTE 1 Examples of various types of *breathing sets* with *patient end adaptors* are depicted in Annex A.

This document is not applicable to *breathing sets* and *breathing tubes* that are intended to be used only for special purposes.

EXAMPLE 1 Ventilators having special *compliance*, pressure or breathing frequency requirements.

EXAMPLE 2 Patient Interface adapters with special connectors for neonatal ventilation, that are not interfacing to a Tracheal tube.

Requirements for breathing system components such as exhalation valves, exhaust valves, *adjustable pressure-limiting (APL) valves*, heat and moisture exchangers (HMEs), breathing filters, and reservoir bags, are not covered by this document but can be found in ISO 80601-2-12, ISO 80601-2-13, ISO 9360-1, ISO 23328-2 and ISO 5362. Requirements for heated *breathing tubes* can be found in ISO 80601-2-74.

Certain tests are performed under constant pressure to simplify the test methodology. It is recognized that this does not reflect clinical use, where pressure is intermittent and peak pressures occur for short periods. The limits in the test methods take this into account. While such test methods do not address product variability, the limits required do take this into account.

Throughout this document, all pressures are denoted in SI units of hPa with corresponding cmH_2O equivalent values rounded to the nearest whole cmH_2O.

NOTE 2 Rounded cmH_2O values are given for information only to allow comparison to medical literature and related breathing system standards.

This document is written following the format of ISO 18190 which is the general standard for airways and related equipment. The requirements in this device-specific standard take precedence over any conflicting requirements in ISO 18190.