ANESTEESIA- JA HINGAMISSEADMED. VÄIKESE PEALEVOOLUGA NINAKAUDSE HAPNIKRAVI KANÜÜLID

Anaesthetic and respiratory equipment - Low-flow nasal cannulae for oxygen therapy (ISO 23368:2022)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 23368:2022 sisaldab Euroopa standardi EN ISO 23368:2022 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 23368:2022 consists of the English text of the European standard EN ISO 23368:2022.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 31.08.2022.	Date of Availability of the European standard is 31.08.2022.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

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English Version

Anaesthetic and respiratory equipment - Low-flow nasal cannulae for oxygen therapy (ISO 23368:2022)

Matériel d'anesthésie et d'assistance respiratoire - Canules nasales à faible débit pour oxygénothérapie (ISO 23368:2022)

Anästhesie- und Beatmungsgeräte - Nasenbrillen für die Atemtherapie (ISO 23368:2022)

This European Standard was approved by CEN on 9 July 2022.

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

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

Ref. No. EN ISO 23368:2022 E

European foreword

This document (EN ISO 23368:2022) 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of an identical text or by endorsement, at the latest by February 2023, and conflicting national standards shall be withdrawn at the latest by February 2023.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.

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.

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Endorsement notice

The text of ISO 23368:2022 has been approved by CEN as EN ISO 23368:2022 without any modification.

Contents

Page

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).

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

Low-flow nasal cannulae are used to guide oxygen directly to the patient's nasal passageways via nasal prongs during the administration of *oxygen therapy*.

Several countries have introduced a fire-activated oxygen flow-stopping device for use with *oxygen therapy* systems especially in the home-care environment that prevents the proliferation of fire along the tubing if it catches light. It is recommended that these flow-stopping devices be fitted as close to the patient as possible.

Anaesthetic and respiratory equipment — Low-flow nasal cannulae for oxygen therapy

1 Scope

This document specifies requirements for *low-flow nasal cannulae*, used in both home care and hospital environments for the administration of *oxygen therapy*.

This document does not include requirements to prevent the proliferation of fire within the tubing but does specify a user-detachable connection that can be used to fit a fire-activated oxygen shut-off device.

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 4135, *Anaesthetic and respiratory equipment – Vocabulary and semantics*

ISO 18190:2016, *Anaesthetic and respiratory equipment — General requirements for airways and related equipment*

ISO 18562-1, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 80369-2,[1)] *Small-bore connectors for liquids and gases in healthcare applications — Part 2: Connectors for respiratory applications*

3 Terms and definitions

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

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

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

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

3.1
inlet connector
connection on the *low-flow nasal cannula* (3.3) that connects to the outlet of the oxygen supply device or the outlet of the therapy tubing

3.2
integral nasal cannula
low-flow nasal cannula (3.3) and therapy tubing with no user-detachable connectors between the *inlet connector* (3.1) and the nasal prongs

3.3
low-flow nasal cannula
patient interface designed for use with flows ≤6 l/min for the administration of oxygen via nasal prongs

1) Under preparation. Stage at time of publication ISO/DIS 80369-2:2022.