Doc No: MHD 11 (25225) WC
April 2024

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

एनेस्थेटिक और श्वसन उपकरण ऑक्सीजन थेरेपी के लिए लौ-फ्लो नेसल कैनुला

Draft Indian Standard

Anaesthetic and Respiratory Equipment Low-Flow Nasal Cannulae for Oxygen Therapy

ICS 11.040.10

Anaesthetic, Resuscitation and Allied Equipment Sectional Committee, MHD 11	Last date for comments 10 May 2024

NATIONAL FOREWORD

(*Adoption clause will be added later*)

This Indian Standard is an identical adoption of ISO 23368: 2022 "Anaesthetic and respiratory equipment — Low-flow nasal cannulae for oxygen therapy".

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'
b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 4135, Anaesthetic and respiratory equipment – Vocabulary and semantics	IS 13200 : 2023/ ISO 4135:2022, Anaesthetic and Respiratory Equipment Vocabulary (*Second Revision*)	Identical

The technical committee responsible for the preparation of this standard has reviewed the provisions of following mentioned International Standards and has decide that they are acceptable for use in conjunction with this standard:

International Standard/ Other Publication	*Title*
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	Small-bore connectors for liquids and gases in healthcare applications — Part 2: Connectors for respiratory applications

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test shall be rounded off in accordance with IS 2: 2022 ‘Rules for rounding off numerical values (revised)’.

This standard also makes a reference to the BIS Certification Marking of the product. Details of which is given in National Annex A.

NATIONAL ANNEX A
(National Foreword)

A-1 BIS CERTIFICATION MARKING

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the BIS Act, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

The technical content of the document has not been enclosed as it is identical with the corresponding ISO standard. For details, please refer to **ISO 23368:2022** or kindly contact:

Head
Medical Equipment and Hospital Planning Department
Bureau of Indian Standards
9 Bahadur Shah Zafar Marg
New Delhi-110002
Email: mhd@bis.gov.in; hmhd@bis.gov.in

Abstract

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.

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, 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.

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.