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BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

एनेस्थटिक एवं श्वशन उपकरण सुपरलैरिंजियल एयरवेज एवं कनेक्टर्स

[ISO 11712:2023, संशोधित]

Draft Indian Standard

Anaesthetic and Respiratory Equipment Supralaryngeal Airways and Connectors

[ISO 11712:2023, MOD]

ICS: 11.040.10

Anaesthetic, Resuscitation and Allied Equipment Sectional Committee, MHD-11	Last date for comments 17 May 2024

NATIONAL FOREWORD

(*Adoption clause will be added later*)

This Indian standard is a modified adoption of ISO 11712:2023 "Anaesthetic and Respiratory Equipment - Supralaryngeal Airways and Connectors".

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	IS 13200: 2023/ISO 4135:2022 Anaesthetic and Respiratory Equipment Vocabulary Second Revision	Identical
ISO 5356-1, Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets	IS/ISO 5356-1: 2015 Anaesthetic and respiratory equipment - Conical connectors: Part 1 cones and sockets (First Revision)	Identical
ISO 18562-1, Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process	MHD 11 (25205) Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 1 Evaluation and testing within a risk management process	Modified
ISO 80369-7, Small-bore connectors for liquids and gases in healthcare applications —Part 7: Connectors with 6 % (Luer) taper for intravascular or hypodermic applications	IS/ISO 80369-7: 2016 Small-Bore Connectors for Liquids and Gases in Healthcare Applications Part 7 Connectors for Intravascular or Hypodermic Applications	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	Anaesthetic and respiratory equipment — General requirements for airways and related equipment

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 11712:2023** or kindly contact:

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INTRODUCTION

A supralaryngeal airway is a medical device placed through the mouth, without passing through the vocal cords, intended to seal the supralaryngeal area to isolate the respiratory pathway from gases and liquids in the pharynx and to maintain airway patency to facilitate ventilation in anaesthetized or unconscious patients with or without delivery of anesthetic gases. Ventilation may be spontaneous, assisted or controlled. Supralaryngeal airways intended to provide a breathing airway and/or to simultaneously provide a guide for the intubation of tracheal tubes, bronchoscopes and suction devices are also included in the scope of this document, as are the connectors inserted into the machine end of these devices.

Examples of supralaryngeal airways are laryngeal masks, laryngeal tubes, airways and seals, cuffed oropharyngeal airways, and pharyngeal airways, and combination airway/oesophageal obturators.

The requirements of this document were developed using the hazard identification for risk assessment in Annex D.

The requirements for testing and disclosure apply to supralaryngeal airways introduced to the market after the publication of this document.

This document is written following the format of ISO 18190. The requirements in this document take precedence over any conflicting requirements in ISO 18190.

1 SCOPE

1.1 This document provides the essential requirements for the design of supralaryngeal airways and connectors. These devices are intended to provide a distinct respiratory pathway to the top of the larynx to provide an unobstructed airway in patients during spontaneous, assisted or controlled ventilation.

1.2 This document specifies the dimensions, basic properties and method of size designation of the available types of supralaryngeal airways. Airways devised for specialized applications are not specifically covered, although most may be classified by the sizing and dimensions (or other characteristics) required by this document.

1.3 The following devices are outside the scope of this document: nasal and oropharyngeal airways, anesthetic masks, oro- and naso-tracheal tubes, cricothyrotomy devices, dental appliances, tracheal stents, tracheal tubes, ventilating laryngoscopes, CPAP devices, esophageal obturators, bougies and devices that require surgical placement.

1.4 This document specifies dimensional disclosure so the operator will know which auxiliary devices, such as tracheal tubes and bronchoscopes will be size-compatible.

1.5 Flammability of airways, for example if used with certain flammable anesthetic gases, electrosurgical units or lasers, is a well-recognized hazard that is outside the scope of this document.