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BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

चिकित्सा उपकरण
स्लीप एपनिया श्वास चिकित्सा
मास्क और अनुप्रयोग सहायक उपकरण

[ISO 17510:2015, संशोधित]

Draft Indian Standard

Medical devices
Sleep Apnoea Breathing Therapy
Masks and Application Accessories

[ISO 17510:2015, MOD]

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 standard is a Modified adoption of ISO 17510: 2015 "Medical devices — Sleep apnoea breathing therapy — Masks and application accessories".

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 4135:2022, Anaesthetic and respiratory equipment — Vocabulary	IS 13200: 2023/ ISO 4135:2022, Anaesthetic and Respiratory Equipment Vocabulary (*Second Revision*)	Identical
ISO 4871:1996, Acoustics — Declaration and verification of noise emission values of machinery and equipment	IS/ISO 4871: 1996, Acoustics - Declaration and Verification of Noise Emission Values of Machinery and Equipment	Identical
ISO 5356-1:2015, 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 5356-2:2012, Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors	IS/ISO 5356-2 : 2012, Anaesthetic and respiratory equipment - Conical connectors: Part 2 screw - Threaded weight - Bearing connectors	Identical
ISO 10993-1:2018, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	IS 17932 (Part 1): 2023, Biological Evaluation of Medical Devices Part 1 Evaluation and Testing within a Risk Management Process (ISO 10993-1: 2018, MOD)	Modified/ Technically Equivalent
ISO 14937:2009, Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices	IS/ISO 14937 : 2009, Sterilization of health care products General requirements for characterization of a sterilizing agent and the development validation and routine control of a sterilization process for medical devices	Identical
ISO 15223-1:2021, Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements	IS/ISO 15223-1: 2016, Medical Devices — Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied Part 1 General Requirements (*Second Revision*)	Non-Identical

ISO 17664:2017, Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices	IS/ISO 17664: 2017, Processing of health care products Information to be provided by the medical device manufacturer for the processing of medical devices	Identical
ISO 80601-2-70:2020, Medical Electrical Equipment — Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment	IS 13450 (Part 2/Sec 70s): 2022/ ISO 80601-2-70:2020, Medical Electrical Equipment Part 2 Particular Requirements for Basic Safety and Essential Performance Section 70 Sleep apnoea breathing therapy equipment	Identical
IEC 60601-1:2005+A1:2012, Medical electrical equipment — Part 1: General requirements for basic safety and essential performance	IS 13450 (Part 1): 2018/ IEC 60601-1: 2012 (Ed 3.1), Medical electrical equipment: Part 1 general requirements for basic safety and essential performance (*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 3744:2010	Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane
ISO 23328-1:2003	Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance
ISO 23328-2:2002	Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects
IEC 61672-1:2013	Electsroacoustics — Sound level meters — Part 1: Specifications

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 17510:2015** or kindly contact:

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Abstract

ISO 17510:2015 applies to masks and their accessories used to connect a sleep apnoea breathing therapy equipment to the patient. It specifies requirements for masks and accessories, including any connecting element, that are required to connect the patient-connection port of sleep apnoea breathing therapy equipment to a patient for the application of sleep apnoea breathing therapy (e.g. nasal masks, exhaust ports and headgear).

Introduction

Sleep apnoea is the clinically significant intermittent absences of normal respiration occurring during sleep. The awareness of the RISKS associated with sleep apnoea has grown significantly in recent years. As a result, the use of SLEEP APNOEA BREATHING THERAPY EQUIPMENT has become common. This International Standard covers basic safety and essential performance requirements for MASKS and other application ACCESSORIES needed to protect PATIENTS during use of this equipment.

In this International Standard, the following print types are used:

- — requirements and definitions: roman type;
- — *test specifications: italic type*;

- — informative material appearing outside of tables, such as notes, examples, and references: in smaller type. Normative text of tables is also in a smaller type;

- — TERMS DEFINED IN CLAUSE 3 IN THIS INTERNATIONAL STANDARD OR AS NOTED: SMALL CAPITALS TYPE.

In referring to the structure of this International Standard, the term

- — "clause" means one of the numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 5 includes 5.1, 5.2, etc.), and
- — "subclause" means a numbered subdivision of a clause (e.g. 5.1, 5.2, and 5.3.1 are all subclauses of Clause 5).

References to clauses within this International Standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular International Standard are by number only.
In this International Standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this International Standard conform to usage described in ISO/IEC Directives Part 2, Annex H. For the purposes of this International Standard, the auxiliary verb:

- — "shall" means that compliance with a requirement or a test is mandatory for compliance with this International Standard;
- — "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this International Standard;
- — "may" is used to describe a permissible way to achieve compliance with a requirement or test.

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.
The attention of Member Bodies is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication not be adopted for mandatory implementation nationally earlier than three years from the date of publication for equipment newly designed and not earlier than five years from the date of publication for equipment already in production.

Scope

This International Standard applies to MASKS and their ACCESSORIES used to connect SLEEP APNOEA BREATHING THERAPY EQUIPMENT to the PATIENT. It specifies requirements for MASKS and ACCESSORIES, including any connecting element, that are required to connect the PATIENT-CONNECTION PORT of SLEEP APNOEA BREATHING THERAPY EQUIPMENT to a PATIENT for the application of sleep apnoea breathing therapy (e.g. nasal MASKS, EXHAUST PORTS and HEADGEAR).

SLEEP APNOEA BREATHING THERAPY EQUIPMENT is covered by ISO 80601-2-70. Figure A.1 shows the typical elements of this International Standard together with the SLEEP APNOEA BREATHING THERAPY EQUIPMENT of ISO 80601-2-70 that form a sleep apnoea breathing system.

This International Standard does not cover ORAL APPLIANCES.