

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

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भारतीय मानक मसौदा
**लेज़र सर्जरी के लिए डिज़ाइन की गई श्वास नलिकाएँ — अंकन और
संबंधित जानकारी के लिए आवश्यकताएँ**

Draft Indian Standard
**Tracheal tubes designed for laser surgery — Requirements for
marking and accompanying information**
[ICS 11.040.10]

Anesthetic, Resuscitation and Allied Equipment Sectional
Committee, MHD 11

Last date for comments:
26 October 2025

NATIONAL FOREWORD

(Adoption clause will be added later)

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:

- Wherever the words ‘International Standard’ appear referring to this standard, they should be read as ‘Indian Standard’; and
- 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:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 7000, Graphical symbols for use on equipment — Registered symbols	IS 16450 : 2023/ISO 7000 : 2019, Graphical Symbols for Use on Equipment — Registered Symbols (First Revision)	Identical

ISO 15223-1:2012, 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)	Identical
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The Committee responsible for the preparation of this standard has reviewed the provisions of the following International Standards referred in this adopted standard and has decided that they are acceptable for use in conjunction with this standard:

<i>International Standard/ Other Publication</i>	<i>Title</i>
ISO 11990-1	Lasers and laser-related equipment — Determination of laser resistance of tracheal tubes — Part 1: Tracheal tube shaft
ISO 11990-2	Lasers and laser-related equipment — Determination of laser resistance of tracheal tubes — Part 2: Tracheal tube cuffs

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

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 (*second revision*)’. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

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 *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

Scope

This International Standard specifies marking, labelling, and information to be supplied by the manufacturer for cuffed and uncuffed tracheal tubes and related materials designed to resist ignition by a laser

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 14408:2016** or kindly contact:

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