

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

(Not to be reproduced without permission of BIS or used as an Indian Standard)

भारतीय मानक मसौदा
**चिकित्सा उपकरणों के निर्माण के लिए स्टेनलेस स्टील सुई ट्यूबिंग -
आवश्यकताएँ और परीक्षण विधियाँ**

Draft Indian Standard

**Stainless Steel Needle Tubing for the Manufacture of Medical
Devices — Requirements and Test Methods**

ICS 11.040.25

Hospital Equipment and Surgical Disposable
Products Sectional Committee, MHD 12

Last date for comments: **07 June 2024**

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'
- 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 3696, Water for analytical laboratory use — Specification and test methods	IS 1070 : 2023, Reagent Grade Water — Specification (<i>Fourth Revision</i>)	Modified

The technical committee 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</i>	<i>Title</i>
ISO 15510	Stainless steels — Chemical composition

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*)’.

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 applies to rigid stainless steel needle tubing suitable for use in the manufacture of hypodermic needles and other medical devices primarily for human use.

This International Standard provides requirements and test methods for the tubes manufactured for needles as component used in medical devices. Additional performance testing on the tube aspect may be required when the component is incorporated in the ready-to-use device.

This International Standard specifies the dimensions and mechanical properties of steel tubing of designated metric sizes 3,4 mm (10 Gauge) to 0,18 mm (34 Gauge).

It does not apply to flexible stainless steel tubing because the mechanical properties differ from those specified for rigid tubing in this International Standard. However, manufacturers and purchasers of flexible tubing are encouraged to adopt the dimensional specifications given in this International Standard.

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 9626:2016 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