

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

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भारतीय मानक मसौदा
एक बार प्रयोग में आने वाले रोगाणु मुक्त हाइपोडर्मिक सिरिंज
भाग 4 पुनः उपयोग रोकथाम सुविधा के साथ सिरिंज

Draft Indian Standard
Sterile Hypodermic Syringes for Single Use
Part 4 Syringes with Re-use Prevention Feature

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 |

| | | |
|---|---|-----------|
| ISO 7864:2016, Sterile hypodermic needles for single use — Requirements and test methods | IS 10654 : 2018/ISO 7864 : 2016, Sterile Hypodermic Needles for Single Use — Requirements and Test Methods (Fourth Revision) | Identical |
| ISO 7886-1:2017, Sterile hypodermic syringes for single use — Part 1: Syringes for manual use | IS 10258 (Part 1):2022/ISO 7886-1: 2017, Sterile hypodermic syringes for single use Part1 Syringes for manual use (<i>Third Revision</i>) | Identical |
| ISO 8537:2016, Sterile single-use syringes, with or without needle, for insulin | IS 12227 : 2020/ISO 8537 : 2016, Sterile Single-Use Syringes, With or Without Needle, for Insulin (<i>Second Revision</i>) | Identical |

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 9626 | Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods |
| ASTM D999-01 | Standard Test Methods for Vibration Testing of Shipping Containers |
| ASTM D5276-98 | Standard Test Method for Drop Test of Loaded Containers by Free Fall |

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 document specifies requirements for sterile single-use hypodermic syringes made of plastic and rubber materials with or without needle, and intended for the aspiration of fluids or for the injection of fluids immediately after filling and of design such that the syringe can be rendered unusable after use.

This document is not applicable to syringes made of glass [specified in ISO 595 (withdrawn)], auto-disable syringes for fixed dose immunization (ISO 7886-3) and syringes designed to be pre-filled. It does not address compatibility with injection fluids. Other standards can be applicable when syringes are used for any other intended purpose than those specified in this document.

NOTE Syringes designed to reduce the risk of needle-stick injuries can also comply with this document with regard to their re-use prevention properties, but it is stressed that anti-needle-stick properties of syringes are not in themselves addressed in this document.

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 7886-4:2018 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