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BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

चिकित्सा उपयोग के लिए सुई-आधारित इंजेक्शन प्रणाली — आवश्यकताएँ और परीक्षण विधियाँ

भाग 2 डबल-एंडेड पेन सुई

Draft Indian Standard

Needle-Based Injection Systems for Medical Use — Requirements and Test Methods

Part 2 Double-Ended Pen Needles

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:

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 10993-1, 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
ISO 10993-11, Biological evaluation of medical devices — Part 11: Tests for systemic toxicity	IS/ISO 10993-11 : 2017, Biological Evaluation of Medical Devices Part 11 Tests for Systemic Toxicity	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:

International Standard	*Title*
ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods
ISO 11608-1:2022	Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems
ISO 11608-3:2022	Needle-based injection systems for medical use — Requirements and test methods — Part 3: Containers and integrated fluid paths

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 and test methods for single-use, double-ended, sterile needles intended to be used with some needle-based injection systems (NISs) that use a non-integrated double-ended needle according to ISO 11608-1.

This document is not applicable to the following:

— needles for dental use;

— pre-attached syringe needles;

— hypodermic needles;

— needles intended for different routes of administration (e.g. intravenous, intrathecal, intraocular);

— materials that form the medicinal product contact surfaces of the primary container closure.

However, while this document is not intended to directly apply to these needle products, it does contain requirements and tests methods that can be used to help design and evaluate them.

NOTE Needles provided by the manufacturer integrated into the fluid path or container are covered in ISO 11608-3, and hypodermic needles provided separately are covered in ISO 7864.

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 11608-2:2022 or kindly contact:

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