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BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

चिकित्सा उपयोग के लिए सुई-आधारित इंजेक्शन प्रणाली — अपेक्षाएँ और परीक्षण पद्धतियाँ

भाग 1 सुई-आधारित इंजेक्शन प्रणाली

Draft Indian Standard

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

Part 1 Needle-Based Injection Systems

[ICS 11.040.25]

Hospital Equipment and Surgical Disposable Products Sectional Committee, MHD 12	Last date for comments: **02 January 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:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'; and
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:	IS 17932 (Part 1) : 2023 Biological evaluation of medical devices Part 1 Evaluation and	Modified

Evaluation and testing within a risk management process	testing within a risk management process (ISO 10993-1 : 2018, MOD)	
ISO 14971:2019 Medical devices — Application of risk management to medical devices	IS/ISO 14971 : 2019 Medical devices — Application of risk management to medical devices (*first revision*)	Identical
ISO 16269-6 Statistical interpretation of data — Part 6: Determination of statistical tolerance intervals	IS/ISO 16269-6 : 2014 Statistical interpretation of data Part 6 Determination of statistical tolerance intervals	Identical
ISO 23908 Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling	IS 18481 : 2024/ISO 23908 : 2011 Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling	Identical
IEC 60529 Degrees of protection provided by enclosures (IP Code)	IS/IEC 60529 : 2001 Degrees of protection provided by enclosures (IP Code)	Identical
IEC 62366-1 Medical devices — Part 1: Application of usability engineering to medical devices	IS 17922 (Part 1) : 2023/IEC 62366-1 : 2015 + AMD 1 : 2020 Medical devices Part 1 Application of usability engineering (*first revision*)	Identical
IEC 60068-2-6:2007 Environmental testing — Part 2-6: Tests — Test Fc: Vibration (sinusoidal)	IS/IEC 60068-2-6 : 2007 Environmental testing Part 2 Tests Section 6 Test Fc: Vibration (sinusoidal)	Identical

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 or analysis 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 document specifies requirements and test methods for Needle-Based Injection Systems (NISs) for single-patient use intended to deliver discrete volumes (bolus) of medicinal product, which can be delivered through needles or soft cannulas for intradermal, subcutaneous and/or intramuscular delivery, incorporating pre-filled or user-filled, replaceable or non-replaceable containers.

This document applies in cases where the NIS incorporates a prefilled syringe. However, stand-alone prefilled syringes defined by ISO 11040-8 are not covered by this document (see exclusions below).

It is important to note that other functions and characteristics of the prefilled syringe, such as dose accuracy, are subject to the requirements (delivered volume) in ISO 11040-8 and not this document, unless the addition impacts the delivery function (e.g. a mechanism that intends to restrict or stop the plunger movement, which would limit the dose delivered). In that case, the system is completely covered by this document and applicable requirements of the ISO 11608 series.

Excluded from the scope are:

— stand-alone prefilled syringes defined by ISO 11040-8 (with noted exceptions above);

— NISs that provide continuous delivery and require a delivery rate clinically specified in the medicinal product labelling or determined by a physician based on clinical relevance (i.e. medication efficacy) as would be the case with insulin patch pumps or traditional infusion pumps (e.g. IEC 60601-2-24, ISO 28620) associated with continuous delivery of medicinal products (e.g. insulin);

— NISs with containers that can be refilled multiple times;

— requirements relating to methods or equipment associated with user filling of containers unless they are dedicated accessories (a component necessary for primary function, whether included in the original kitted product or not);

— NISs intended for dental use;

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

NOTE These products that are excluded might benefit from elements in this document but might not completely fulfil the basic safety and effectiveness of such products.

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 11608-1:2022 or kindly contact:

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