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BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

प्रीफिल सिरिंज

भाग 4 भरने के लिए तैयार इंजेक्टिबल और विसंक्रमित सबअसेंबल्ड सिरिंज के लिए ग्लास बैरल

[IS/ISO 11040-4 : 2015 का पहला पुनरीक्षण]

Draft Indian Standard

Prefilled Syringes

Part 4 Glass Barrels for Injectables and Sterilized Subassembled Syringes Ready for Filling

[First Revision of IS/ISO 11040-4 : 2015]

[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*)

This standard was first published in 2021 and was identical with ISO 11040-4 : 2015 'Prefilled syringes — Part 4: Glass barrels for injectables and sterilized sub-assembled syringes ready for filling'. The first revision of this standard has been undertaken to align it with the latest version of ISO 11040-4:2024. After publication of this standard, IS/ISO 11040-4 : 2015 stands withdrawn.

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 720 Glass — Hydrolytic resistance of glass grains at 121 °C — Method of test and classification	IS 2303 (Part 1/Sec 2) : 2021/ISO 720 : 2020 Grading glass for alkalinity Part 1 Hydrolytic resistance of glass grains Section 2 Determination and classification of hydrolytic resistance at 121°C (*third revision*)	Identical
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 9626 Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods	IS 18866 : 2024/ISO 9626 : 2016 Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods	Identical
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 10993-7 Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals	IS 17932 (Part 5) : 2024, Biological evaluation of medical devices Part 5 Ethylene oxide sterilization residuals (ISO 10993-7 : 2008, MOD)	Modified
ISO 11040-5 Prefilled syringes — Part 5: Plunger stoppers for injectables	IS/ISO 11040-5 : 2012 Prefilled syringes Part 5 Plunger stoppers for injectables	Identical
ISO 80369-1 Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements	IS/ISO 80369-1 : 2018 Small-bore connectors for liquids and gases in healthcare applications Part 1 General requirements	Identical

ISO 80369-7 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications	MHD/12/25955 Small-bore connectors for liquids and gases in healthcare applications Part 7 Connectors for intravascular or hypodermic applications (*first revision*)	Identical

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:

International Standard	*Title*
ISO 4802-1	Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 1: Determination by titration method and classification
ISO 4802-2	Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 2: Determination by flame spectrometry and classification
ISO 8871-1	Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 1: Extractables in aqueous autoclavates
ISO 80369-20	Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods

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 materials, dimensions, quality, and performance requirements, as well as relevant test methods.

This document also specifies components that are part of the sterilized subassembled syringe ready for filling.

This document is applicable to
— tubing-glass barrels (single-chamber design) for injection preparations, and
— sterilized subassembled syringes ready for filling.

Glass barrels and sterilized subassembled syringes ready for filling in accordance with this document are intended for single use only.

Components to complete the subassembled syringe, such as plunger stopper and plunger rod, are outside the scope of this document.

NOTE National or regional regulations such as Ph.Eur., USP, or JP can apply.

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 11040-4:2024 or kindly contact:

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