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BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

एकल उपयोग के लिए बाँझ हाइपोडर्मिक सीरिंज

भाग 2 बिजली चालित सिरिंज पंपों के साथ उपयोग के लिए सीरिंज

(ISO 7886-2:2020, संशोधित)

Draft Indian Standard

Sterile Hypodermic Syringes for Single Use

Part 2 Syringes for Use With Power-Driven Syringe Pumps

(ISO 7886-2:2020, MOD)

ICS 11.040.25

Hospital Equipment and Surgical Disposable Products Sectional Committee, MHD 12

Last date for comments:12-08-2023

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 3696 Water for analytical laboratory use — Specification and test methods	IS 1070:2023 Reagent Grade Water Specification (*Fourth Revision*)	Modified
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 (*Third Revision*)	Identical
ISO 80369-7, Small-bore connectors for liquids and gases in healthcare applications Part 7 Connectors for intravascular or hypodermic applications	IS/ISO 80369-7 : Small-Bore Connectors for Liquids and Gases in Healthcare Applications Part 7 Connectors for Intravascular or Hypodermic Applications	Identical

The technical committee has reviewed the provisions of the following International Standard referred in this draft standard proposed to be adopted and has decided that it is acceptable for use in conjunction with this standard:

International Standard/ Other Publication	*Title*
ISO/IEC Guide 99	International vocabulary of metrology — Basic and general concepts and associated terms (VIM)

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 same as that of the specified value in this standard.

This standard also makes a reference to the BIS Certification Marking of the product. Details of which is given in National Annex A.

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 Standard Act, 2016* and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

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 7886-2:2020 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
mhd12@bis.gov.in

Introduction

0.1 General

In the preparation of this document, it was recognized at an early stage that the absolute criterion of performance is achieved by the combination of the power-driven syringe pump and the syringe working as a complete system. The dependence of one element of the system on the performance of the other is a key factor. It is essential for the manufacturer of one of these components to liaise with the manufacturer of the other when considering changes in design, in order to ensure satisfactory operation of the system. In particular, a syringe manufacturer should give information on tolerances and relationships between the syringe dimensions specified in this document and on performance characteristics such as the force to move the plunger, and the variation which might be expected.

The selection of test speeds for flow rate accuracy recognized that low speeds are worse-case and result in large variation; however, selecting speeds of less than 1 ml/h was considered inappropriate due to limitations of the gravimetric test method error (due to factors such as balance stabilization and difficulty in measuring micro amounts of fluid using balances designed for static measurements).

It is recognized that start-up time and travel through parking position may impact pump forces and should be considered for exclusion, if necessary.

The syringe driver and measurement equipment characteristics might influence test method error; therefore, it is recommended to include the appropriate level of accuracy and precision of equipment and to perform test method validations.

0.2 Design criteria

The use of syringes which were initially designed and used as manually-operated devices in syringe pumps now makes it desirable to achieve much tighter tolerances on syringe dimensions than normally required for manual use.

It is understood that the degree of investment worldwide by all syringe manufacturers in molding and manufacturing equipment is such that a change such as modifying diameters of push-buttons or the barrel inner diameter (ID) is largely out of reach of the syringe industry.

Typically, the hard height of a syringe has never been regarded as a particularly critical dimension. Its tolerances are relatively loose. The hard-height dimension is a function of not only the total length of plunger rod and the barrel, but also the thickness of the piston and barrel flanges. The piston thickness, by virtue of its relatively unsophisticated manufacturing process, can vary considerably. Because all these components are manufactured in multi-cavity molds

from many molds around the world, the cumulative extreme tolerance buildup from cavity to cavity and mold to mold and location to location is such that these previously noncritical dimensions cannot be instantly tightened.

0.3 Syringe identification

It is important that when a syringe is fitted to a syringe pump, the pump is correctly programmed to perform satisfactorily with the particular syringe installed.

In view of the consequences of incorrect syringe identification by the pump, the need for an automatic system is recognized. Methods already in use, such as mechanical sensing of the syringe outer diameter, are not deemed feasible in the long term to reduce errors in syringe identification. This is due to overlapping ranges of diameter of syringes produced by different manufacturers. It is also recognized that standardization of syringe barrel diameters (IDs) across the industry is not a realistic option.

A means by which the pump could automatically identify the syringe model and use this to program such information as barrel inner diameter (ID), plunger force and occlusion alarm settings is seen as the next stage of this standard. A possible method of recognition is to identify the syringe and nominal capacity by means of a marking code on the barrel, printed at the same time as the syringe scale, and to use this to program the pump automatically. It is recommended that development of such a system be worked on as soon as possible

0.4 Infusion speeds and syringe size selection

The flow rates described in this document are for syringe tests and are not recommendations for clinical practice.

In general, as flow rate accuracy is dependent on linear travel of the plunger/pump driver, smaller size syringes tend to have a higher resolution and they also tend to have a higher flow rate accuracy at slower speeds.

Guidance on transition periods for implementing the requirements of this document is given in ISO/TR 19244[1].

Scope

This document specifies requirements for sterile single-use hypodermic syringes of nominal capacity 1 ml and above, made of plastic materials and intended for use with power-driven syringe pumps.

This document does not apply to syringes with auto-disable syringe features (ISO 7886-3[2]), syringes for use with insulin (ISO 8537[3]), single-use syringes made of glass, syringes prefilled with the injection by the manufacturer and syringes supplied with the injection as a kit for filling by a pharmacist. It does not address compatibility with injection fluids