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BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

चिकित्सा उपकरण — गैर-विद्युत चालित पोर्टेबल इन्फ्यूजन उपकरण

Draft Indian Standard

Medical Devices — Non-Electrically Driven Portable Infusion Devices

ICS 11.040.20

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 15223-1, Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	IS 18105 (Part 1) : 2023/ISO 15223-1 : 2021, Medical Devices — Symbols to be Used with Information to be Supplied by the Manufacturer Part 1 General Requirements (*Third Revision*)	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 80369-6, Small bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications	IS/ISO 80369-6 : 2016, Small Bore Connectors for Liquids and Gases in Healthcare Applications Part 6 Connectors for Neuraxial Applications	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 80369-7	Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications

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 essential requirements and related test methods for non-electrically driven portable infusion devices, thereafter called “device”.

It is applicable to devices designed for continuous (fixed or adjustable) flow and/or for bolus neuraxial and intravascular or hypodermic applications.

NOTE Sites for the neuraxial application include the spine, intrathecal or subarachnoid space, ventricles of the brain and the epi-, extra- or peri-dural space. Neuraxial application anaesthetics can be administered regionally, affecting a large part of the body, such as a limb, and include plexus blocks, such as the branchial plexus blocks or single nerve blocks. Neuraxial application procedures include continuous infusion of wounds with local anaesthetic agents.

These devices can be used in health care and non-health care settings. They can be applied or administered by health care professionals or by the intended patient.

These devices can be pre-filled by the manufacturer or filled before use by a health care professional or the intended patient.

This document does not apply to

- — electrically driven or electrically controlled infusion pumps that are covered by IEC 60601-2-24,
- — devices for single patient use intended to deliver discrete volumes (bolus) of medicinal product that are covered by the ISO 11608 series,
- — implantable devices,
- — enteral devices,
- — transdermal delivery devices, and
- — devices where the energy for infusion is not provided by the device or through active intervention by the patient (e.g. devices only powered by gravity).

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 28620:2020 or kindly contact:

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