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**BUREAU OF INDIAN STANDARDS**

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*भारतीय मानक मसौदा*

# चिकित्सा चुसण उपकरण
# भाग 4: सामान्य आवश्यकताएँ

*[ISO 10079-4:2021, संशोधित]*

*Draft Indian Standard*

# Medical Suction Equipment
# Part 4: General Requirements

*[ISO 10079-4:2021, MOD]*

ICS 11.040.10

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|---|---|
| Anaesthetic, Resuscitation and Allied Equipment Sectional Committee, MHD-11 | Last date for comments 10 May 2024 |

NATIONAL FOREWORD

(*Adoption clause will be added later*)

This Indian Standard is a modified adoption of ISO 10079-4: 2021 "Medical suction equipment Part 4: General requirements".

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 5356-1, Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets | IS/ISO 5356-1: 2015, Anaesthetic and respiratory equipment - Conical connectors: Part 1 cones and sockets (*First Revision)* | Identical |
| ISO 7000, Graphical symbols for use on equipment — Registered symbols | IS 16450: 2023/ISO 7000:2019, Graphical Symbols for Use on Equipment Registered Symbols | 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 14155, Clinical investigation of medical devices for human subjects — Good clinical practice | IS/ISO 14155: 2020, Clinical investigation of medical devices for human subjects - Good clinical practice | Identical |
| ISO 14971, 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 20417, Medical devices — Information to be provided by the manufacturer | MHD/14/23491/ ISO 20417: 2021, Medical devices — Information to be provided by the manufacturer | Identical |
| ISO 80369-6, Small bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications | IS/IEC 80369-6: 2016/ ISO 80369-6:2016, Small bore connectors for liquids and gases in healthcare applications Part 6 Connectors for neuraxial applications | 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: 2016/ ISO 80369-7: 2016, Small-Bore Connectors for Liquids and Gases in Healthcare Applications Part 7 Connectors for Intravascular or Hypodermic Applications | Identical |

| | | |
|---|---|---|
| IEC 60601-1:2005+AMD1:2012+AMD2:2020, Medical electrical equipment — Part 1: General requirements for safety | MHD/15/22648/ IEC 60601-1:2020, Medical electrical equipment : Part 1 General requirements for basic safety and essential performance (Third Revision) | Identical |
| IEC 61672-1, Electroacoustics - Sound level meters — Part 1: Specifications | IS 15575 (Part 1): 2016/ IEC 61672-1, Electroacoustics - Sound level meters: Part 1 specifications (*First Revision*) | Identical |
| IEC 80369-5, Small-bore connectors for liquids and gases in healthcare applications— Part 5 Connectors limb cuff inflation applications | IS/IEC 80369-5: 2016, Small-bore connectors for liquids and gases in healthcare applications Part 5 Connectors for limb cuff inflation applications | Identical |

The technical committee responsible for the preparation of this standard has reviewed the provisions of following mentioned International Standards and has decide that they are acceptable for use in conjunction with this standard:

| *International Standard/ Other Publication* | *Title* |
|---|---|
| ISO 3744 | Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane |
| ISO 80369-2 | Small-bore connectors for liquids and gases in healthcare applications — Part 2: Connectors for respiratory applications |
| ISO 80369-3 | Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications |
| EN 15986 | Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates |

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 (revised)’.

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 BIS 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 10079-4:2021** or kindly contact:

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## Introduction

Previously the ISO 10079 series of medical suction equipment standards comprised parts ISO 10079-1, ISO 10079-2 and ISO 10079-3 which had many common requirements. It was thought that combining these common requirements into this new part 4 would prevent the inconsistencies that had resulted from developing three different parts with common requirements and would make any future revision/amendment easier to manage.

This document contains those requirements that are common to electrically, manually and gas-powered medical suction equipment.

## Scope

This document specifies general requirements for medical suction equipment that are common to all parts of the ISO 10079 series.

This document is not applicable to the following:

a) end-pieces such as suction catheters, drains, curettes, Yankauer suckers and suction tips;
b) syringes;
c) dental suction equipment;
d) anaesthetic gas scavenging systems;
e) laboratory suction;
f) autotransfusion systems;
g) mucus extractors including neonatal mucus extractors;
h) suction equipment where the collection container is downstream of the vacuum pump;
i) ventouse (obstetric) equipment;
j) suction equipment marked for endoscopic use only; and
k) plume evacuation systems.