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BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

संवेदनाहारी और श्वसन उपयोग के लिए श्वास प्रणाली फिल्टर
भाग 2: गैर-निस्पंदन पहलू
[ISO 23328-2:2002, संशोधित]

Draft Indian Standard

Breathing system filters for anaesthetic and respiratory use
Part 2: Non-filtration aspects
[*ISO 23328-2:2002, MOD*]

ICS: 11.040.10

Anaesthetic, Resuscitation and Allied Equipment Sectional Committee, MHD-11	Last date for comments 09 August 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 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 5356-2, Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors	IS/ISO 5356-2 : 2012, Anaesthetic and respiratory equipment - Conical connectors: Part 2 screw - Threaded weight - Bearing connectors	Identical
ISO 9360-1:2000, Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml	MHD/11/25373/ ISO 9360-1:2000, Anaesthetic and respiratory equipment Heat and moisture exchangers HMEs for humidifying respired gases in humans Part 1: HMEs for use with minimum tidal volumes of 250 ml	Modified
ISO 11607, Packaging for terminally sterilized medical devices	IS/ISO 11607 : 2019, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials sterile barrier systems and packaging systems *(First Revision)*	Identical
IEC 60601-1:1988, Medical electrical equipment — Part 1: General requirements for safety; Amendment 1:1991 and Amendment 2:1995	MHD/15/22648/ IS 13450 (Part 1) : 2024, Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance (IEC 60601-1 : 2020, MOD) (*Third Revision*)	Modified

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 23328-2:2002** 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; hmhd@bis.gov.in

SCOPE

This part of ISO 23328 specifies requirements for non-filtration aspects of breathing system filters (BSF) intended for anaesthetic and respiratory use, and addresses connection ports, leakage, resistance to flow, packaging, marking and information supplied. The test method is intended for BSF used with a clinical breathing system.

It is not applicable to other types of filter, e.g. those designed to protect vacuum sources or gas sample lines, to filter compressed gases, or to protect test equipment for physiological respiratory measurements.

NOTE A method for assessing filtration performance of BSF is given in ISO 23328-1.