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BUREAU OF INDIAN STANDARDS

भारतीय मानक मसौदा

स्वास्थ्य देखभाल अनुप्रयोगों में श्वास गैस मार्गों की जैव अनुकूलता मूल्यांकन
भाग 3: वाष्पशील कार्बनिक पदार्थों के उत्सर्जन के लिए परीक्षण

Draft Indian Standard

Biocompatibility evaluation of breathing gas pathways in healthcare applications
Part 3: Tests for emissions of volatile organic substances

ICS: 11.040.10

Anaesthetic, Resuscitation and Allied Equipment Sectional Committee, MHD-11	Last date for comments 25 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 16000-3, Indoor air — Part 3: Determination of formaldehyde and other carbonyl compounds in indoor and test chamber air — Active sampling method	IS 17118 (Part 3) : 2022/ISO 16000-3 : 2011, Indoor Air Part 3 Determination of Formaldehyde and Other Carbonyl Compounds in Indoor Air and Test Chamber Air — Active Sampling Method	Identical
ISO 16000-4:2011, Indoor air — Part 4: Determination of formaldehyde — Diffusive sampling method	IS 17118 (Part 4) : 2022/ ISO 16000-4 : 2011, Indoor Air Part 4 Determination of Formaldehyde — Diffusive Sampling Method	Identical
ISO 18562-1:2024, Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process	MHD/11/25205/ ISO 18562-1: 2024, Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 1: Evaluation and testing within a risk management process	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 16000-6:2021	Indoor air — Part 6: Determination of organic compounds (VVOC, VOC, SVOC) in indoor and test chamber air by active sampling on sorbent tubes, thermal desorption and gas chromatography using MS or MS FID

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 18562-3:2024** or kindly contact:

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SCOPE

This document specifies tests for the emissions of *volatile organic substances* from the *gas pathways* of a *medical device*, its parts or *accessories,* which are intended to provide respiratory care or supply substances via the respiratory tract to a *patient* in all environments. The tests of this document are intended to quantify emissions of *volatile organic substances* that are added to the respirable gas stream by the materials of the *gas pathway*. This document establishes acceptance criteria for these tests.

NOTE Gaseous emission of *volatile organic substances* includes emissions of *volatile organic compounds*, *semi-volatile organic compound*s and *very volatile organic compounds*.

This document addresses potential contamination of the gas stream arising from the *gas pathways* of *medical devices* or *accessories*, which is then conducted to the *patient*.

This document applies over the *expected lifetime* of the *medical device* in *normal use* and takes into account the effects of any intended *processing*.

This document does not address biological evaluation of the surfaces of *gas pathways* that are in direct contact with the *patient*. The requirements for direct contact surfaces are found in the ISO 10993 series.

Medical devices, parts or *accessories* containing *gas pathways* that are addressed by this document include, but are not limited to, ventilators, anaesthesia workstations (including gas mixers), breathing systems, oxygen conserving devices, oxygen concentrators, nebulizers, low-pressure hose assemblies, humidifiers, heat and moisture exchangers, respiratory gas monitors, respiration monitors, masks, medical respiratory personal protective equipment, mouth pieces, resuscitators, breathing tubes, breathing systems filters, Y-pieces and any breathing *accessories* intended to be used with such devices. The enclosed chamber of an incubator, including the mattress, and the inner surface of an oxygen hood are considered to be *gas pathways* and are also addressed by this document.

This document does not address contamination already present in the gas supplied from the gas sources while *medical devices* are in *normal use*.

EXAMPLE

Contamination arriving at the *medical device* from gas sources such as *medical gas pipeline systems* (including the non-return valves in the pipeline outlets), outlets of pressure regulators connected or integral to a medical gas cylinder or room air taken into the *medical device* is not addressed by ISO 18562 series.

This document is intended to be read in conjunction with ISO 18562-1.