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BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

स्वास्थ्य देखभाल अनुप्रयोगों में श्वास गैस मार्गों की जैव अनुकूलता मूल्यांकन भाग 2: कण पदार्थ के उत्सर्जन के लिए परीक्षण

Draft Indian Standard

Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications Part 2: Tests for Emissions of Particulate Matter

ICS: 11.040.10

Anaesthetic, Resuscitation and Allied Equipment Sectional Committee, MHD 11	Last date for comments: 9 May 2024

NATIONAL FOREWORD

(*Adoption clause will be added later*)

This standard is an identical adoption of ISO 18562-2:2024 "Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 2: Tests for emissions of particulate matter".

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 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

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 18562-2:2024** or kindly contact:

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Abstract

This document specifies tests for the emissions of particulate matter 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 particles from 0,25 µm diameter to 10 µm diameter that are emitted by the medical device, its parts or accessories into the respirable gas stream. This document establishes acceptance criteria for these tests.

This document does not address nanoparticles. Insufficient data exist to establish exposure limits for particles less than 0,25 µm diameter.

This document does not address particles larger than 10 µm diameter. These particles are deposited in the nasal cavity. Additional information can be needed for medical devices or accessories that bypass the nose. This is outside the scope of this document but can be required by some authorities having jurisdiction.

This document therefore adopts the same approach as the US Environmental Protection Agency (EPA) in setting limits based solely on particle size and not their chemistry.

This document addresses potential contamination of the gas stream arising from the gas pathways, 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 particles that are deliberately released by a nebulizer (i.e. the therapeutic agent).

This document does not address biological evaluation of the surfaces of gas pathways that have 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 (all parts).

Introduction

This document is intended to protect *patients* connected to *medical devices* from excessive amounts of *particulate matter* that arises from within *gas pathways* of *medical devices*.

This document is intended to cover the biological evaluation of *gas pathways* of *medical devices* within a *risk management process*, as part of the overall *medical device* evaluation and development. This approach combines the review and evaluation of existing data from all sources with, where necessary, the selection and application of additional tests.

In general, the ISO 10993 series[2] is intended to cover the biological evaluation of *medical devices*. However, the ISO 10993 series does not appropriately address the biological evaluation of the *gas pathways* of *medical devices*. For example, the ISO 10993 tests do not evaluate inspired *particulate matter*.

It is not within the scope of this document to address contamination arising from the source of the breathing gases entering such *medical devices*, but rather to address only the potential contamination generated from within the *medical device* itself. This contamination might be from the original manufacturing *process* or be generated by the *medical device* itself during use.

This document is concerned with *particulate matter* that could be conveyed to the *patient* by the breathing gases. The smaller the particle, the deeper into the lungs it can penetrate and the longer it takes the body to eliminate it. Originally, the main health concerns with regard to *particulate matter* were focused on respiratory health, but now there is emerging evidence of effects on the cardiovascular system as well.

The tests for the presence of *particulate matter* generated by respiratory *medical devices* are based on standard laboratory practice and require no advanced techniques or equipment.

The acceptable levels of contamination are based on worldwide published health data for *particulates*. It is accepted that there is no point in setting a level that is lower than that found in air that people might breathe every day of their lives.

This document has been prepared in consideration of:

- — the *Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices*, IMDRF/GRRP WG/N47:2018[5] as indicated in Annex B;
- — the *Labelling Principles for Medical Devices and IVD Medical Devices*, IMDRF/GRRP WG/N52:2019[6] as indicated in Annex B;
- — the *essential principles of safety and performance* on the *information supplied by the manufacturer* of a *medical device* according to ISO 16142-1:2016[3] as indicated in Annex C; and
- — the general safety and performance requirements of a *medical device* according to regulation (EU) 2017/745[7].

In this document, the following verbal forms are used:

- — “shall” indicates a requirement;
- — “should” indicates a recommendation;
- — “may” indicates a permission;

- — "can" indicates a possibility or capability.

1 Scope

NOTE There is guidance or rationale for this Clause contained in Clause A.2.

This document specifies tests for the emissions of *particulate matter* 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 particles from 0,25 µm *diameter* to 10 µm *diameter* that are emitted by the *medical device*, its parts or *accessories* into the respirable gas stream. This document establishes acceptance criteria for these tests.

This document does not address nanoparticles. Insufficient data exist to establish exposure limits for particles less than 0,25 µm *diameter*.

This document does not address particles larger than 10 µm *diameter*. These particles are deposited in the nasal cavity. Additional information can be needed for *medical devices* or *accessories* that bypass the nose. This is outside the scope of this document but can be required by some *authorities having jurisdiction*.

This document therefore adopts the same approach as the US Environmental Protection Agency (EPA) in setting limits based solely on particle size and not their chemistry.

This document addresses potential contamination of the gas stream arising from the *gas pathways*, 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 particles that are deliberately released by a nebulizer (i.e. the therapeutic agent).

This document does not address biological evaluation of the surfaces of *gas pathways* that have 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 (all parts).