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BUREAU OF INDIAN STANDARDS

भारतीय मानक मसौदा

स्वास्थ्य देखभाल अनुप्रयोगों में श्वास गैस मार्गों की जैव अनुकूलता मूल्यांकन
भाग 4: कंडेनसेट में लीचेबल्स के लिए परीक्षण
(ISO 18562-4:2024, संशोधित)

Draft Indian Standard

Biocompatibility evaluation of breathing gas pathways in healthcare applications
Part 4: Tests for leachables in condensate
(ISO 18562-4:2024, MOD)

ICS: 11.040.10

Anaesthetic, Resuscitation and Allied Equipment Sectional Committee, MHD-11	Last date for comments 28 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 10993-1:2018, 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 10993-5:2009, Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	IS/ISO 10993-5 : 2009, Biological evaluation of medical devices Part 5 Tests for in vitro cytotoxicity	Identical
ISO 10993-10:2021, Biological evaluation of medical devices — Part 10: Tests for skin sensitization	IS 17932 (Part 6) : 2023, Biological Evaluation of Medical Devices Part 6 Tests for Skin Sensitization (ISO 10993-10 : 2021, MOD)	Modified
ISO 10993-12:2021, Biological evaluation of medical devices — Part 12: Sample preparation and reference materials	IS/ISO 10993-12 : 2021, Biological Evaluation of Medical Devices Part 12 Sample Preparation and Reference Materials	Identical
ISO 10993-18:2020+AMD1:2022, Biological evaluation of medical devices — Part 18: Chemical characterization of materials within a risk management process	IS/ISO 10993-18 : 2020, Biological evaluation of medical devices Part 18 Chemical characterization of medical device materials within a risk management process	Identical
ISO 10993-23:2021, Biological evaluation of medical devices — Part 23: Tests for irritation	MHD/19/22473/ISO 10993-23:2021, Biological Evaluation of Medical Devices Part 7 Tests for irritation ISO 10993-23:2021 MOD	Modified
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*
ICH Q3D(R2):2022	Guideline for elemental impurities

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 18562-4:2024** or kindly contact:

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SCOPE

This document specifies tests for substances leached by liquid water condensing in *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 chemical characterization methods described in this document apply to chemical substances that could leach from the *medical device*, its parts or *accessories* into the condensate. This document establishes verifiable acceptance criteria for these tests. The identity and quantity of each chemical released is intended for toxicological *risk assessment* as described in ISO 18562-1:2024.

This document addresses potential contamination of the gas stream arising from the *gas pathways*, which deliver breathing gas 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 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*.

This document does not address contact with drugs or anaesthetic agents. If a *medical device* or *accessory* is intended to be used with anaesthetic agents or drugs, then additional testing can be required. This document is intended to quantify hazardous water-soluble substances that are leached from the *medical device*, its parts or *accessories* by condensate and then conveyed by that liquid to the *patient*.