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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 1: जोखिम प्रबंधन प्रक्रिया के भीतर मूल्यांकन और परीक्षण

[ISO 18562-1:2017, संशोधित]

Draft Indian Standard

Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 1: Evaluation and testing within a risk management process

[ISO 18562-1:2017, MOD]

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 a modified adoption of ISO 18562-1: 2017 'Biocompatibility evaluation of breathing gas pathways in healthcare applications —Part 1: Evaluation and testing within a risk management process'.

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 7396-1:2016, Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum	IS 18466-1: 2024/ ISO 7396-1: 2016 Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum	Identical
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	Modified/Technically Equivalent
ISO 10993-17:2023, Biological evaluation of medical devices — Part 17: Toxicological risk assessment of medical device constituents	IS/ISO 10993-17 : 2002, Biological Evaluation of Medical Devices Part 17: Establishment of Allowable Limits for Leachable Substances	Non-Identical
ISO 14971:2019, 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

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 18562-2:2024	Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 2: Tests for emissions of particulate matter
ISO 18562-3:2024	Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 3: Tests for emissions of volatile organic substances
ISO 18562-4:2024	Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 4: Tests for leachables in condensate

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 18562-1:2024** or kindly contact:

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Abstract

This document specifies:

— the general principles governing the biological evaluation within a risk management process of 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 general categorization of gas pathways based on the nature and duration of their contact with the gas stream;

— the evaluation of existing relevant data from all sources;

— the identification of gaps in the available data set on the basis of a risk analysis;

— the identification of additional data sets necessary to analyse the biological safety of the gas pathway;

— the assessment of the biological safety of the gas pathway.

This document covers general principles regarding biocompatibility assessment of medical device materials, which make up the gas pathway, in normal use and normal condition. This document does not cover biological hazards arising from mechanical damage.

The other parts of ISO 18562 cover specific tests that address potentially hazardous substances that are added to the respirable gas stream and establish acceptance criteria for these substances.

This document addresses potential contamination of the gas stream arising from the gas pathways within the medical device, which might then be conducted to the patient.

This document applies over the expected lifetime of the medical device when operated according to the instructions for use. This includes degradation arising from exposure to environmental conditions as well as cleaning, disinfection and sterilisation (i.e. processing). It also includes user action or inaction (omission) that leads to an unintended or unexpected outcome (result) (i.e. use error). It does not include conscious/intentional action or inaction that violates the instructions for use and is beyond reasonable risk control by the manufacturer (i.e. abnormal use).

This document does not address biological evaluation of the surfaces of medical devices that have direct contact with the patient or user. 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 equipment, 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 system filters and Y-pieces as well as any breathing accessories intended to be used with such medical 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 represents the application of the best-known science, in order to improve *patient* safety, by addressing the *risk* of potentially hazardous substances being conveyed to the *patient* by the gas stream.

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 is intended to cover the biological evaluation of *medical devices*. However, the ISO 10993 series does not sufficiently address the biological evaluation of the *gas pathways* of *medical devices*.

Before this document was developed, some *authorities having jurisdiction* interpreted the ISO 10993-1:2009, Table A.1 to mean that as materials in the *gas pathway* form "indirect contact" with the *patient*, they should be subjected to tests equivalent to those required for tissue contact parts of *medical devices*. This interpretation can lead to tests that are not optimized for evaluation of *gas pathways* including possible *hazards* not being detected.

ISO 10993-1:2018 states that it is not intended to provide a rigid set of test methods as this might result in an unnecessary constraint on the development and use of novel *medical devices*. ISO 10993-1:2018 also states where a particular application warrants it, experts in the product or in the area of application concerned can choose to establish specific tests and criteria, described in a product-specific vertical standard. This series of standards is intended to address the specific needs for the evaluation of *gas pathways* that are not adequately covered by ISO 10993-1:2018.

This document provides a guide to the development of a biological evaluation plan that minimizes the number and exposure of test animals by giving preference to chemical constituent testing and *in vitro* models.

The initial version of this series of standards was intended to cover only the most commonly found potentially harmful substances. It was felt that it was best to get a functioning document published that would test for the bulk of the currently known substances of interest. With the use of the *TTC* (*threshold of toxicological concern*) approach, this document has the potential to be used to assess the safety of essentially any compound released from the *gas pathways* of respiratory *medical devices*, with very few exceptions (e.g. PCBs, dioxins), and not just the most commonly found potentially harmful substances.

ISO 18562-1 does not address all possible biological *hazards* that can be associated with *gas pathways*. Other, additional evaluations can be appropriate. These evaluations can require further *risk control* before finishing the biological evaluation.

Future parts of this series might be added to this series to address other relevant aspects of biological testing including additional contamination that might arise from the *gas pathway* because of the presence of drugs and anaesthetic agents added to the gas stream, and potential contamination by emission of inorganic gases such as ozone, CO, CO_2, and NO_x.

NOTE Some *authorities having jurisdiction* require evaluation of these *risks* as part of a biological evaluation.

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[13] as indicated in Annex B;
- — the *Labelling Principles for Medical Devices and IVD Medical Devices*, IMDRF/GRRP WG/N52:2019[14] as indicated in Annex B;
- — the *essential principles of safety and performance* of a *medical device* according to ISO 16142-1:2016 as indicated in Annex C; and
- — the general safety and performance requirements of a *medical device* according to regulation (EU) 2017/745[15].

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

This document specifies:

- — the general principles governing the biological evaluation within a *risk management process* of 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 general categorization of *gas pathways* based on the nature and duration of their contact with the gas stream;
- — the evaluation of existing relevant data from all sources;
- — the identification of gaps in the available data set on the basis of a *risk analysis*;
- — the identification of additional data sets necessary to analyse the biological safety of the *gas pathway*;
- — the assessment of the biological safety of the *gas pathway*.

This document covers general principles regarding *biocompatibility* assessment of *medical device* materials, which make up the *gas pathway*, in *normal use* and *normal condition*. This document does not cover biological *hazards* arising from mechanical damage.

The other parts of ISO 18562 cover specific tests that address potentially hazardous substances that are added to the respirable gas stream and establish acceptance criteria for these substances.

This document addresses potential contamination of the gas stream arising from the *gas pathways* within the *medical device*, which might then be conducted to the *patient*.

This document applies over the *expected lifetime* of the *medical device* when operated according to the instructions for use. This includes degradation arising from exposure to environmental conditions as well as cleaning, disinfection and sterilisation (i.e. *processing*). It also includes user action or inaction (omission) that leads to an unintended or unexpected outcome (result) (i.e. *use error*). It does not include conscious/intentional action or inaction that violates the instructions for use and is beyond reasonable *risk control* by the *manufacturer* (i.e. *abnormal use*).

This document does not address biological evaluation of the surfaces of *medical devices* that have direct contact with the *patient* or *user*. 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 equipment, oxygen concentrators, nebulizers, low-pressure hose assemblies, humidifiers, heat and moisture exchangers, respiratory gas monitors, respiration monitors, masks, medical respiratory personal protective equipment[23][25][28-30], mouth pieces, resuscitators, breathing tubes, breathing system filters and Y-pieces as well as any breathing *accessories* intended to be used with such *medical 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).