SLOVENSKI STANDARD
oSIST prEN ISO 18562-2:2023

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Ovrednotenje biokompatibilnosti vdihanega plina za uporabo v zdravstvu - 2. del: Preskusi emisij delcev (ISO/DIS 18562-2:2022)

Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter (ISO/DIS 18562-2:2022)

Beurteilung der Biokompatibilität der Atemgaswege bei medizinischen Anwendungen - Teil 2: Prüfungen für Emissionen von Partikeln (ISO/DIS 18562-2:2022)

Évaluation de la biocompatibilité des chemins de gaz respiratoires dans les applications de soins de santé - Partie 2: Essais concernant les émissions de matières particulaires (ISO/DIS 18562-2:2022)

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ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

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Biocompatibility evaluation of breathing gas pathways in healthcare applications —

Part 2:
Tests for emissions of particulate matter

Évaluation de la biocompatibilité des chemins de gaz respiratoires dans les applications de soins de santé —

Partie 2: Essais concernant les émissions de matières particulaires

ICS: 11.040.10

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of ISO standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition of ISO 18562-2 cancels and replaces the first edition of ISO 18562-2.

The main changes compared to the previous edition are as follows:

— reformatted according to most recent Central Secretariat editing rules;

— added informative mapping annexes to relevant regulatory requirements;

— clarified terms and definitions used in the document.

A list of all parts in the ISO 18562 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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.

In this document, the following print types are used:

— requirements and definitions: roman type;

— informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

— *terms defined in clause 3 of this document or as noted and test specifications: italic type;*

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 conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

For the purposes of this document, the auxiliary verb:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— "can" is used to describe a possibility or capability;

— "must" is used express an external constraint.

Requirements in this document have been decomposed so that each requirement is uniquely delineated. This is done to support automated requirements tracking.

Biocompatibility evaluation of breathing gas pathways in healthcare applications —

Part 2: Tests for emissions of particulate matter

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 0,2 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 0,2 µm in *diameter*.

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, 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).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 18562-1:—,[1)]*Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18562-1:— and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at https://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

NOTE For convenience, an alphabetized index of terms and their sources used in this document is found at the end of this document.

3.1
diameter
aerodynamic diameter
diameter of a sphere of density 1 g/cm^3 with the same terminal velocity due to gravitational force in calm air as the particle of interest, regardless of its geometric size, shape and true density, under the prevailing conditions of temperature, pressure and relative humidity

[SOURCE: ISO 7708:1995, 2.2, modified — added "of interest, regardless of its geometric size, shape and true density"]

4 General principles

4.1 *Type tests*

The tests described in this document are *type tests*. *Type tests* are performed on the final *medical device*, a component of the *medical device* or a representative sample of the *medical device*, part or *accessory* being evaluated.

a) If representative samples are used (i.e. manufactured and processed by equivalent methods), consideration shall be given to whether or not the differences between the representative sample and the final *medical device* or component could affect the results of the test.

b) Testing of representative samples (manufactured and processed by equivalent methods) instead of the final *medical device* should:

   1) be supported by a description of any differences between the representative sample and the final *medical device*; and

   2) include a detailed rationale for why each difference is not expected to impact the *biocompatibility* of the final *medical device*.

      NOTE Some *authorities having jurisdiction* evaluate these differences and rationales.

4.2 General

All *gas pathways* from which the *patient* inspires gas shall be evaluated using the strategy detailed in ISO 18562-1.

1) Under preparation. Stage at the time of publication: ISO/DIS 18562-1:2022.

5 *Particulate matter* emissions

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

5.1 General

a) During its *expected lifetime*, a *medical device*, part or *accessory* shall not add to the gas that could be inspired by the *patient* levels of *particulate matter:*

1) less than or equal to 2,5 µm *diameter*, in excess of 12 µg/m^3;

2) less than or equal to 10 µm *diameter*, in excess of 150 µg/m^3.

NOTE 1 The allowable limits are taken from the US EPA 40 § CFR Part 50[8].

b) All *gas pathways* from which the *patient* inspires gas shall be evaluated for *particulate matter* emissions. The evaluation should use the *risk management process* to assess if testing is required.

NOTE 2 The evaluation of some components, which are identical in *formulation*, *processing* and preparation for use to an existing component of a *medical device* that has been previously tested, might conclude that no further testing is required. Refer to ISO 18562-1:—, Figure 2.

c) Evaluation and, if required, testing shall take in to account:

1) the *expected lifetime*;

2) the effects of any intended manufacturing *processes*;

NOTE 3 Manufacturing *processes* include *processing* (i.e. cleaning/disinfection/sterilization during manufacturing).

3) the effects of transportation and storage prior to use; and

4) the effects of any intended application *processes*;

NOTE 4 Application *processes* include *processing* (i.e. cleaning/disinfection/sterilization either prior to use or between uses).

5) the worst-case *patient* exposure.

d) The *manufacturer* shall document in the report this evaluation as well as the criteria for selection of test articles and methodologies, including component parts to be tested and the duration of testing in relation to the intended duration of clinical use.

e) If the *risk management process* determines that testing is required, testing shall be performed according to:

1) 5.5;

i) For testing according to 5.5, use the setup according to either 5.3 or 5.4.

ii) The *manufacturer* may choose the appropriate test method.

2) 5.6; or

3) 5.7.

Compliance is checked by examining the *report* and *risk management file*.

5.2 Testing methods overview

a) There is a great variety of components and *medical devices* within the scope of this document, and so several different methods are proposed. The *manufacturer* should select the most appropriate