SLOVENSKI STANDARD
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Ovrednotenje biokompatibilnosti vdihanega plina za uporabo v zdravstvu - 3. del: Preskusi emisij hlapnih organskih spojin (VOC) (ISO/DIS 18562-3:2022)

Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic substances (ISO/DIS 18562-3:2022)

Beurteilung der Biokompatibilität der Atemgaswege bei medizinischen Anwendungen - Teil3: Prüfungen für Emissionen von flüchtigen organischen Verbindungen (VOCs) (ISO/DIS 18562-3:2022)

Évaluation de la biocompatibilité des chemins de gaz respiratoires dans les applications de soins de santé - Partie 3: Essais concernant les émissions de substances organiques volatils (ISO/DIS 18562-3:2022)

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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 3:
Tests for emissions of volatile organic substances

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

Partie 3: Essais concernant les émissions de substances organiques volatils

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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 18562-3 cancels and replaces the first edition of ISO 18562-3.

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 of 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 volatile organic substances that arise from within the *gas pathways* of those *medical devices*. This document represents the application of the best-known science by addressing the *risks* from potentially hazardous volatile organic 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[1] 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 detect *VOCs*.

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 only address the potential contamination generated from within the *medical device* itself. This contamination might be from the original manufacturing *process* or generated by the *medical device* itself during use.

This document is concerned with volatile organic substances that could be conveyed to the *patient* by the breathing gases. Volatile organic substances can have health effects ranging from unpleasant odour and irritation of the mucous membranes to possible long-term effects on the nervous system. It is accepted that there is no point in setting levels that are lower than those found in air that people might breathe every day.

The tests for the presence of volatile organic substances generated by respiratory *medical devices* are based on advanced laboratory practice and require specialist training and equipment to generate meaningful results.

The methods to determine the acceptable levels of contamination are contained in ISO 18562-1.

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[4] as indicated in Annex B;

— the *Labelling Principles for Medical Devices and IVD Medical Devices,* IMDRF/GRRP WG/N52:2019[5] as indicated in Annex B;

— the the *essential principles of safety and performance* according to ISO 16142-1:2016[2] as indicated in Annex C; and

— the general safety and performance requirements of a *medical device* according to regulation (EU) 2017/745[6].

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 3: Tests for emissions of volatile organic substances

1 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 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*, 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[1].

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 series.

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

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 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*

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

ASTM D5466-15, *Standard Test Method for Determination of Volatile Organic Chemicals in Atmospheres (Canister Sampling Methodology)*

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 all defined terms and their sources used in this document are given in Annex C.

3.1
rated
<value> term referring to a value assigned by the *manufacturer* for a specified operating condition

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.97]

3.2
thermal stability
condition under which the temperature of an object does not change by more than 2 °C over a period of 1 h

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.125, modified — “increase” has been changed to “change”.]

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 made regarding 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*.

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

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:—.

The fundamental consideration in assessing a substance is "what is the *exposure dose* of this substance to the *patient*?"

Limits for toxicological purposes are most often quoted in µg/kg body weight/d (*tolerable intake*). Limits for environmental purposes, and the quantity that is measured by test laboratories, are usually quoted as concentrations in $\mu g/m^3$. The *exposure dose* depends on the concentration of the substance (in $\mu g/m^3$) multiplied by the volume (in m^3) inhaled by the *patient*.

Standard daily breathing volumes are found in ISO 18562-1:—, 6.1.

5 Volatile organic substance emissions

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

5.1 General

a) All *gas pathways* from which the *patient* inspires gas shall be evaluated for the emission of volatile organic substances.

NOTE 1 Gaseous emission of organic substances includes emissions of *VOCs*, *SVOCs* and *VVOCs*.

b) In the selection of materials to be used in the *medical device* manufacture, the first consideration should be given for fitness for purpose with regard to characteristics and properties of the material, which include physical, mechanical, chemical and toxicological properties.

1) Knowledge of materials should inform the nature and extent of screening for substances including any targeted compounds.

2) Specific sampling methods may be required for targeted compounds.

EXAMPLE Aldehydes from polyoxymethylene plastics and isocyanates from polyurethanes

c) 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*, manufacturing or application *processes* 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. Manufacturing and application *processes* include *processing* (i.e. cleaning/disinfection/sterilization either prior to use or between uses).

d) A *medical device*, part or *accessory* shall not add to the gas that could be inspired by the *patient* substances at levels that create an unacceptable *risk* to the *patient.*

NOTE 3 Parts downstream of the *patient* can be evaluated for emissions if there is a *risk* that the *patient* might inspire gas that has been in contact with them.

e) If the *risk management process* determines that testing is required, the tests of 5.3 shall be performed.

5.2 Acceptance criteria

a) The *exposure dose* of any substance for which a *TI* is calculated shall be below that *TI*.