ICS 11.040.10 SLOVENSKÁ TECHNICKÁ NORMA Január 2025

STN	**Hodnotenie biokompatibility ciest dýchacích plynov v zdravotníckych aplikáciách Časť 3: Skúšky emisií prchavých organických zlúčenín (ISO 18562-3: 2024)**	**STN EN ISO 18562-3** 85 2134

Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic substances (ISO 18562-3:2024)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 12/24

Obsahuje: EN ISO 18562-3:2024, ISO 18562-3:2024

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EUROPEAN STANDARD

NORME EUROPÉENNE

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EN ISO 18562-3

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ICS 11.040.10

Supersedes EN ISO 18562-3:2020

English Version

Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic substances (ISO 18562-3:2024)

Évaluation de la biocompatibilité des chemins de gaz respiratoire utilisés dans le domaine de la santé - Partie 3: Essais concernant les émissions de substances organiques volatiles (ISO 18562-3:2024)

Beurteilung der Biokompatibilität der Atemgaswege bei medizinischen Anwendungen - Teil3: Prüfungen für Emissionen von flüchtigen organischen Verbindungen (VOCs) (ISO 18562-3:2024)

This European Standard was approved by CEN on 15 March 2024.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 18562-3:2024 E

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European foreword

This document (EN ISO 18562-3:2024) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2025, and conflicting national standards shall be withdrawn at the latest by April 2025.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 18562-3:2020.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 18562-3:2024 has been approved by CEN as EN ISO 18562-3:2024 without any modification.

Annex ZA
(informative)

Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up.

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA Regulations.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall be indicated in Table ZA.3 in this Annex Z. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the European regulation for medical devices (EU) 2017/745).

For application of this European standard under Regulation (EU) 2017/745, its scope is limited to medical devices for use with human patients. This affects all clauses of this European standard.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/745. This means that risks have to be ‘reduced as far as possible’, ‘reduced to the lowest possible level’, ‘reduced as far as possible and appropriate’, ‘removed or reduced as far as possible’, ‘eliminated or reduced as far as possible’, ’removed or minimized as far as possible’, or ‘minimized’, according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer’s policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European standard and Annex I of Regulation (EU) 2017/745 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
10.1 a)	Clause 4, Clause 5	This requirement is only partly covered by this document, since the standard does not provide requirements on manufacture. However, this standard provides a means to assess toxicity of volatile organic substances added by the medical device to the gas pathways of manufactured medical devices. Other forms of toxicity and flammability are not covered.
10.1 b)	Clause 4, Clause 5	This requirement is only partly covered by this document, since the standard does not provide requirements on manufacture. However, this standard provides a means to assess toxicity of volatile organic substances added by the medical device to the gas pathways of manufactured medical devices.
10.2	Clause 4, Clause 5	This requirement is only partly covered by this document, since the standard does not provide requirements on manufacture and packaging. However, this standard provides a means to assess risks to the patient associated with the toxicity of volatile organic substances added by the medical device to the gas pathways of manufactured medical devices. It is within the scope to address the potential contamination generated from the original manufacturing process or generated by the medical device itself during use. Packaging is not covered. Risks to other persons involved in the transport, storage and use are not covered.

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
10.4.1 (first paragraph only)	Clause 4, Clause 5	This requirement is only partly covered by this document, since the standard does not provide requirements on manufacture. However, this standard provides a means to assess risks to the patient associated with the toxicity of volatile organic substances added by the medical device to the gas pathways of manufactured medical devices. Other forms of toxicity are not covered. Risks from substances or particles released from the device outside of the gas pathways are not covered.

WARNING 1 Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

Table ZA.2 — Applicable Standards to confer presumption of conformity as described in this Annex ZA

Column 1 Reference in Clause 2	Column 2 International Standard Edition	Column 3 Title	Column 4 Corresponding European Standard Edition
ISO 16000-3:2022	ISO 16000-3:2022	Indoor air — Part 3: Determination of formaldehyde and other carbonyl compounds in indoor and test chamber air — Active sampling method	—
ISO 16000-4:2011	ISO 16000-4:2011	Indoor air — Part 4: Determination of formaldehyde — Diffusive sampling method	—
ISO 18562-1:2024	ISO 18562-1:2024	Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process	EN ISO 18562-1:2024

The documents listed in the Column 1 of Table ZA.2, in whole or in part, are normatively referenced in this document, i.e. are indispensable for its application. The achievement of the presumption of conformity is subject to the application of the edition of Standards as listed in Column 4 or, if no European Standard Edition exists, the International Standard Edition given in Column 2 of Table ZA.2.

Table ZA.3 — Prevailing terms of Regulation (EU) 2017/745 for use of this European standard under that Regulation

Term used in this EN	Clause / sub-clause where this term is defined in this EN	Article in (EU) 2017/745 that defines or uses this term	Differences / Consequences
N/A	N/A	N/A	No legally relevant terms are defined in this Standard

International Standard

ISO 18562-3

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 respiratoire utilisés dans le domaine de la santé —

Partie 3: Essais concernant les émissions de substances organiques volatiles

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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

For an explanation of the voluntary nature of 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 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 cancels and replaces the first edition (ISO 18562-3:2017), which has been technically revised.

The main changes are as follows:

— added informative mapping annexes to relevant regulatory requirements;

— clarified terms and definitions used in the document;

— broke the term *VOC* (now *VOS*) into parts based on boiling point.

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 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 series does not provide guidance how to evaluate the presence of *VOSs*.

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.

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[7] as indicated in Annex B;

— the *Labelling Principles for Medical Devices and IVD Medical Devices,* IMDRF/GRRP WG/N52:2019[8] as indicated in Annex B;

— the the *essential principles of safety and performance* 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[9].

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.

International Standard **ISO 18562-3:2024(en)**

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 *volatile 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* of *medical devices* or *accessories*, 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.

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 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 16000-3:2022, *Indoor air — Part 3: Determination of formaldehyde and other carbonyl compounds in indoor and test chamber air — Active sampling method*

ISO 16000-4:2011, *Indoor air — Part 4: Determination of formaldehyde — Diffusive sampling method*

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 18562-1:2024, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*