

<b>STN</b>	<b>Hodnotenie biokompatibility ciest dýchacích plynov v zdravotníckych aplikáciách</b> <b>Časť 1: Hodnotenie a skúšanie v rámci procesu riadenia rizík (ISO 18562-1: 2024)</b>	<b>STN</b> <b>EN ISO 18562-1</b>  85 2134
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Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process (ISO 18562-1:2024)

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

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English Version

## Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process (ISO 18562-1:2024)

Évaluation de la biocompatibilité des chemins de gaz respiratoire utilisés dans le domaine de la santé -  
Partie 1: Évaluation et essais au sein d'un processus de gestion du risque (ISO 18562-1:2024)

Beurteilung der Biokompatibilität der Atemgaswege bei medizinischen Anwendungen - Teil 1: Beurteilung und Prüfung innerhalb eines Risikomanagement-Prozesses (ISO 18562-1:2024)

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  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

**EN ISO 18562-1:2024 (E)**

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## **European foreword**

This document (EN ISO 18562-1:2024) 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 18562-1:2020.

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 18562-1:2024 has been approved by CEN as EN ISO 18562-1:2024 without any modification.

**EN ISO 18562-1:2024 (E)****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 [O] 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, Clause 6, Clause 7, Clause 8, Clause 9, Clause 10, Clause 11	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 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, Clause 6, Clause 7, Clause 8, Clause 9, Clause 10, Clause 11	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 substances added by the medical device to the gas pathways of manufactured medical devices.
10.2	Clause 4, Clause 5, Clause 6, Clause 7, Clause 8, Clause 9, Clause 10, Clause 11	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 substances added by the medical device to the gas pathways of manufactured medical devices. Risks to other persons involved in the transport, storage and use of the devices are not covered.
10.3	Clause 4, Clause 5, Clause 6, Clause 7, Clause 8, Clause 9, Clause 10, Clause 11	This requirement is only partly covered by this document, since the standard does not provide requirements on manufacture. Only the aspects relating to contamination of medical gases by contact with the gas pathways are covered.  Risks to the patient associated with medicinal substances added to the gas stream are not covered.

**EN ISO 18562-1:2024 (E)**

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)	Clause 4, Clause 5, Clause 6, Clause 7, Clause 8, Clause 9, Clause 10, Clause 11	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 substances added by the medical device to the gas pathways of manufactured medical devices. This does not include all aspects of degradation as these cannot be fully evaluated using the tests of ISO 18562 alone. Other forms of toxicity 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**

<b>Column 1 Reference in Clause 2</b>	<b>Column 2 International Standard Edition</b>	<b>Column 3 Title</b>	<b>Column 4 Corresponding European Standard Edition</b>
ISO 10993-1:2018	ISO 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1:2020
ISO 10993-17:2023	ISO 10993-17:2023	Biological evaluation of medical devices — Part 17: Toxicological risk assessment of medical device constituents	EN ISO 10993-17:2023
ISO 14971:2019	ISO 14971:2019	Medical devices — Application of risk management to medical devices	EN ISO 14971:2019 EN ISO 14971:2019/A11:2021
ISO 18562-2:2024	ISO 18562-2:2024	Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 2: Tests for emissions of particulate matter	EN ISO 18562-2:2024
ISO 18562-3:2024	ISO 18562-3:2024	Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 3: Tests for emissions of volatile organic substances	EN ISO 18562-3:2024
ISO 18562-4:2024	ISO 18562-4:2024	Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 4: Tests for leachables in condensate	EN ISO 18562-4:2024

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.

## EN ISO 18562-1:2024 (E)

**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
Accessory	3.2	Term defined in Art. 2(2)	For use under MDR, only “accessories for a medical device” are in focus, instead of accessories “for use with equipment”. Art. 1(4) of MDR summarizes medical devices and accessories for medical devices as “devices” for diverse requirements throughout the MDR. Annex VIII 3.2 requires classification of accessories in their own right; Annex II 1 requires technical documentation of accessories.
Hazard	3.12	Legally relevant term used in Art. 1(12), Art. 106, GSPR 3 et al.	For use under MDR, the term only refers to potential sources of harm in the meaning of harm as listed above. This is the only difference in the meaning of harm in MDR and in this EN.
Manufacturer	3.17	Term defined in Art. 2(30)	For use under MDR, the term includes also full refurbishment as well as marketing of a device under its name or trademark.
Patient	3.23	Legally relevant term used in Art. 2 (3,4,36, 52) et al.	For use under MDR, the term only refers to medical devices for human use, but not to medical devices for use on animals.
Process	3.24	Legally relevant term used in Art. 2 (1,17,39, 40,44,71), Art. 5,10, GSPR 3, 13.1 et al.	No difference between the use of the term in MDR and the definition in this EN. For use under MDR, the specifically addressed process in the context of the term applies (e.g., manufacturing process, risk management process, handling processes, conformity assessment process, reprocessing process, physiological process, clinical evaluation process, reporting / monitoring process).
Residual Risk	3.26	Legally relevant term used in Art. 32, GSPR 4,10.4.5,23.1 et al.	No difference between the use of the term in MDR and the definition in this EN. For use under MDR, the specifically addressed residual risk in the context of the term applies (e.g., residual risk associated with each hazard, overall residual risk).

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
Risk	3.27	Term defined in Art. 2(23)	Identical definitions in MDR and this standard, however, MDR has a narrower meaning of the term “harm” used in the definition for risk, see above, which prevails for use of this EN under the MDR.
Risk Management	3.31	Legally relevant term used in Art. 1,8,10 et al., GSPR 3,17.2 et al.	GSPR 3 to 5 of MDR provide more detailed (but not contradicting) specifications of the term than in the definition of this EN. However, in contrast to use in MDR, the note to the definition in this EN and the requirements in 4.2.2 exclude risk management activities of planning for and monitoring of production and post-production information. For use under MDR, the use of the MDR term “risk management” prevails and the GSPR coverage of this EN is limited, accordingly.



# International Standard

**ISO 18562-1**

## **Biocompatibility evaluation of breathing gas pathways in healthcare applications —**

### **Part 1: Evaluation and testing within a risk management process**

*Évaluation de la biocompatibilité des chemins de gaz respiratoire  
utilisés dans le domaine de la santé —*

*Partie 1: Évaluation et essais au sein d'un processus de gestion du  
risque*

**Second edition  
2024-03**

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## ISO 18562-1:2024(en)

### 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](http://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](http://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](http://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 18562-1:2017), 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;
- expanded the *patient* groups to include: premature, small child, child, and adolescent;
- introduction of inhalation dose;
- the *threshold of toxicological concern* is changed;
- expanded the range of *volatile organic substances* that are tested;
- clarified the appropriate breathing gas volumes to be used in testing for *VOS*; and
- clarified the appropriate breathing gas volumes to be used in the analysis.

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](http://www.iso.org/members.html).

## ISO 18562-1:2024(en)

### 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<sub>2</sub>, and NO<sub>x</sub>.

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<sup>[13]</sup> as indicated in [Annex B](#);
- the *Labelling Principles for Medical Devices and IVD Medical Devices*, IMDRF/GRRP WG/N52:2019<sup>[14]</sup> 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<sup>[15]</sup>.

**ISO 18562-1:2024(en)**

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.

# Biocompatibility evaluation of breathing gas pathways in healthcare applications —

## Part 1: Evaluation and testing within a risk management process

### 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<sup>[23][25][28-30]</sup>, 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.

## ISO 18562-1:2024(en)

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 10993-1:2018, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-17:2023, *Biological evaluation of medical devices — Part 17: Toxicological risk assessment of medical device constituents*

ISO 14971:2019, *Medical devices — Application of risk management to medical devices*

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*

**koniec náhľadu – text ďalej pokračuje v platenej verzii STN**