



# SLOVENSKI STANDARD SIST EN ISO 18562-4:2024

01-december-2024

Nadomešča:

SIST EN ISO 18562-4:2020

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**Ovrednotenje biokompatibilnosti vdihanega plina za uporabo v zdravstvu - 4. del:  
Preskusi izlužnin v kondenzatih (ISO 18562-4:2024)**

Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4:  
Tests for leachables in condensate (ISO 18562-4:2024)

Beurteilung der Biokompatibilität der Atemgaswege bei medizinischen Anwendungen -  
Teil 4: Prüfungen für herauslösbare Substanzen in Kondensaten (ISO 18562-4:2024)

Évaluation de la biocompatibilité des chemins de gaz respiratoire utilisés dans le  
domaine de la santé - Partie 4: Essais concernant les relargables dans le condensat  
(ISO 18562-4:2024)

Ta slovenski standard je istoveten z: **EN ISO 18562-4:2024**

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**ICS:**

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

**SIST EN ISO 18562-4:2024**

**en,fr,de**



EUROPEAN STANDARD

EN ISO 18562-4

NORME EUROPÉENNE

EUROPÄISCHE NORM

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ICS 11.040.10

Supersedes EN ISO 18562-4:2020

English Version

## Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate (ISO 18562-4:2024)

Évaluation de la biocompatibilité des chemins de gaz respiratoire utilisés dans le domaine de la santé -  
Partie 4: Essais concernant les relargables dans le condensat (ISO 18562-4:2024)

Beurteilung der Biokompatibilität der Atemgaswege bei medizinischen Anwendungen - Teil 4: Prüfungen für herauslösbare Substanzen in Kondensaten (ISO 18562-4:2024)

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.

CEN members are the national standards bodies of 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 United Kingdom.

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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

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## European foreword

This document (EN ISO 18562-4:2024) 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 18562-4:2020.

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 18562-4:2024 has been approved by CEN as EN ISO 18562-4:2024 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 [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	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 the condensate from 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	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 the condensate from the gas pathways of manufactured medical devices.
10.2	Clause 4, Clause 5, Clause 6	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 the condensate from the gas pathways of manufactured medical devices. Risks to other persons involved in the transport, storage and use of the devices are not covered.

## EN ISO 18562-4:2024 (E)

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
10.3	Clause 4, Clause 5, Clause 6	<p>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 the gas pathways by contact with water are covered.</p> <p>Risks to the patient associated with medicinal substances added to the gas stream are not covered.</p>
10.4.1 (first paragraph only)	Clause 4, Clause 5, Clause 6	<p>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 the condensate from the gas pathways of manufactured medical devices. Other forms of toxicity are not covered.</p>
14.2 c)	Clause 4, Clause 5, Clause 6	<p>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 the condensate from the gas pathways of manufactured medical devices.</p>

**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 10993-5:2009	ISO 10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	EN ISO 10993-5:2009
ISO 10993-10:2021	ISO 10993-10:2021	Biological evaluation of medical devices — Part 10: Tests for skin sensitization	EN ISO 10993-10:2023
ISO 10993-12:2021	ISO 10993-12:2021	Biological evaluation of medical devices — Part 12: Sample preparation and reference materials	EN ISO 10993-12:2021
ISO 10993-18:2020 +AMD1:2022	ISO 10993-18:2020 +AMD1:2022	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process	EN ISO 10993-18:2020 +A1:2023
ISO 10993-23:2021	ISO 10993-23:2021	Biological evaluation of medical devices — Part 23: Tests for irritation	EN ISO 10993-23:2021
ISO 18562-1:2024 <sup>a</sup>	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
ICH Q3D(R2):2022	—	ICH guideline Q3D (R2) for elemental impurities	—

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

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# International Standard

**ISO 18562-4**

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

### **Part 4: Tests for leachables in condensate**

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

*Partie 4: Essais concernant les relargables dans le condensat*

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