SLOVENSKI STANDARD
SIST EN ISO 18562-1:2024

01-december-2024

Nadomešča:
SIST EN ISO 18562-1:2020

Ovrednotenje biokompatibilnosti vdihanega plina za uporabo v zdravstvu - 1. del: Ovrednotenje in preskušanje znotraj procesa obvladovanja tveganja (ISO 18562-1:2024)

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

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)

Ta slovenski standard je istoveten z: **EN ISO 18562-1:2024**

ICS:

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

SIST EN ISO 18562-1:2024 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 18562-1

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ICS 11.040.10

Supersedes EN ISO 18562-1:2020

English Version

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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.

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 18562-1:2024) 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.

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, 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.

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

Column 1 Reference in Clause 2	Column 2 International Standard Edition	Column 3 Title	Column 4 Corresponding European Standard Edition
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.

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

Second edition
2024-03

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

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