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**Ovrednotenje biokompatibilnosti vdihanega plina za uporabo v zdravstvu - 4. del:  
Preskusi izlužnin v kondenzatih (ISO 18562-4:2017)**

Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4:  
Tests for leachables in condensate (ISO 18562-4:2017)

Beurteilung der Biokompatibilität der Atemgaswege bei medizinischen Anwendungen -  
Teil 4: Prüfungen für herauslösbare Substanzen in Kondensaten (ISO 18562-4:2017)

Évaluation de la biocompatibilité des voies de gaz respiratoires dans les applications de  
soins de santé - Partie 4: Essais concernant les substances relargables dans le  
condensat (ISO 18562-4:2017)

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**Ta slovenski standard je istoveten z: EN ISO 18562-4:2020**

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**ICS:**

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN ISO 18562-4**

February 2020

ICS 11.040.10

English Version

**Biocompatibility evaluation of breathing gas pathways in  
healthcare applications - Part 4: Tests for leachables in  
condensate (ISO 18562-4:2017)**

Évaluation de la biocompatibilité des voies de gaz  
respiratoires dans les applications de soins de santé -  
Partie 4: Essais concernant les substances relargables  
dans le condensat (ISO 18562-4:2017)

Beurteilung der Biokompatibilität der Atemgaswege  
bei medizinischen Anwendungen - Teil 4: Prüfungen  
für herauslösbare Substanzen in Kondensaten (ISO  
18562-4:2017)

This European Standard was approved by CEN on 11 November 2019.

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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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

The text of ISO 18562-4:2017 has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 18562-4:2020 by 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 August 2020, and conflicting national standards shall be withdrawn at the latest by August 2020.

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.

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, Turkey and the United Kingdom.

## iTeh STANDARD PREVIEW Endorsement notice (standards.iteh.ai)

The text of ISO 18562-4:2017 has been approved by CEN as EN ISO 18562-4:2020 without any modification.

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# INTERNATIONAL STANDARD

ISO  
18562-4

First edition  
2017-03

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

### Part 4: Tests for leachables in condensate

**iTeh STANDARD PREVIEW**  
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*Évaluation de la biocompatibilité des voies de gaz respiratoires dans  
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## ISO 18562-4:2017(E)

## 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](http://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](http://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](http://www.iso.org/iso/foreword.html). (standards.iteh.ai)

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

A list of all parts of the ISO 18562 series can be found on the ISO website.

## Introduction

This document is intended to protect PATIENTS connected to MEDICAL DEVICES from excessive amounts of harmful substances that might be contained in water that has condensed in the GAS PATHWAYS of those MEDICAL DEVICES. This document represents the application of the best-known science by addressing the RISKS from potentially hazardous substances in the condensate being conveyed to the PATIENT by the GAS PATHWAY. The condensate itself will be distilled water, having condensed from the vapour phase, but liquid water present in the breathing system might be able to leach or absorb other substances from within the MEDICAL DEVICE. This contamination might be from the original manufacturing PROCESS or be generated by the MEDICAL DEVICE itself during use.

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.

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 substances that could be conveyed to the PATIENT by liquid condensate forming in the MEDICAL DEVICE and then subsequently reaching the lungs of the PATIENT. Potentially harmful substances that could be found in condensate include salts and metals. Condensate management is part of most healthcare institution protocols, with the primary aim of preventing the condensate reaching the PATIENT in the first place. The absolute volume of liquid reaching a PATIENT by this route should therefore be low, but it might happen. This document outlines tests for substances contained in the liquid.

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;
- *test specifications: italic type;*
- terms defined in [Clause 3](#) of this DOCUMENT or as noted: small capitals type.

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.

The verbal forms used in this document conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

- a) “shall” means that compliance with a requirement or a test is mandatory for compliance with this document;
- b) “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
- c) “may” is used to describe a permissible way to achieve compliance with a requirement or test.