SLOVENSKI STANDARD
SIST EN ISO 18562-2:2020

01-april-2020

Ovrednotenje biokompatibilnosti vdihanega plina za uporabo v zdravstvu - 2. del: Preskusi emisij delcev (ISO 18562-2:2017)

Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter (ISO 18562-2:2017)

Beurteilung der Biokompatibilität der Atemgaswege bei medizinischen Anwendungen - Teil 2: Prüfungen für Emissionen von Partikeln (ISO 18562-2:2017)

Évaluation de la biocompatibilité des voies de gaz respiratoires dans les applications de soins de santé - Partie 2: Essais concernant les émissions de matières particulaires (ISO 18562-2:2017)

Ta slovenski standard je istoveten z: **EN ISO 18562-2:2020**

ICS:

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

SIST EN ISO 18562-2:2020 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 18562-2

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ICS 11.040.10

English Version

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

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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 18562-2:2017 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 18562-2:2020 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of an identical text or by endorsement, at the latest by August 2020, and conflicting national standards shall be withdrawn at the latest by August 2020.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.

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Endorsement notice

The text of ISO 18562-2:2017 has been approved by CEN as EN ISO 18562-2:2020 without any modification.

INTERNATIONAL STANDARD

ISO 18562-2

First edition
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Biocompatibility evaluation of breathing gas pathways in healthcare applications —

Part 2: Tests for emissions of particulate matter

Évaluation de la biocompatibilité des voies de gaz respiratoires dans les applications de soins de santé —

Partie 2: Essais concernant les émissions de matières particulaires

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Foreword

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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).

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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.

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 in 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 PARTICULATE MATTER that arises from within GAS PATHWAYS of MEDICAL DEVICES.

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[2] 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 tests do not evaluate inspired PARTICULATE MATTER.

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 address only the potential contamination generated from within the MEDICAL DEVICE itself. This contamination might be from the original manufacturing PROCESS or be generated by the MEDICAL DEVICE itself during use.

This document is concerned with PARTICULATE MATTER that could be conveyed to the PATIENT by the breathing gases. The smaller the particle, the deeper into the lungs it can penetrate and the longer it takes the body to eliminate it. Originally, the main health concerns with regard to PARTICULATE MATTER were focused on respiratory health, but now there is emerging evidence of effects on the cardiovascular system as well.

The tests for the presence of PARTICULATE MATTER generated by respiratory MEDICAL DEVICES are based on standard laboratory practice and require no advanced techniques or equipment.

The acceptable levels of contamination are based on worldwide published health data for particulates. It is accepted that there is no point in setting a level that is lower than that found in air that people might breathe every day of their lives.

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:

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

— "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

