SLOVENSKI STANDARD
SIST EN ISO 18562-1:2020

01-april-2020

Ovrednotenje biokompatibilnosti vdihanega plina za uporabo v zdravstvu - 1. del: Ovrednotenje in preskušanje znotraj procesa obvladovanja tveganja (ISO 18562-1:2017)

Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process (ISO 18562-1:2017)

Beurteilung der Biokompatibilität der Atemgaswege bei medizinischen Anwendungen - Teil 1: Beurteilung und Prüfung innerhalb eines Risikomanagement-Prozesses (ISO 18562-1:2017)

Évaluation de la biocompatibilité des voies de gaz respiratoires dans les applications de soins de santé - Partie 1: Évaluation et essais au sein d'un processus de gestion du risque (ISO 18562-1:2017)

Ta slovenski standard je istoveten z: **EN ISO 18562-1:2020**

ICS:

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

SIST EN ISO 18562-1:2020 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 18562-1

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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 18562-1:2017)

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

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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

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European foreword

The text of ISO 18562-1:2017 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 18562-1:2020 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 18562-1:2017 has been approved by CEN as EN ISO 18562-1:2020 without any modification.

INTERNATIONAL STANDARD

ISO 18562-1

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

Part 1: Evaluation and testing within a risk management process

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

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

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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).

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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.

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 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 materials in the GAS PATHWAY form "indirect contact" with the PATIENT, and should be subjected to tests equivalent to those required for tissue contact parts of MEDICAL DEVICES. This interpretation can lead to tests with questionable benefit and also to possible HAZARDS not being detected.

ISO 10993-1:2009 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 10993-1:2009 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 new series of standards is intended to address the specific needs for the evaluation of GAS PATHWAYS that are not adequately covered by ISO 10993-1:2009.

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. Later amendments and additional parts are planned to explicitly cover less common substances.

In this document, the following print types are used:

— requirements and definitions: roman type;

— *test specifications: italic 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;

— terms defined in Clause 3 of this DOCUMENT or as noted: small capitals.

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.

The attention of Member Bodies is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

