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Biocompatibility evaluation of breathing gas pathways in healthcare applications —

Part 4: Tests for leachables in condensate

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

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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).

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).

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 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.

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 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.

