Anæstesi- og respirationsudstyr – Nebulisatorsystemer og tilhørende komponenter

Anaesthetic and respiratory equipment – Nebulizing systems and components (ISO 27427:2023)

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Contents

Page

European foreword

This document (EN ISO 27427:2023) 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of an identical text or by endorsement, at the latest by January 2024, and conflicting national standards shall be withdrawn at the latest by January 2024.

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 27427:2019.

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.

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Endorsement notice

The text of ISO 27427:2023 has been approved by CEN as EN ISO 27427:2023 without any modification.

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Anaesthetic and respiratory equipment — Nebulizing systems and components

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Contents

Page

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 of the voluntary nature of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related equipment*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 27427:2013), which has been technically revised.

The main changes are as follows:

— Alignment with the general standard for airway devices, ISO 18190;

— updating of references.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Nebulizers are widely used to deliver drugs and vaccines in an aerosol form to humans through the respiratory system. *Nebulizers* are also used for diagnostic purposes using radioisotopes for lung challenge tests. These drugs can be in the form of a solution, suspension or emulsion. *Aerosol* inhalation is the preferred route of administration for some drugs. Some drugs are intended for treatment of systemic diseases and other drugs are intended to treat respiratory diseases. To achieve the intended treatment, *aerosol* particles are deposited in specific parts of the respiratory tract. Different size particles tend to deposit in different parts of the respiratory system; therefore, the performance profile and the intended use of the *nebulizer* is specified by the manufacturer and in the accompanying documentation.

This document was developed to cover "general purpose" *nebulizers* and is based on adult test parameters which are likely to be different than stated when testing for paediatric or infant patient populations. It was specifically written to ensure that the results of the various tests declared by the manufacturer are meaningful to the users and buyers of *nebulizers*.

The objectives of this document are to ensure

— suitability of the *nebulizers* for the intended use as disclosed by the manufacturer;

— safety, particularly for *electrically powered nebulizers*;

— compatibility between the materials of the components and the dispensed liquid; and

— biocompatibility of the materials of the components that come into contact with the human body.

This document is written following the format of ISO 18190, which is the general standard for airways and related *equipment.* The requirements in this device-specific standard take precedence over any conflicting requirements in ISO 18190.

Anaesthetic and respiratory equipment — Nebulizing systems and components

1 Scope

This document specifies requirements for the safety and performance testing of general-purpose *nebulizing systems* intended for continuous or breath-actuated delivery of liquids, in *aerosol* form, to humans through the respiratory system.

This document includes *gas-powered nebulizers* (which can be powered by, e.g., compressors, pipeline systems, cylinders, etc.) and *electrically powered nebulizers* [e.g. spinning disc, ultrasonic, vibrating mesh (active and passive), and capillary devices] or *manually powered nebulizers*. This document does not specify the electrical requirements of *electrically powered nebulizers*.

This document does not specify the minimum performance of *nebulizing systems*.

This document does not apply to:

a) devices intended for nasal deposition;

b) devices intended solely to provide humidification or hydration by providing water in *aerosol* form.

NOTE 1 ISO 80601-2-74 and ISO 20789 cover these devices.

c) drug-specific *nebulizers* or their components (e.g. metered dose inhalers, metered liquid inhalers, dry powder inhalers).

NOTE 2 ISO 20072 covers these devices.

NOTE 3 See Annex A for rationale.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 7396-1, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 18190:2016, *Anaesthetic and respiratory equipment — General requirements for airways and related equipment*

ISO 18562-1, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 23328-1, *Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance*

ISO 80369-2, *Small-bore connectors for liquids and gases in healthcare applications — Part 2: Connectors for breathing systems and driving gases applications*