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Anaesthetic and respiratory equipment — General requirements for airway devices and related equipment

Matériel d'anesthésie et de réanimation respiratoire — Exigences générales pour canules et équipement connexe

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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 document 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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This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airway devices and related equipment.*

This second edition cancels and replaces the first edition (ISO 18190:2016), which has been technically revised.

The main changes are as follows:

— Title altered from airways to airway devices.

— The introduction has been changed to clarify that this standard can be used in the absence of a device specific standard.

— Definitions for *clinical evaluation* and *clinical investigation* added.

— Risk management process and *clinical evaluation* now mandated.

— A new requirement recommending that manufacturers consider the environmental impact of their device and its packaging during its lifetime has been added.

— A requirement for the biological evaluation for devices with breathing gas pathways has been added.

— Information provided by the manufacturer, including marking, now refers to ISO 20417 for the common requirements and only lists those requirements specific to *airway devices and related equipment.*

— Devices that are safe, conditionally safe or unsafe to be used in an MR environment are now to be marked accordingly.

— The requirements for positioning of controls and protection against inadvertent adjustments have been deleted as they were deemed not applicable to airway devices.

— A new requirement for shelf life has been added.

— All requirements relating to sterility have been condensed into one clause.

— A new requirement has been added for cleanliness and disinfection and combined with sterility.

— A new requirement to disclose the transport and environmental conditions that the airway device can withstand has been added.

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

This document provides the general requirements for basic safety and performance for the design, materials, packaging, marking and labelling that are generally applicable to all *airway devices and related equipment.*

This document is intended to consolidate the general requirements that are common among the set of standards within the category of *airway devices and related equipment* and serve as a reference for these common requirements, allowing each device-specific standard to focus on the unique safety and essential requirements more concisely for that device.

This document should be used in conjunction with device-specific *airway devices and related equipment* standards.

The requirements in a device-specific standard take priority over any conflicting requirements in this document.

If there is no airway device-specific standard, then this document can be referenced for all the applicable requirements.

NOTE The terms defined in Clause 3 are denoted throughout the document in *italic font.*

Anaesthetic and respiratory equipment — General requirements for airway devices and related equipment

1 Scope

This document specifies the general requirements common to *airway devices and related equipment.*

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 4135, *Anaesthetic and respiratory equipment — Vocabulary*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 14155:2020, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15001:2010, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

ISO 15223-1:2021, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

ISO 17664-1, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

ISO 17664-2, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices*

ISO 17665, *Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices*

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

ISO 18601, *Packaging and the environment — General requirements for the use of ISO standards in the field of packaging and the environment*

ISO 20417, *Medical devices — Information to be supplied by the manufacturer*

ISO 20857, *Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 22441, *Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 25424, *Sterilization of health care products — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2:2014+AMD1:2020, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic disturbances — Requirements and tests*

IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

IEC 62570:2014, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*

ASTM F640, *Standard test methods for determining radiopacity for medical use*

EN 556-1, *Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 1: Requirements for terminally sterilized medical devices*

EN 15986, *Symbol for use in the labelling of medical devices — Requirements for labelling of medical devices containing phthalates*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135, ISO 14971, ISO 20417 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
airway devices and related equipment
devices that provide an interface to the patient's airways, either through direct contact, or as an intermediate component to other anaesthetic and respiratory equipment

3.2
clinical evaluation
assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer

[SOURCE: ISO 13485:2016, 3.3]

3.3
clinical investigation
systematic investigation in one or more human subjects undertaken to assess the clinical performance, effectiveness or safety of a medical device

Note 1 to entry: For the purpose of this document, "clinical trial" or "clinical study" are synonymous with "*clinical investigation*".

[SOURCE: ISO 14155:2020, 3.8]

3.4
biophysical or modelling research
application of validated physical methods and theories to biological problems

EXAMPLE The use of a combination of models (i.e. mathematical, computer, physical, cell and tissue culture, and animal) in a complementary and interactive manner to simulate the performance of medical devices.

4 General requirements

4.1 Risk management

Manufacturers shall apply an established risk management process to the design and manufacture of *airway devices and related equipment*. The risk management process shall include the following elements:

a) risk analysis;

b) risk evaluation;

c) risk control; and

d) production and post-production information.

NOTE 1 See Annex B for a list of hazards that can be used as guidance in the risk management process.

NOTE 2 A risk management process compliant with ISO 14971 is considered to meet this requirement.

NOTE 3 Conformity with ISO/TR 20416 is considered to compliment the requirements in ISO 14971 for production and post-production activities.

NOTE 4 There is rationale for this subclause in A.2.

Check conformance by inspection of the *risk management file.*

4.2 Alternative test methods

The manufacturer may use type tests different from those detailed within this document, if an equivalent degree of safety is obtained. However, in the event of dispute, the methods specified herein shall be used as the reference methods.

4.3 Usability

The manufacturer shall apply a usability engineering process to assess and mitigate any *risks* caused by usability problems associated with correct use (i.e. normal use) and use errors.

NOTE A usability process compliant with IEC 60601-1-6 or IEC 62366-1 is considered to meet this requirement.

Check conformance by inspection of the usability engineering file.

4.4 *Clinical evaluation* and *clinical investigations*

4.4.1 Manufacturers shall carry out a *clinical evaluation* under the conditions for which performance is claimed.

NOTE *Clinical evaluation* carried out according to ISO 18969[1)] is considered to meet this requirement.

4.4.2 *Clinical investigations* shall conform with the requirements of ISO 14155.

NOTE Clinical data can be sourced from:

a) *clinical investigation*(s) of the device concerned;

b) *clinical investigation*(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated; or

c) published and/or unpublished reports on other clinical experience with either the device in question or a similar device for which equivalence to the device in question can be demonstrated.

Check conformance by inspection of the technical file.

4.5 *Biophysical or modelling research*

Where appropriate, validated *biophysical or modelling research* shall be performed under the conditions for which performance is claimed.

Check conformance by inspection of the technical file.

5 Materials

5.1 Environmental impact

5.1.1 Manufacturers should consider when developing *airway devices and related equipment* the environmental impact throughout the lifetime of the device.

NOTE ISO 14001 can be used to assess the environmental impact.

5.1.2 Manufacturers shall assess the environmental impact of packaging used for *airway devices and related equipment.*

Check conformance by the tests given in ISO 18601.

5.2 Biological evaluation

5.2.1 *Airway devices and related equipment* that come into direct or indirect contact with the patient's body, shall, after any preparation for use recommended by the manufacturer, satisfy appropriate biological evaluation according to ISO 10993-1.

Check conformance by inspection of the technical file.

5.2.2 *Airway devices and related equipment* that provide a gas pathway to the patient shall, after any preparation for use recommended by the manufacturer, satisfy appropriate biological evaluation according to ISO 18562-1.

Check conformance by inspection of the technical file.

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1) Under preparation. Stage at the time of publication: ISO/WD 18969:2024.