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**Anaesthetic and respiratory  
equipment — General requirements  
for airways and related equipment**

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

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Reference number  
ISO 18190:2016(E)

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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](http://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](http://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 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](http://www.iso.org/iso/foreword.html).

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related equipment*.

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## Introduction

This International Standard provides the general requirements for basic safety and performance for the design, packaging, marking and labelling that are generally applicable to all AIRWAYS AND RELATED EQUIPMENT.

This International Standard is intended to replace or supplement the often, repetitive general requirements that are common among the set of standards within the category of AIRWAYS AND RELATED EQUIPMENT. The aim of this International Standard is to serve as a central catalogue of these common requirements, allowing each device-specific standard to more concisely focus on the unique safety and essential requirements for the equipment.

For certain types of AIRWAYS AND RELATED EQUIPMENT, these general requirements are either supplemented or modified by the specific requirements of a device-specific standard. Where device-specific standards exist, this International Standard should not be used alone.

For the purposes of clarity, the following conventions have been used:

- DEFINED TERMS APPEAR IN SMALL CAPS TYPE;
- clauses/subclauses for which a rationale is provided in [Annex A](#) is indicated by an asterisk (\*);
- *compliance checks are given in italics type.*

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# Anaesthetic and respiratory equipment — General requirements for airways and related equipment

## 1 Scope

This International Standard specifies the general requirements common to AIRWAYS AND RELATED EQUIPMENT and applicable to those device-specific standards that reference it.

The requirements of a device-specific standard take priority over this International Standard.

NOTE General requirements contained in this International Standard have historically been referenced in more than two other AIRWAYS AND RELATED EQUIPMENT standards.

## 2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE See [Annex A](#) for information on the use of dated and undated normative references.

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

ISO 10524-1, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

ISO 10524-3, *Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves*

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

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

ISO 11137-1:2006/Amd.1:2013, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices/Amendment 1*

ISO 14155:2011/Cor.1:2011, *Clinical investigation of medical devices for human subjects — Good clinical practice/Technical Corrigendum 1*

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

ISO 80369-7<sup>1)</sup>, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

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

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

IEC 60601-1-8:2006, *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*

1) To be published.

EN 556-1:2001, *Sterilization of medical devices — Requirements for medical devices to be designated “STERILE” — Part 1: Requirements for terminally sterilized medical devices*

EN 1041, *Information supplied by the manufacturer of medical devices*

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

ASTM F2052, *Standard test method for measurement of magnetically induced displacement force on medical devices in the magnetic resonance environment*

ASTM F2213, *Standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment*

ASTM F2503, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*

### 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

#### 3.1

##### **AIRWAYS 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

##### **ANTISTATIC**

property of material or a procedure that disperses or inhibits the accumulation of electrostatic charges

#### 3.3

##### **RISK**

combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO 14971:2007, 2.16]

#### 3.4

##### **RISK ANALYSIS**

systematic use of available information to identify hazards and to estimate the RISK ([3.3](#))

[SOURCE: ISO 14971:2007, 2.17, modified]

Note 1 to entry: RISK ANALYSIS includes examination of different sequences of events that can produce hazardous situations and harm (see [Annex B](#) and ISO 14971:2007, Clause 4).

#### 3.5

##### **RISK ASSESSMENT**

overall process comprising a RISK ANALYSIS ([3.4](#)) and a RISK EVALUATION ([3.6](#))

[SOURCE: ISO 14971:2007, 2.18]

#### 3.6

##### **RISK EVALUATION**

process of comparing the estimated RISK ([3.3](#)) against given RISK criteria to determine the acceptability of the RISK

[SOURCE: ISO 14971:2007, 2.21]

**3.7****RISK MANAGEMENT**

systematic application of MANAGEMENT policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring RISK (3.3)

[SOURCE: ISO 14971:2007, 2.22]

**3.8****RISK MANAGEMENT FILE**

set of records and other documents that are produced by RISK MANAGEMENT (3.7)

[SOURCE: ISO 14971:2007, 2.23]

**3.9****SINGLE FAULT CONDITION**

condition in which a single means for reducing a RISK (3.3) is defective or a single abnormal condition is present

[SOURCE: IEC 60601-1:2005, 3.116]

**3.10****VALIDATION**

confirmation through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled

Note 1 to entry: The term “validated” is used to designate the corresponding status.

Note 2 to entry: The use conditions for VALIDATION can be real or simulated.

## **4 General requirements for AIRWAYS AND RELATED EQUIPMENT**

### **4.1 \* RISK MANAGEMENT**

**4.1.1** This International Standard specifies requirements that are generally applicable to risks associated with AIRWAYS AND RELATED EQUIPMENT. An established RISK MANAGEMENT process shall be applied to the design of AIRWAYS AND RELATED EQUIPMENT. The RISK MANAGEMENT process shall include the following elements:

- RISK ANALYSIS;
- RISK EVALUATION;
- RISK control - production and post-production information.

EXAMPLE ISO 14971.

NOTE See [Annex B](#) for a list of hazards that can be used as guidance in the RISK ASSESSMENT.

*Check compliance by inspection of the RISK MANAGEMENT FILE.*

### **4.2 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 (see IEC 60601-1-6 and IEC 62366-1).

*Check compliance by inspection of the usability engineering file.*