International

ISO 18190

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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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 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.

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.*