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Anaesthetic and respiratory equipment — Supralaryngeal airways and connectors

*Matériel d'anesthésie et de réanimation respiratoire — Canules
supralaryngées et raccords*



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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 11712 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Tracheal tubes and other equipment*.

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Introduction

* A **supralaryngeal airway** is a device placed through the mouth, intended to seal the supralaryngeal area to maintain airway **patency** without passing through the vocal cords and to independently facilitate ventilation with or without delivery of anesthesia gases. Devices intended to provide a breathing airway and/or to simultaneously provide a guide for the intubation of **tracheal tubes**, bronchoscopes and suction devices are also included in the scope of this International Standard, as are the connectors inserted into the **machine end** of these devices.

* Examples of **supralaryngeal airway** devices are laryngeal masks, laryngeal tubes, airways and seals, cuffed **oropharyngeal airways**, and pharyngeal airways, and combination airway/esophageal obturators.

The requirements of this International Standard were developed using the hazard identification for risk assessment in Annex D.

The requirements for testing and disclosure apply to devices introduced to the market after the publication of this International Standard.

Throughout this International Standard, terms defined in ISO 4135 or in this International Standard appear in **bold type**.

Throughout this International Standard, text for which a rationale is provided in Annex A is indicated by an asterisk (*).