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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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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).

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).

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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.

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.*