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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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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

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).

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.

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

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*.

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[1)], *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.