Anaesthetic and respiratory equipment - Oropharyngeal airways (ISO 5364:2008)

EESTI STANDARDIKESKUS
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NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 5364:2011 sisaldab Euroopa standardi EN ISO 5364:2011 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 5364:2011 consists of the English text of the European standard EN ISO 5364:2011.
Standard on kinnitatud Eesti Standardikeskuse 31.05.2011 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.05.2011 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 27.04.2011.	Date of Availability of the European standard text 27.04.2011.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.10

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 5364

April 2011

ICS 11.040.10

Supersedes EN 12181:1998

English Version

Anaesthetic and respiratory equipment - Oropharyngeal airways (ISO 5364:2008)

Matériel d'anesthésie et de réanimation respiratoire - Canules oropharyngées (ISO 5364:2008)

Anästhesie- und Beatmungsgeräte - Oropharyngealtuben (ISO 5364:2008)

This European Standard was approved by CEN on 24 March 2011.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

The text of ISO 5364:2008 has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 5364:2011 by Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2011, and conflicting national standards shall be withdrawn at the latest by October 2011.

This document supersedes EN 12181:1998.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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Endorsement notice

The text of ISO 5364:2008 has been approved by CEN as a EN ISO 5364:2011 without any modification.

Contents

Page

Introduction

This International Standard specifies dimensions and other requirements for oropharyngeal airways.

Airway size is designated by length, which is important when selecting an oropharyngeal airway to hold forward the base of the tongue to prevent obstruction of the airway by the soft tissues.

Anaesthetic and respiratory equipment — Oropharyngeal airways

1 Scope

This International Standard specifies requirements for oropharyngeal airways of plastics materials and/or rubber, including those with a reinforcement insert made of plastics materials and/or metal.

This International Standard is not applicable to metal oropharyngeal airways, nor to requirements concerning flammability of oropharyngeal airways.

Flammability of oropharyngeal airways, for example if flammable anaesthetics, electrosurgical units or lasers are used, is a well-recognized hazard. It is addressed by appropriate clinical management, which is outside the scope of this International Standard.

This International Standard is not applicable to supralaryngeal airways without an internal, integral sealing mechanism.

2 Normative references

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

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

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

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

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 980, *Graphical symbols for use in the labelling of medical devices*

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

3 Terms and definitions

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

3.1
oropharyngeal airway
device intended to maintain a gas pathway through the oral cavity and pharynx

[ISO 4135]