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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 0977-2023

Replacing YY/T 0977-2016

**Anaesthetic and respiratory equipment - Oropharyngeal
airways**

麻醉和呼吸设备 口咽通气道

(English Translation)

Issued on: September 5, 2023

Implemented on: September 15, 2024

Issued by: State Drug Administration

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents" Drafting.

This document replaces YY/T 0977-2016 "Anesthesia and Respiratory Equipment Oropharyngeal Airway". Compared with YY/T 0977-2016, except for the in addition to structural adjustments and editorial changes, the main technical changes are as follows.

- a) Added legibility requirements and test methods (see 10.3.2);
- b) Added color coding for indicating specific specifications (see 10.3.3, 10.3.4).

This document is modified to adopt ISO 5364:2016 "Anesthesia and Respiratory Equipment Oropharyngeal Airway".

The technical differences between this document and ISO 5364:2016 and their reasons are as follows.

---Replaced ISO 10993-1 (see Chapter 5) with the normatively cited GB/T 16886.1 to adapt to my country's national conditions;

---Replaced ISO 11607-1 (see 9.2) with the normatively quoted GB/T 19633.1 to adapt to my country's national conditions;

---Replaced ISO 15223-1 (see 10.2) with normatively quoted YY/T 0466.1 to adapt to my country's national conditions.

Please note that some content in this document may be subject to patents. The publisher of this document assumes no responsibility for identifying patents.

Introduction

This document specifies the dimensions and other requirements for oropharyngeal airways.

Oropharyngeal airway dimensions are indicated by length. In order to insert the oropharyngeal airway forward to the base of the tongue to prevent soft tissue from blocking the human airway, when selecting an oropharyngeal airway, its length is an important selection parameter.

Oropharyngeal airway specifications are indicated with clear markings and color coding, which is very useful for quick identification and selection in emergency situations.

important.

Terms marked with an asterisk (*) have basic principles stated in Appendix A.

The basic principles of this document are shown in Appendix A. Appendix B gives the test method for the resistance to flattening of the buccal part. Appendix C gives the test method for unblocking the inner cavity.

See Appendix D for test methods, materials and design guidelines.

Anesthesia and Respiratory Equipment Oropharyngeal Airways

1 Scope

This document specifies oropharyngeal airways made of plastic and/or rubber materials (including with reinforced inserts made of plastic and/or metal materials).

oropharyngeal airway).

This document does not specify flammability requirements for oropharyngeal airways.

NOTE: The flammability of the oropharyngeal airway is a recognized hazard in applications such as those involving flammable anesthetics, electrosurgical equipment, or laser use. This is the scope of clinical management, not within the scope of this document.

This document does not apply to metallic oropharyngeal airways and upper laryngeal airways without internal, integral sealing devices.

2 Normative reference documents

The contents of the following documents constitute essential provisions of this document through normative references in the text. Among them, the dated quotations for undated referenced documents, only the version corresponding to that date applies to this document; for undated referenced documents, the latest version (including all amendments) applies to this document.

GB/T 16886.1 Biological evaluation of medical devices Part 1: Evaluation and testing during risk management process (GB/T 16886.1-2022,ISO 10993-1:2018,IDT) GB/T 19633.1 Packaging of terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems (GB/T 19633.1-2015,ISO 11607-1:2006,IDT) YY/T 0466.1 Medical devices Symbols used for labeling, marking and providing information on medical devices Part 1: General requirements (YY/T 0466.1-2016,ISO 15223-1:2012,IDT) YY/T 0615.1-2007 Requirements for marking "sterile" medical devices Part 1: Requirements for terminally sterilized medical devices (EN556-1:2001,IDT) isteredsymbols)

3 Terms and definitions

The following terms and definitions apply to this document.

Oropharyngeal airwayoropharyngealairway A device used to maintain the passage of air through the mouth and pharynx.

[Source. GB/T 4999-2003, 6.1.1, with modifications] 3.2 pharyngealend the oropharyngeal airway (3.1) is intended to be inserted into the patient's pharynx at one end.

[Source. GB/T 4999-2003, 6.1.1.2, with modifications] 3.3 flangedend the flanged end of the oropharyngeal airway (3.1), intended to be external to the teeth or gums.