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

YY/T 0486-2024

Replacing YY/T 0486-2016

**Tracheal tubes designed for laser surgery - Requirements for
marking and accompanying information**

激光手术专用气管导管 标记和随附信息的要求

(English Translation)

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Table of Contents

Preface
Introduction
1 Scope
2 Normative references
3 Terms and Definitions
4 Marking and labeling
4.1 Use of symbols
4.2 Mark
4.3 Labelling of packaging
4.4 Labelling of shelf-ready packaging or multi-unit packaging
5 Information provided by the manufacturer
5.1 Instructions for the preparation and use of laser-resistant endotracheal tubes and endotracheal tube handling
5.2 Instructions for use
5.3 Warnings and precautions for use with catheters
5.4 Laser resistance test results shown in Figure
References

Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part 1: Structure and drafting rules for standardization documents" Drafting.

This document replaces the revision of YY/T 0486-2016 "Requirements for marking and random information of endotracheal tubes for laser surgery" Compared with YY/T 0486-2016, in addition to editorial changes, the main technical changes are as follows.

--- Changed the normative reference documents;

--- Added the selection of label symbols (see Chapter 4, 4.3, 4.4).

This document is modified to adopt the international standard ISO 14408:2016 "Requirements for marking and accompanying information of endotracheal tubes for laser surgery".

The technical differences between this document and ISO 14408:2016 and their reasons

are as follows.

--- ISO 11990-1 and ISO 11990-2 (see 5.3 and 5.4) are replaced by the normative reference ISO 11990 to adapt to my country National conditions.

Compared with ISO 14408:2016, this document has made the following editorial changes.

--- Changed the standard name of ISO 5361;

---ISO 20417 replaced EN1041.

Introduction

The purpose of this document is to specify the characteristics of endotracheal tubes that are designed to resist ignition by lasers and have been tested for laser resistance in accordance with ISO 11990.

Requirements for identification, labelling and the information to be provided, including a standard format for reporting results obtained when tests are carried out in accordance with ISO 11990.

By limiting the requirements to disclosure of information determined according to the ISO 11990 test methods, manufacturers can Maximize the selection.

Tracheal tube for laser surgery Requirements for marking and accompanying information

1 Scope

This document specifies the marking, labeling, and manufacturing of cuffed and uncuffed endotracheal tubes and related materials designed to resist laser ignition.

Requests for information from suppliers.

2 Normative references

The contents of the following documents constitute the essential clauses of this document through normative references in this document.

For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to this document.

YY/T 0466.1-2016 Medical devices Symbols for labeling, marking and providing information on medical devices Part 1: General requirements Request (ISO 15223-1:2012, IDT)
isteredsymbols) ISO 11990 Lasers and laser-related equipment - Determination of laser resistance of endotracheal tubes and endotracheal tube cuffs cuffs

3 Terms and definitions

The following terms and definitions apply to this document.

tracheal tube

A tube designed to be inserted through the larynx into the trachea and to deliver gases and steam through the trachea.

[Source. GB/T 4999-2003, 6.3.1] 3.2 Cuff A permanently attached, inflatable balloon at the patient-adjacent end of an endotracheal tube that provides an effective seal between the tube and the trachea.

[Source. GB/T 4999-2003, 6.3.6, modified] 3.3 Manufacturers design endotracheal tubes specifically for use in airway laser surgery.

Note: This includes devices that are preassembled or sold in kit form.

A covering and/or surface treatment that renders a laser-intolerant endotracheal tube suitable for airway laser surgery.