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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0338-2023

Replacing YY/T 0338.1-2002; YY/T 0338.2-2002

Tracheostomy tubes and adapters

气管切开插管和接头

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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 0338.1-2002 "Tracheostomy Intubation Part

1.Intubation and Connectors for Adults" and YY/T 0338.2-2002 "Tracheostomy Intubation Part

1.Tracheostomy Intubation in Pediatrics", which is the same as YY/T 0338.1-2002 and Compared with YY/T 0338.2-2002, in addition to structural adjustments and editorial changes, the main technical changes are as follows:

a) Changed the scope and added special tracheostomy tubes applicable to common characteristics (see Chapter 1, YY/T 0338.1- 2002 and Chapter 1 of YY/T 0338.2-2002);

b) Delete the definitions of pediatric tracheostomy intubation and pediatric tracheostomy intubation connectors (see YY/T 0338.2-2002 3.1, 3.2);

c) Added that manufacturers should evaluate the inner diameter of 15mm connectors and YY/T 0916 series small-bore connectors during the risk management process Requirements for the risk of incorrect connections (see 6.3.1.4);

d) Added the requirement that the locking mechanism of the adjustable fixed wings should not cause the internal dimensions of the tracheostomy tube to be reduced by more than 10% (See 6.3.2.3);

e) Added that when the tracheostomy tube is in situ, it should be possible to visually determine whether the internal tube is present without disconnecting the respiratory system. requirements (see 6.3.3.3);

f) Added requirements related to the design and appearance of the cuff (see 6.3.4);

g) Added the requirement that the patient end should have no sharp edges (see 6.3.8.2);

h) Added the requirement that it should not be possible to connect the machine end to the respiratory system unless the intubation core has been removed (see 6.3.9.3);

i) Added design and appearance requirements for radiopaque markings (see 6.3.10);

j) Added kink-resistant design and appearance requirements (see 6.3.11);

1 Scope

YY/T 0338 covers tracheostomy tubes and the adapters that connect them to breathing systems. It sets the requirements such tubes have to meet and the test methods that verify them, covering the dimensions that decide whether a tube fits the airway and mates with standard connectors, the cuff that seals it, the strength of the tube and flange, the biocompatibility of the material and the marking that identifies the size. A tracheostomy tube is the airway of a patient who has no other, and a disconnection or a failure at the connector is immediately life-threatening, which is why the connector geometry is standardised worldwide. The 2023 edition consolidates and replaces YY/T 0338.1-2002 and YY/T 0338.2-2002, merging a two-part series into one document. For a manufacturer this is the text a Chinese registration is assessed against.

This document specifies the requirements for tracheostomy tubes and connectors for adult and pediatric use. This document applies to intubations designed primarily for patients requiring anesthesia, artificial ventilation, or other assisted breathing. This document applies to specialized tracheostomy tubes with common characteristics, such as those without connectors at the machine end and suitable for spontaneous breathing. Tracheostomy tubes for patients, as well as tubes with reinforced walls or made of metal or with shoulders, tapered tubes, and tubes with a A cannula for suctioning or monitoring or delivering drugs or other gases. NOTE. The flammability of tracheostomy tubes (e.g. electrosurgical instruments or lasers used with flammable anesthetics in oxygen-rich air) is a well-known hazard and is a In the scope of clinical management, it is not included in the scope of this document. ISO /T R11991 gives guidance on avoiding airway burning.

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 1962.1-2015 Syringes, injection needles and other medical devices 6% (Luer) conical connectors Part

3 Terms and definitions

The terms and definitions defined in GB/T 4999-2003 and the following apply to this document. NOTE. A diagram of a typical tracheostomy tube and related terminology is shown in Figure 1.

3.1 angleofbevel The angle between the plane of the bevel (3.2) and the longitudinal axis of the tracheostomy tube (3.13).

3.2 Bevel The angled portion of the patient end (3.12) of the tracheostomy tube (3.13).

3.3 cuff An inflatable balloon located near the patient end of a tracheostomy tube to form a seal between the tube and trachea.