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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0753.2-2009

Breathing system filters for anaesthetic and respiratory use - Part 2: Non-filtration aspects

麻醉和呼吸用呼吸系统过滤器 第2部分：非过滤方面

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Table of Contents

Foreword

YY/T 0753 "anesthesia and respiratory breathing system filters," including the following sections.

--- Part 1. Evaluation of filter salt test methods;

--- Part 2. Non-filtration aspects. This is Part 2. This part identical with ISO 23328-2.2002 "anesthesia and respiratory breathing system filters - Part 2. Non-filtration aspects." This part of the National Standardization Technical Committee on Narcotic breathing apparatus and (SAC/TC116) and focal points. This section is drafted. Shandong Medical Devices Product Quality Inspection Center. The main drafters of this section. Wan Min, Zhang Bo, Gu Yufei, Limei. YY/T 0753.2-2009/ISO 23328-2.2002

YY/T 0753 This section gives breathing system filters (BSF) non-filter requirements. Breathing system filters for reducing inhaled or exhaled by the number of particulate matter (including microbial). Breathing system filters in clinical use are exposed to various levels of humidity. Since this exposure may affect the respiratory system filters The filter performance test method of breathing system filters in order to simulate clinical use it is exposed to moist air. Involving filtration Test can see YY/T 0753.1-2009. YY/T 0753.2-2009/ISO 23328-2.2002 Anesthesia and respiratory breathing system filters Part 2. Non-filtration aspects

1 Scope

YY/T 0753.2 is Part 2 of the Chinese standard for breathing system filters, covering everything about the filter except its filtration: the connector dimensions that decide whether it fits the circuit, the resistance to flow it adds to every breath, the dead space it introduces, and the labelling and information the manufacturer has to supply. Those properties matter most in exactly the patients filters are most used on, small children and anyone with limited respiratory reserve, where added dead space and resistance are not incidental. Part 1 covers the salt test method for filtration performance. For a manufacturer or an importer of breathing system filters and HME filters for the Chinese market, this is the governing standard for the non-filtration requirements.

YY/T 0753 provisions of this section for respiratory anesthesia breathing system filters

(BSF) non-filter, including its connection end Mouth, leaks, choke, packaging, labeling, and information provided. Test Method BSF intended for clinical use in the respiratory system. This section does not apply to other types of filters, such as specifically to protect a source of vacuum or gas sampling line, the filter pressurized gas Respiratory protection or measuring physiological test equipment filters.

Note. YY/T 0753.1 gives evaluate respiratory filter performance test method.

2 Normative references

The following documents contain provisions which, through reference in this text, constitute provisions of this part. For dated references, subsequent Amendments (not including errata content) or revisions do not apply to this section, however, encourage the parties to this part of the research agreement Whether the latest versions of these documents. For undated reference documents, the latest versions apply to this section.

GB 9706.1-2007 Medical electrical equipment - Part 1. General requirements for safety (IEC 60601-1. 1988, IDT)

GB/T 19633 Packaging for terminally sterilized medical devices (GB/T 19633-2005, ISO 11607.2003, IDT)

YY 1040.1 respiratory and anesthesia equipment taper fittings - Part 1. cone and cone sleeve (YY 1040.1-2003, ISO 5356- 1.1996, IDT)

YY 1040.2-2008 respiratory and anesthesia equipment conical fittings - Part 2. Threaded cone bearing joints (ISO 5356-2. 1987, IDT)

YY/T 0735.1-2009 anesthesia equipment and respiratory gas humidification human respiratory heat and moisture exchanger (HME) - Part 1. The minimum tidal volume of 250mL of HME (ISO 9360-1.2000, IDT)

3 Terms and Definitions

The following terms and definitions apply YY/T 0753 of this section.

3.1 Is expected to reduce the respiratory system, including the device includes microbial biomass particles spread.

3.2 Breathing system filters connected to the respiratory system port.

3.3 Breathing system filters expectations and intubation, tracheal or bronchial tube connectors masks and other equipment connected to the port.

3.4 Breathing system filters and auxiliary equipment (such as for gas sampling, monitoring and pressure measurement) port. YY/T 0753.2-2009/ISO 23328-2.2002