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PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

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YY/T 0339-2019

Replacing YY 0339-2009

Suction Catheters for Use in the Respiratory Tract

(ISO 8836:2014, MOD)

呼吸道用吸引导管

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Foreword

This Standard was drafted as per the rules specified in GB/T 1.1-2009.

This Standard replaced YY 0339-2009 *Suction Catheters for Use in the Respiratory Tract*. Compared with YY 0339-2009, the major technical changes besides the editorial modifications of this Standard are as follows:

--- Add the requirements for the closed suction catheter (see 7.4 of this Standard);

--- Modify the requirements for the therapy ventilator (see 8.4 and 8.5 of this Standard);

--- Modify the requirements for the risk management (see 4.1 of this Standard);

--- According to ISO 8836, correct the instructions for the Positions 1 and 2 in Figure C.1 (see Figure C.1 of this Standard; Figure B.1 in YY 0339-2009).

This Standard uses the re-drafting method to modify and adopt the international standard ISO 8836:2014 *Suction Catheters for Use in the Respiratory Tract* (English Version).

Compared with ISO 8836:2014, the major technical differences of this Standard are as follows:

--- Regarding the normative references, this Standard made the adjustments in technical differences, so as to adapt to China's technical conditions. The adjustments were centrally reflected in Clause 2 "Normative References"; the specific adjustments are as follows:

- Use the national standard GB/T 1962.1 to replace the international standard ISO 594-1 (see 7.4.5);
- Use the national standard GB/T 1962.2 to replace the international standard ISO 594-2 (7.4.5);
- Use the national standard GB/T 4999 to replace the international standard ISO 4135:2001 (see Clause 3);
- Use the national standard GB/T 9706.1 to replace the international standard IEC 60601-1:2005 (see 10.2);
- Use the national standard GB/T 16273.1 to replace the international standard of ISO 7000 (see 10.2);
- Use the national standard GB/T 16886.1 to replace the international

standard ISO 10993-1 (see 6.1);

- Use the national standard GB/T 19633.1 to replace the international standard ISO 11607-1 (see 9.2.2);
- Use the national standard GB/T 19633.2 to replace the international standard ISO 11607-2 (see 9.2.2);
- Use the industry standard YY/T 0316 to replace the international standard ISO 14971:2007 (see 4.1.1);
- Use the industry standard YY/T 0466.1 to replace the international standard ISO 15223-1 (see 10.2);
- Use the industry standard YY/T 0466.2 to replace the international standard ISO 15223-2 (see 10.2);
- Use the industry standard YY 0636.1 to replace the international standard ISO 10079-1 (see 7.3.1 and 7.3.6);
- Use the industry standard YY 0636.2 to replace the international standard ISO 10079-2 (see 7.3.1 and 7.3.6);
- Use the industry standard YY 0636.3 to replace the international standard ISO 10079-3 (see 7.3.1 and 7.3.6);
- Use the industry standard YY/T 1040.1 to replace the international standard ISO 5356-1 (see 7.3.5, 7.4.2.1 and 7.4.2.2).

Compared with ISO 8836:2014, the editorial modifications of this Standard are as follows:

--- The instructions of major differences between ISO 8836:2014 and the former edition are transferred to this Foreword;

--- Correct the editorial errors in ISO 8836:2004;

- Change the sub-clause number from 7.3.6, 7.3.7 and 7.3.8 to 7.3.5, 7.3.6, and 7.3.7;
- Transfer the normative reference ISO 4135:2001 from the Bibliography to Clause 2 Normative References;
- Transfer the non-normative reference IEC 62366-1 from Clause 2 Normative References to the Bibliography; which is replaced by the corresponding industry standard YY/T 1474.

Suction Catheters for Use in the Respiratory Tract

1 Scope

This Standard specifies requirements for suction catheters, including open and closed suction catheters, made of flexible materials and intended for use in suctioning of the respiratory tract.

Angled-tip suction catheters (e.g.: Coudé catheters) and suction catheters with aspirator collectors are not considered to be specialized and are therefore included in the scope of this Standard.

Suction catheters intended for use with flammable anaesthetic gases or agents, lasers or electrical surgical equipment are not covered by this Standard.

NOTE: See ISO/TR 11991 [6] for guidance on airway management during laser surgery of the upper respiratory tract.

2 Normative References

The following documents are essential to the application of this document. For the dated documents, only the versions with the dates indicated are applicable to this document; for the undated documents, only the latest version (including all the amendments) is applicable to this document.

GB/T 1962.1 Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and Certain other Medical Equipment - Part 1: General Requirement (GB/T 1962.1-2015, ISO 594-1:1986, IDT)

GB/T 1962.2 Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and Certain other Medical Equipment - Part 2: Lock Fittings (GB/T 1962.2-2001, ISO 594-2:1998, IDT)

GB/T 4999 Anaesthetic and respiratory equipment – Vocabulary (GB/T 4999-2003, ISO 4135:2001, IDT)

GB 9706.1 Medical Electrical Equipment - Part 1: General Requirements for Safety (GB 9706.1-2007, IEC 60601-1:1988, IDT)

GB/T 16273.1 Graphical Symbols for Use on Equipment - Part 1: Common Symbols (GB/T 16273.1-2008, ISO 7000:2004, NEQ)

GB/T 16886.1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process (GB/T 16886.1-2011, ISO 10993-1:2009, IDT)

GB/T 19633.1 Packaging for 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)

GB/T 19633.2 Packaging for Terminally Sterilized Medical Devices - Part 2: Validation Requirements for Forming, Sealing and Assembly Processes (GB/T 19633.2-2015, ISO 11607-2:2006, IDT)

YY/T 0316 Medical Devices – Application of Risk Management to Medical Devices (YY/T 0316-2016, ISO 14971:2007, IDT)

YY/T 0466.1 Medical Devices - Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied - Part 1: General Requirements (YY/T 0466.1-2016, ISO 15223-1:2007, IDT)

YY/T 0466.2 Medical Devices - Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied - Part 2: Symbol Development, Selection and Validation (YY/T 0466.2-2015, ISO 15223-2:2010, IDT)

YY 0636.1 Medical Suction Equipment - Part 1: Electrically Powered Suction Equipment - Safety Requirements (YY 0636.1-2008, ISO 10079-1:1999, MOD)

YY 0636.2 Medical Suction Equipment - Part 2: Manually Powered Suction Equipment (YY 0636.2-2008, ISO 10079-2:1999, IDT)

YY 0636.3 Medical Suction Equipment - Part 3: Suction Equipment Powered from a Vacuum or Pressure Source (YY 0636.3-2008, ISO 10079-3:1999, IDT)

YY/T 1040.1 Anaesthetic and Respiratory Equipment - Conical Connectors - Part 1: Cones and Sockets (YY/T 1040.1-2015, ISO 5356-1:2004, IDT)

ISO 5367:2014 Anaesthetic and Respiratory Equipment – Breathing Sets and Connectors

ISO 11135 Sterilization of Health-Care Products – Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices

ISO 11137-1 Sterilization of Health-Care Products – Radiation – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices

ISO 14155 Clinical Investigation of Medical Devices for Human Subjects – Good

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