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

YY/T 0104-2018

Replacing YY 0104-1993

Three-edged needle

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Foreword

4.1 of this standard is a recommended clause, and the rest are mandatory. This standard was drafted in accordance with the rules given in GB/T 1.1-2009. This standard replaces YY 0104-1993 "Triangular Needle", compared with YY 0104-1993, except for editorial changes, major technical changes as follows:

- Revised the requirements for the size and size of the triangular needle (see 3.3, 4.3,.1993, 3.2, 3.3, 4.2);
- Revised the surface roughness requirements and test methods (see 4.3, 5.3,.1993 edition of 4.10, 5.2);
- Increased the requirements and test methods for needle tip penetration force (see 4.4, Appendix B);
- Added the requirement for non-integrally formed triangular edges for their connection fastness (see 4.5);
- Increased sterility requirements for disposable sterile triangular needles (see 4.7);
- Increased ethylene oxide residue requirements for single-use sterile triangular needles (see 4.8);
- Increased requirements for biocompatibility (see 4.9);
- Modified packaging, marking, instructions for use and storage requirements (see Chapter 6, Chapter 7, Chapter 8, Chapter 7 of the.1993 edition);
- Added Appendix A;
- Modified the content of the inspection rules (see Appendix C, Chapter 6 of the.1993 edition);

--- Removed the requirements for manufacturing materials for triangular needles (4.3 of 1993 edition). Please note that some of the contents of this document may involve patents. The issuing organization of this document is not responsible for identifying these patents. This standard was proposed by the State Drug Administration. This standard is under the jurisdiction of the National Medical Electrical Equipment Standardization Technical Committee Physical Therapy Equipment Subcommittee (SAC/TC10/SC4). This standard was drafted by Tianjin Medical Device Quality Supervision and Inspection Center, Suzhou Medical Products Factory Co., Ltd. The main drafters of this standard are Zhang Haiming, Qi Lijing, Zhang Wei, Qian Xuebo, Xu Aimin. The previous versions of the standards replaced by this standard are.

---YY 0104-1993. Triangular needle

1 Scope

YY/T 0104 is the Chinese standard for the three-edged needle, the wide triangular-section needle used in traditional Chinese medicine to draw a few drops of blood at a point rather than to stimulate it. It specifies the structure of the needle and the names of its parts, the classification into sterile and non-sterile and into integrally and non-integrally formed types, the dimensional specifications, the requirements and the test methods, together with the packaging, marking, instructions for use, transport and storage. The 2018 edition tightened surface roughness, added a puncture force test in a normative annex, added a connection fastness requirement for needles whose tip and handle are joined rather than formed in one piece, and introduced sterility, ethylene oxide residue and biocompatibility requirements for the single-use sterile version. It replaces YY 0104-1993 and is the text a Chinese registration is assessed against.

This standard specifies the structure, classification and specifications, requirements, test methods, packaging, marking, instructions for use, transportation and storage of triangular needles. This standard applies to triangular needles for use in triangular needle therapy.

2 Normative references

The following documents are indispensable for the application of this document. For dated references, only dated versions apply to this article. For undated references, the latest edition (including all amendments) applies to this document.

GB/T 191-2008 packaging storage and transportation icon

GB/T 4340.1-2009 Steel materials - Vickers hardness test - Part 1. Test methods

GB/T 9969 General guidelines for the use of industrial products

GB/T 10610-2009 Product Geometrical Specification (GPS) Surface structure profile method for assessing surface structure rules and method

GB/T 14233.1-2008 Medical infusions, blood transfusions, injecting machines - Test methods - Part 1

GB/T 14233.2-2005 Medical infusions, blood transfusions, injecting machines - Test methods - Part 2

GB/T 16886.1-2011 Biological evaluation of medical devices - Part 1. Evaluation and testing in the process of risk management

YY/T 0149-2006 Test method for corrosion resistance of stainless steel medical instruments

YY/T 0466.1 Medical devices for use in medical devices - Labels, markings and information provided - Part 1 . General requirements

3 Structure, classification and specifications

3.1 Structure The typical structure of the triangular needle and the name of each component are shown in Figure 1. Description. L1

---all lengths; L2

---tip length; D

--- needle body outer diameter; d

--- The outer diameter of the needle tip is the widest. Figure