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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 15811-2025

Sterile hypodermic needles for single use

一次性使用无菌注射针

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Standardization Administration of the PRC

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1 Scope

GB 15811-2025 is the Chinese mandatory standard for sterile single-use hypodermic needles, a product China makes in billions and exports worldwide. Everything about the specification follows from the fact that the needle is pushed through skin by hand: the penetration force depends on the bevel geometry and the finish of the point, and a needle that is blunt, burred or bent hurts and injures; the cannula must not break or separate from the hub under the forces of insertion and withdrawal; the lumen must be patent and clean; and the whole must be sterile and free of pyrogens. The standard sets the designation of tubular and tapered needles and the geometry and naming of the point, then the requirements: the dimensions and tolerances of the cannula and the hub, the limits on surface defects and cleanliness, the point geometry and penetration performance, the stiffness and the resistance to breakage, the bond between cannula and hub, the patency, the colour coding, the sterility and biological requirements and the packaging and labelling. It is mandatory in China and takes effect on 1 September 2028.

This document specifies the requirements for sterile hypodermic needles for single use (hereinafter referred to as the "hypodermic needles") whose needle tubing has a nominal outer diameter of

0.18 mm ~

1.2 mm. This document applies to hypodermic needles used in conjunction with GB 15810 and other suitable injection devices for intradermal, subcutaneous, intramuscular and intravenous injection of liquid medications. For single-use hypodermic needles used in conjunction with GB 15810 and provided in a non-sterile state, this document may be taken as a reference. This document does not apply to single-use dental syringe needles, needles used with needle injection systems (NIS) or single-use dispensing needles.

2 Normative References

The contents of the following documents constitute indispensable clauses of this document through the normative references in the text. In terms of references with a specified date, only versions with a specified date are applicable to this document. In terms of references without a specified date, the latest version (including all the modifications) is applicable to this document.

GB/T 6682 Water for Analytical Laboratory Use - Specification and Test Methods

GB/T 14233.1-2022 Test Methods for Infusion, Transfusion, Injection Equipment for Medical Use - Part

3 Terms and Definitions

The following terms and definitions are applicable to this document.

3.1 tubular needle A hypodermic needle with tubular needle tubing. NOTE. the outer diameter of the needle tubing is a specified nominal dimension.

3.2 tapered needle A hypodermic needle with tapered needle tubing. NOTE. the outer diameter of the needle tubing spans at least two consecutive specified nominal dimensions.

4 Examples of Marking

4.1 Tubular Needle The marking (specification) for a tubular needle consists of the nominal outer diameter of the needle tubing, the nominal length (L in Figure 1), the tube wall type, and the first bevel angle (alpha). The outer diameter and length are expressed in millimeters (mm). The tube wall type is indicated as RW (regular wall), TW (thin wall), ETW (extra-thin wall) or UTW (ultra-thin wall). The first bevel angle is indicated as LB (long bevel angle) or SB (short bevel angle). A schematic diagram of the tubular needle is shown in Figure 1. EXAMPLE. a tubular needle with a nominal outer diameter of

0.7 mm for the needle tubing, a length (L) of 30 mm, a thin wall tube type, and a long first bevel angle is marked as.

5 Materials

5.1 The materials used to manufacture needle tubing shall comply with the requirements of GB/T 18457-2024. NOTE. for tapered needles, the manufacturer shall conduct appropriate testing of the rigidity and toughness of the needle tubing and implement a corresponding risk assessment in accordance with GB/T 42062-2022.

5.2 The materials used to manufacture the needle hub shall satisfy the requirements of Chapter 7 and Chapter 8.

6 Physical Requirements

6.1 Cleanliness Under the illumination of 300 lx ~ 700 lx, with normal or corrected vision and without magnification, observe the surface of the needle tubing, and at 2.5 magnification, observe the surface of the needle hub, both shall be clean and free of foreign matter.

6.2 Color Coding For the hypodermic needles, the nominal outer diameter of the needle tubing shall be identified by the color of the needle hub and / or sheath, in accordance with the requirements of YY/T 0296. NOTE. for tapered needles, the nominal outer diameter of the needle tip shall be used as the basis for identifying the color coding.

6.3 Straightness Visually inspect the connection between the needle hub and the needle tubing. It shall be straight, and the needle tubing shall not be noticeably skewed.

6.4 Connection Firmness The connection between the needle hub and the needle tubing shall be firm. Secure the needle tubing to a dedicated instrument, and in the direction of needle hub removal, under the load specified in Table 1, perform a non-impact pull-out test. The two shall not loosen or separate. For tapered needles, use the outer diameter of the needle tubing at the needle hub end as shown in Figure 2 as the nominal outer diameter. Under the load specified in Table 1, perform a non- impact pull-out test. The two shall not loosen or separate.

6.10 Protection against Sharps Injury When a product has the function of protection against sharps injury, the device shall comply with the requirements of GB/T 42063.

7 Chemical Requirements

7.1 Preparation of Test Solution Immerse 25 hypodermic needles, with their sheaths and / or sharps injury protection devices removed, in 250 mL of freshly prepared Grade-3 water complying with the requirements of GB/T 6682.Maintain the water constant at 37 °C 1 °C for 1 hour. Remove the hypodermic needles and obtain the test solution. Simultaneously, use the same method described above to prepare a blank control solution, without placing the hypodermic needles.

7.2 pH When tested in accordance with the method specified in

5.4.1 of GB/T 14233.1-2022, the pH difference between the test solution and the control solution from the same batch shall not exceed 1.

7.3 Total Heavy Metal Content (metal ions) When tested in accordance with the method specified in

5.9 of GB/T 14233.1-2022, the total content of lead, tin, zinc and iron in the test solution shall not exceed 5 g/mL. The cadmium content shall not exceed 0.1 g/mL. When tested in accordance with the method specified in

5.6.1 of GB/T 14233.1-2022, the color of the test solution shall not exceed that of a standard control solution with a mass concentration of rho(Pb2+) = 5 g/mL.

8 Biological Requirements

8.1 General Requirements In accordance with the requirements of GB/T 16886.1, conduct biological evaluation of the hypodermic needles. The evaluation results shall demonstrate the absence of biological hazards. The basic requirements for biological evaluation of the hypodermic needles shall comply with Appendix D.

8.2 Sterility Each initially packaged hypodermic needles shall be sterilized using an appropriate method. The sterilization process shall be validated and routinely controlled to ensure that the probability of bacterial survival on the product is less than 10