NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 15810-2019

Sterile syringes for single use

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Foreword

The full technical content of this Standard is mandatory.

This Standard is drafted in accordance with the rules given in GB/T 1.1-2009.

This Standard replaces GB 15810-2001 "Sterile hypodermic syringes for single use". Compared with GB 15810-2001, the main technical changes of this Standard are as follows.

- Modify the "Scope" (see Clause 1; Clause 1 of the 2001 edition);
- ADD the definitions of "two-piece syringe", "three-piece syringe", "dead space", "piston", "barrel flanges", "needle cap or shield", and "plunger" (see 3.6, 3.7, 3.11, 3.12, 3.13, and 3.14);
- Modify Figure 1 and its name (see Figure 1; Figure 1 of the 2001 edition);
- Modify the requirement for lubricant (see 5.1.4; 5.1.4 of the 2001 edition);
- Modify the requirement for "Push-button spacing" (see 5.5.1; 5.5.1 of the 2001 edition);
- Delete "Rubber plunger stoppers shall be free of rubber thread, rubber scraps, foreign impurities, and frost and shall comply with the provisions of YY/T 0243.Plunger stoppers made of other materials shall meet the requirements of corresponding standards" (5.8.1 of the 2001 edition);
- ADD "Fit of plunger stopper/plunger in barrel" (see 5.7.4);
- Delete "The syringe shall be pyrogen-free" (see 5.12.2 of the 2001 edition);
- Delete "Hemolysis. no hemolytic reaction in the syringe" (see 5.12.3 of the 2001 edition);
- Delete "Acute systemic toxicity. Syringes shall be free of acute systemic toxicity" (see 5.12.4 of the 2001 edition);
- Delete the "Test methods" (see Clause 6 of the 2001 edition);

- Modify the requirements for "Primary packaging" and add the requirements for primary packaging materials and needle packaging forms (see 8.1; 7.1 of the 2001 edition);

- ADD "Structural changes of this Standard compared with ISO 7886-1.2017" (see Annex A);

- ADD "Methods for determination of capacity tolerance and dead space" (see Annex B);

- ADD "Test method for leakage at syringe plunger stopper or seal under forward compression" (see Annex C);

- ADD "Test method for leakage past syringe plunger stopper or seal during aspiration, and for separation of plunger stopper and plunger" (see Annex D);

- Modify "Test method for the determination of forces required to operate the piston" (see Annex E);

- ADD "Test method for fit of plunger stopper/plunger in barrel" (see Annex F);

- ADD "Preparation of extracts and test method" (see Annex G);

- Combine "Biological evaluation" and "Material guide" into "Guidelines for design and material" and modify them (see Annex H; Annex D and Annex E of the 2001 edition);

- Delete "Hemolysis test" (see Annex B of the 2001 edition);

- Delete "Inspection rules" (see Annex C of the 2001 edition).

This Standard uses the redraft law to modify and adopt ISO 7886-1.2017 "Sterile hypodermic syringes for single use - Part 1.Syringes for manual use".

This Standard, compared with ISO 7886-1.2017, has more adjustments in structure. Annex A gives the table for comparison of clause-subclause numbers of this Standard and ISO 7886-1.2017.

The technical differences between this Standard and ISO 7886-1.2017 and

their reasons are as follows.

- As for the normative references, this Standard has adjusted the technical differences, to adapt to the technical conditions of China. The adjustments are reflected in Clause 2 "Normative references". The specific adjustments are as follows.

? Replace ISO 15223-1.2016 with YY/T 0466.1 identical to the international standard;

? Delete ISO 23908;

? Delete ISO 80369-7;

? ADD reference to GB/T 1962.1 (see 5.6.1);

? ADD reference to GB/T 1962.2 (see 5.6.1);

? ADD reference to GB/T 6682 (see B.1.2.3, B.2.2.2, C.2.4, E.2.4, F.2, G.1.2.1, G.2);

? ADD reference to GB/T 14233.1-2018 (see 6.3, G.2);

? ADD reference to GB/T 14233.2 (see 7.3);

? ADD reference to YY/T 0466.1 (see 9.1);

- Modify the requirements of "Scope" and delete the requirement that syringes without a needle are intended for use with sterile hypodermic needles for single use;

- Delete unit packaging, user packaging, self-contained syringe, and multiple unit pack in "Terms and definitions";

- Modify the requirements for "Appearance" and adjust the expression of test conditions;

- Incorporate design requirements and lubricant requirements into Annex H (informative) "Guidelines for design and material" and modify them;

- ADD requirements for readily-oxidizable substance (see 6.3) and ethylene oxide residue (see 6.4) in chemical requirements;

- ADD requirements for sterility (see 7.2) and bacterial endotoxin (see 7.3) in