GB

NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

ICS 11.040.20
C 31

GB 15810-2019

Replacing GB 15810-2001

Sterile syringes for single use

一次性使用无菌注射器

(ISO 7886-1:2017, Sterile hypodermic syringes for single use - Part 1: Syringes for manual use, MOD)

Issued on: October 14, 2019 **Implemented on: November 01, 2020**

Issued by: State Administration for Market Regulation;

Standardization Administration of the PRC.

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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 biological requirements;

- Modify the requirements of 8.1 “Primary packaging” and add the requirement that primary packaging shall use breathable packaging materials and the requirement for needle packaging form;

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

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

- Modify “Preparation of extracts of acidity or alkalinity/limits for extractable metals/readily-oxidizable substance” (see G.1);

- ADD “Test method for ethylene oxide residue” (see G.2);

- Delete “Test method for the quantity of silicone” (See Annex F of ISO 7886-

Sterile syringes for single use

1 Scope

This Standard specifies the nomenclature, physical requirements, chemical requirements, biological requirements, packaging, marking, storage, etc. of sterile syringes for single use (hereinafter referred to as “syringes”).

This Standard applies to manual syringes for aspiration of fluids or for immediate injection after aspirating fluids.

This Standard excludes syringes for use with insulin, syringes made of glass, syringes with needle permanently, syringes for use with power-driven syringe pumps, auto-disable fixed-dose vaccine syringes, syringes against reuse, syringes pre-filled by the manufacturer, and syringes matched with liquid medicine, etc.

2 Normative references

The following documents are indispensable for the application of this document. For the dated references, only the editions with the dates indicated are applicable to this document. For the undated references, the latest edition (including all the amendments) are 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 6682 Water for analytical laboratory use - Specification and test methods (GB/T 6682-2008, ISO 3696:1987, MOD)

GB/T 14233.1-2008 Test methods for infusion transfusion injection equipment for medical use - Part 1: Chemical analysis methods

GB/T 14233.2 Test methods for infusion, transfusion, injection equipment for medical use - Part 2: Biological test methods

YY/T 0466.1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General

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