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PROFESSIONAL STANDARD OF THE PEOPLE'S  
REPUBLIC OF CHINA

中华人民共和国医药行业标准

YY 1001.1-2004

Replace YY/T 91001-1999

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**Glass syringes—Part 1: Syringes with all-glass**

**玻璃注射器 第 1 部分：全玻璃注射器**

Issued on October 10, 2004

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Issued by China Food and Drug Administration

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## Foreword

YY1001 glass syringes consist of the two parts below:

- Part 1: syringes with all-glass;
- Part 2: Blue syringes with all-glass.

This is Part 1 of YY 1001.

This part is not equivalent to ISO 595-1:1986 "*Reusable All-glass or Metal-and-Glass Syringes for Medical Use. Part 1: Dimensions*" and ISO 595-2:1987 "*Reusable All-glass or Metal-and-Glass Syringes for Medical Use.-Part 2: Structure, Performance Requirements and Tests*" (English).

The main technical differences between the part and the not equivalent ISO standard adopted are as follows:

- The syringe capacity tolerance indicator and watertight indicator between the barrel and plunger in this part are higher than the partial provisions of ISO.
- This part adds the fusion firmness indicator between syringe and conehead and indicator of the amount of residual liquid compared with ISO standard.

This part is the revised version of YY91001-1999. The main technical differences between this part and YY 91001-1999 are as follows:

- This part explicitly stipulates that the syringes with all-glass are made of silicon boron aluminum, and stipulates the hydrolytic resistance indicator. YY91001-1999 only stipulates the acid, alkali and hydrolytic resistance indicators.
- This part requires one thermal shock test. YY 91001-1999 requires five thermal shock tests.
- The conehead length and aperture size in YY 91001-1999 are divided into large, medium and small. The syringe conehead in this part must meet GB/T1962.1-2001 "*The Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment Part 1: General Requirements*"
- YY 91001-1999 adopts measurement method and this part adopts glass etching test for printing penetration depth.
- This part cancels batch inspection, and stipulates periodic inspection.

- This part revises the supplement to minor cosmetic defects in YY 91001-1999, and directly adds requirements to standard terms.
- This part deletes the acceptable quality level indicators of individual test items.
- This part deletes the classification indicators.

This part will replace YY91001-1999 from its implementation date, and YY 91001-1999 will be void simultaneously.

This part is proposed by the State Food and Drug Administration.

This part is under the jurisdiction of National Technical Committee on Injector for Medical Purpose of Standardization Administration of China.

Drafting units: Ningbo Peace Syringe Factory, Shanghai Testing & Inspection Institute for Medical Devices

Main drafters of the regulation: Zhao Cuidi, Jiang Juling and Weng Bingnai

This part has replaced the previous standards below:

- GB 1959—1959, GB 1959—1980, GB 1959—1988;
- GBn208—1983.

# **Glass syringes—Part 1: Syringes with all-glass**

## **1 Scope**

This part of YY 1001 specifies the classification, terminology, requirements, test methods, inspection rules, signs, instructions and requirements for packaging, transport and storage of syringes with all-glass.

This part applies to syringes with all-glass (hereinafter referred to as syringes); the product is for human subcutaneous, intramuscular and intravenous injection of liquid and liquid extraction, etc. after the injection needle is provided.

## **2 Normative references**

The articles contained in the following documents have become this part when they are quoted herein. For the dated documents so quoted, all the modifications (excluding corrections) or revisions made thereafter shall not be applicable to this part. For the undated documents so quoted, the latest editions shall be applicable to this part.

GB/T 191-2000 Packaging-Pictorial Marking for Handling of Goods

GB/T1962.1-2001 The Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment Part 1: General Requirements

GB/T 2829-2002 Sampling Procedures and Tables for Periodic Inspection by Attributes (Apply to Inspection of Process Stability)

GB/T 6582-1997 Glass--Hydrolytic Resistance of Glass Grains at 98°C--Method of Test and Classification

GB/T 9969.1-1998 General Principles for Preparation of Instructions for Use of Industrial Products

YY 91017 Test Method of Leakage between Barrel and Plunger of Medical Glass Syringes

## **3 Terms and definitions**

For the purpose of this part of YY 1001, the following terms and definitions apply.

### **3.1**

#### **Syringes with all-glass**

The barrel, plunger and conehead are made of silicate-boron-aluminum glass materials, and the syringes are reusable for medical use after sterilization.

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