CONTENT

REFERENCE: ISO 7886-1-2017

CORPORATE INFORMATION

Name: Anhui JN Medical Device Co.,Ltd.
Adresse: Caicun Town ,Jing County, Xuancheng City, 242525 Anhui,China
CE Certificate: DD 60140171 0001
ISO Certificate: SX 60140170 0001

Ⅰ. SCOPE

Product name: 1ML STERILE DISPOSABLE SYRINGE FOR SINGLE USE.

Intended use: Disposable Sterile Syringe with needle is a **Latex-Free**,sterile, single-use, and disposable syringe which is intended to provide a safe and reliable method for intramuscular and subcutanceous injection of medication into patient.

Ⅱ. GENERAL REQUIREMENTS

The general requirements are considered to be design inputs for manufacturers.

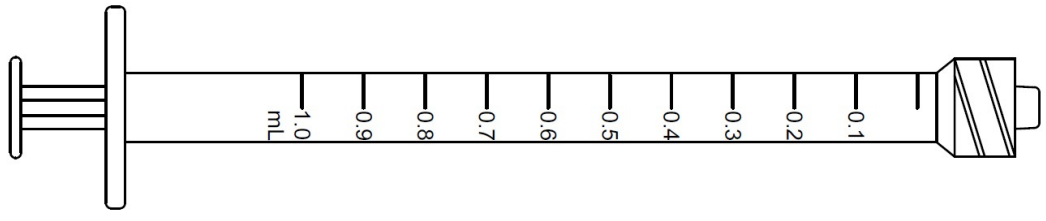
A) Syringe shall be free from defects affecting appearance ,safety and perfor mance for their intended use.Syringe with integrated or add-on sharps protection shall comply ISO 23908.

B) The design and validation of the packaging shall take into consideration the final use of the syringe and the storage and shipping conditions and the defined shelf life.

III. TECHNICAL DATA

A) Materials and Schematics:

Disposable sterile syringe	Anhui JN Medical Device Co.Ltd. 安徽江南医疗器械股份有限公司



NO.	Part name	QTY	Material	Note
1	Plunger	1	PP	Transparent
2	Barrel	1	PP	Transparent
3	Piston	1	Synthetic rubber	Black

4	Nozzle	1	PP	Transparent
5	Luer-Adapted	1	PP	Transparent

B) Extraneous matter

General:
The surfaces of the syringe that come in contact with injection fluids during normal use shall be free from particles and extraneous matter.

Limits for acidity or alkalinity:
Exposure of distilled water to the finished syringe product shall not change its pH value by more than one unit.

Limits for extractable metals:
Exposure of distilled water to the finished syringe product shall not change its content of metals by more than a combined total of 5mg/kg of lead,tin,zinc and iron;the cadmium content shall be less than 0.1mg/kg.

C) Lubricant

When the plunger stopper is fully inserted the amount of lubricant applied into the barrel shall not reach the Luer channel of the nozzle.

For lubricants applied to interior surface of the syringe,the quantity of lubricant applied shall not exceed 0.25mg/cm2 of the interior surface area of the syringe in contact with the injection fluid.

D) Tolerance on graduated capacity

The tolerances on the graduated capacity shall meet:

Nominal capacity of syringe V ml	Tolerance on any graduated capacity		Maximum dead space ml	Minimum overall length of scale to nominal capacity mark mm	Scale interval ml	Increment between graduation lines to be numbered ml	Forces for leakage testing (see Annex D)	
	Less than half nominal capacity	Equal to or greater than half nominal capacity					Side force (±5 %) N	Axial pressure (gauge) (±5 %) kPa
$V < 2$	±(1,5 % of V + 2 % of expelled volume)	±5 % of expelled volume	0,07	57	0,05	0,1	0,25	300

E) Graduated scale

Scale:
The syringe shall have either only one scale or more than one identical scales,which shall be graduated and numbered at least at the intervals given .the unit of volume shall be marked on the barrel.

The total graduated capacity may be equal to,or greater than,than nominal capacity.If the scale is extended beyond the nominal capacity,the extended portion shall be differentiated from the rest of the scale.

Graduation lines shall be of uniform thickness. They shall lie in planes at right angles to the axis of the barrel.

Graduation lines shall be evenly spaced along the longitudinal axis between the zero graduation line and the line for the total graduated capacity.

When the syringe is held vertically, the ends of all graduation lines of similar length shall be vertically

beneath each other.
The lengths of the short graduation lines on each scale are recommended to be approximately half the length of the long lines. If different graduation line configurations are used, this could be submitted to usability evaluation according to IEC 62366.

Numbering of scales:
Graduation lines shall be numbered at least at the volume increments given in Table 1. In addition, the line denoting the nominal capacity or the lines denoting the nominal capacity and the total graduated capacity, if these differ, shall be numbered.

When the syringe is held vertically with the conical tip uppermost and with the scale to the front, the numbers shall appear vertical on the scale and be approximately centred on the graduation lines to which they relate. The numbers shall be close to, but shall not touch, the ends of the graduation lines to which they relate.

F) Barrel

Dimensions:
Maximum capacity shall be determined by risk assessment with consideration of, for example, removal of air bubbles or risk of overdose.

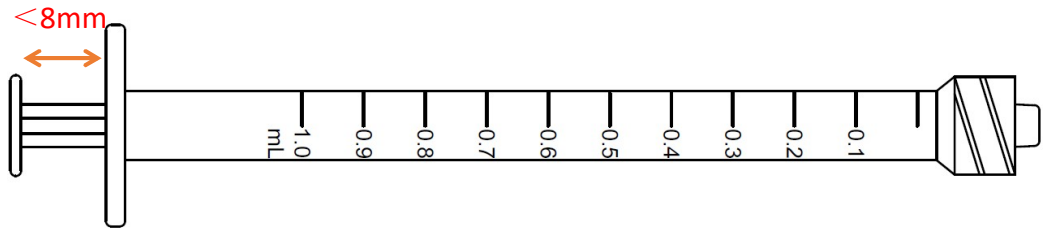
Barrel flanges:
The open end of the barrel shall be provided with barrel flanges. Barrel flanges shall be of adequate size, shape and strength for the intended purpose and shall enable the syringe to be held securely during use. The syringe design, such as barrel flanges, shall be such that the syringe will not roll more than 180° when it is placed on a flat surface at an angle of 10° to the horizontal. The barrel flanges shall be free from flash and sharp edges.

G) Plunger stopper

Design:

The plunger shall be of a length adequate to allow the plunger stopper to traverse the full length of the barrel, but it shall not be possible to easily withdraw the piston completely from the barrel.

The projection of the plunger and the configuration of the push-button should be such as to allow the plunger to be operated without difficulty. When the fiducial line of the plunger stopper coincides with the zero graduation line, the minimum length of the plunger from the surface of the barrel flanges nearer to the push-button, as shown in Figure, shall be at least 8 mm.



H) Nozzle

Conical fitting:
The male conical fitting of the syringe nozzle shall be in accordance with ISO 80369-7.
If the syringe has a locking fitting, it shall be in accordance with ISO 80369-7.
Position of nozzle on end of barrel:
On syringes of nominal capacity of less than 5 ml, the syringe nozzle shall be situated centrally, i.e. it shall be coaxial with the barrel.

Nozzle lumen:
The nozzle lumen shall have a diameter of not less than 1.2 mm.

Ⅳ. PACKAGING

100pcs/box,5000pcs/carton;

61.5x37.5x48cm;

G.W.16KG,N.W.14KG

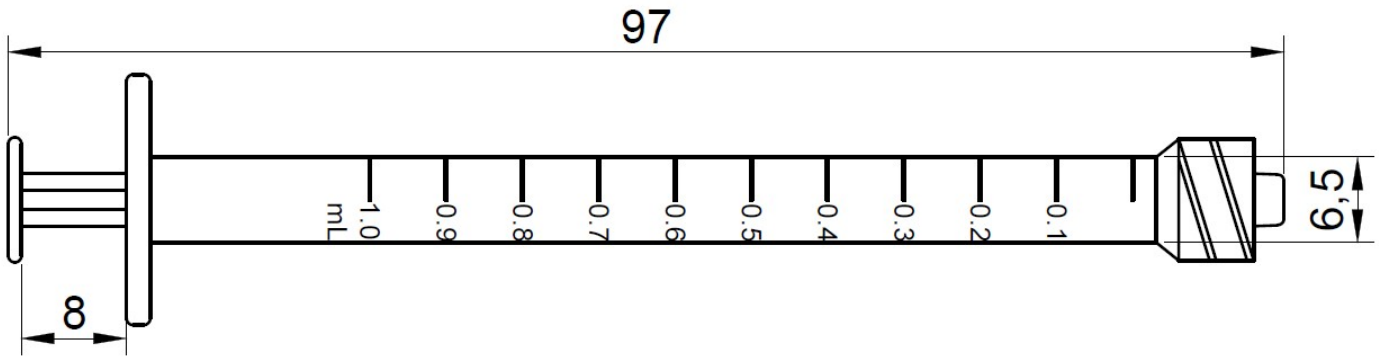
Ⅴ. PRODUCT IDENTIFICATION

Products are identified by lot number：

Style: YYYY/MM/DD
Such as: 20200101

Means that the first batch in January 2020.

VI. SYRINGE SIZE



Unit:mm