



SUBJECT Chemical & Physical Test

TEST LOCATION TÜV SÜD China
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No. 1999 Du Hui Road, Minhang District
Shanghai 201108, P.R. China

CLIENT NAME Jiangsu Kanghua Medical Equipment Co. Ltd.

CLIENT ADDRESS SANHEKOU CHANGZHOU JIANGSU CHINA

TEST PERIOD 21-Jun-2022~01-Aug-2022

TEST REQUEST Limits for heavy metals, Limits for acidity or alkalinity, Appearance, Tolerance on graduated capacity, Graduated scale, Barrel flanges, Plunger stopper/ plunger assembly, Nozzle, Dead space, Freedom from air and liquid leakage past plunger stopper, Force to operate the piston, Fit of plunger stopper/ plunger in barrel
- with reference to ISO 7886-1:2017

Prepared By

(Shao Xiaomin)
Report Drafter

Authorized By

(Leo Liu)
Authorized Signatory

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RECEIPT DATE/ TEST DATE

21-Jun-2022/ 21-Jun-2022

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED

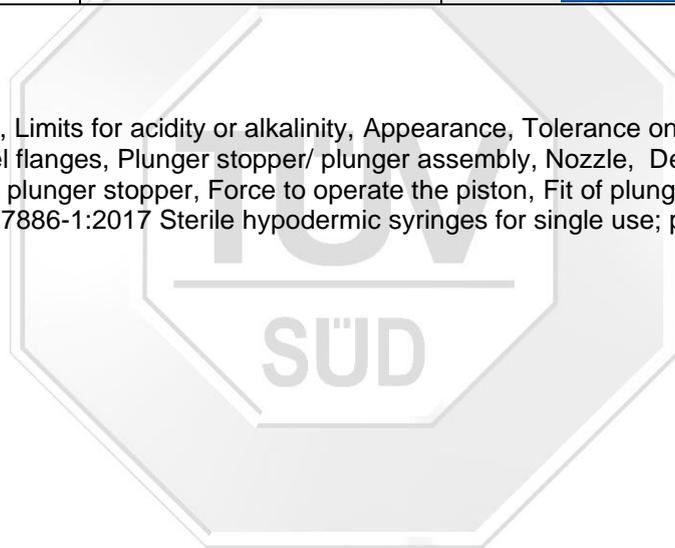
BY/ ON BEHALF OF THE CLIENTS AS:

Sample Name: Disposable sterile syringe
Sample Specification: 5ml (21G x 1 1/2)
Batch No/ Date: 220116
Manufacturer: Jiangsu Kanghua Medical Equipment Co. Ltd.

SAMPLE NO.	DESCRIPTION	PHOTOGRAPH
721672617-1	Medical device	

TEST METHOD(S)

Limits for heavy metals, Limits for acidity or alkalinity, Appearance, Tolerance on graduated capacity, Graduated scale, Barrel flanges, Plunger stopper/ plunger assembly, Nozzle, Dead space, Freedom from air and liquid leakage past plunger stopper, Force to operate the piston, Fit of plunger stopper/ plunger in barrel - with reference to ISO 7886-1:2017 Sterile hypodermic syringes for single use; part 1: syringes for manual use





TEST RESULT(S)

Test Item(s)	Clause	Standard Requirement(s)	Test Result(s)		
Limits for extractable metals	6.3	Total contents: <5 mg/kg	Lead	<0.001 mg/kg	Total contents: <5 mg/kg
			Iron	<0.010 mg/kg	
			Zinc	<0.010 mg/kg	
			Tin	<0.001 mg/kg	
		<0.1mg/kg	Cadmium	<0.1 mg/kg	
Limits for acidity or alkalinity	6.2	<1	0.60		

Test Item(s)	Clause	Standard Requirement(s)	Test Result(s)			
Appearance	5	No particles and extraneous matter	None			
			None			
			None			
			None			
			None			
			None			
			None			
			None			
			None			
			None			
	Defection	5	No defects	None		
				None		
				None		
				None		
				None		
Transparency	5	Sufficient clarity to enable dosages to be read without difficulty	Sufficient clarity			
			Sufficient clarity			
			Sufficient clarity			
			Sufficient clarity			
			Sufficient clarity			





Test Item(s)	Clause	Standard Requirement(s)	Test Result(s)	
Tolerance on graduated capacity	8	Less than half nominal capacity: $\pm(1,5\% \text{ of } V + 2\% \text{ of expelled volume})$	Limit of tolerance on graduated capacity	Measured tolerance on graduated capacity
		Equal to or greater than half nominal capacity: $\pm 5\% \text{ of expelled volume}$	Limit of tolerance on graduated capacity	Measured tolerance on graduated capacity
Graduated scale	9.1.1	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 in Table 1. The unit of volume shall be marked on the barrel.	Complied with the requirement Nominal capacity:5.0 mL	
			Complied with the requirement Nominal capacity:5.0 mL	
			Complied with the requirement Nominal capacity:5.0 mL	
			Complied with the requirement Nominal capacity:5.0 mL	
			Complied with the requirement Nominal capacity:5.0 mL	
	9.1.2	The total graduated capacity may be equal to, or greater than, the nominal capacity. If the scale is extended beyond the nominal capacity, the extended portion shall be differentiated from the rest of the scale.	The total graduated capacity equal to the nominal capacity. Not Applicable	
	9.1.3	Graduation lines shall be of uniform thickness. They shall lie in planes at right angles to the axis of the barrel.	Complied with the requirement	
Complied with the requirement				
Complied with the requirement				
Complied with the requirement				





Test Item(s)	Clause	Standard Requirement(s)	Test Result(s)
Graduate scale	9.1.4	Graduation lines shall be evenly spaced along the longitudinal axis between the zero graduation line and the line for the total graduated capacity.	Complied with the requirement
			Complied with the requirement
			Complied with the requirement
			Complied with the requirement
			Complied with the requirement
	9.1.5	It has different graduation line configurations are used, this could be submitted to usability evaluation according to IEC 62366.	Complied with the requirement
			Complied with the requirement
			Complied with the requirement
			Complied with the requirement
			Complied with the requirement
	9.2.1	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.	Result Complied with Table 1. Increment between graduation lines to be numbered: 1 mL 1 mL 1 mL 1 mL 1 mL Scale interval: 0.2 mL 0.2 mL 0.2 mL 0.2 mL 0.2 mL
	9.2.2	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.	Complied with the requirement
			Complied with the requirement
			Complied with the requirement
			Complied with the requirement
Complied with the requirement			





Test Item(s)	Clause	Standard Requirement(s)	Test Result(s)
Graduated scale	9.3	The overall length of the scale shall be as given in Table 1.	Overall length of scale to nominal capacity mark: 42.52mm 42.32mm 42.19mm 42.21mm 42.30mm
			9.4
	Complied with the requirement		
	Complied with the requirement		
	Complied with the requirement		
	Barrel flanges	10.2	Not roll more than 180° when it is placed on a flat surface at an angle of 10° to the horizontal
Not rolled			
		Be free from sharp edges	No sharp edges
			No sharp edges



Test Item(s)	Clause	Standard Requirement(s)	Test Result(s)
Plunger stopper / Plunger assembly	11	When tested in accordance with Annex B, the plunger stopper shall not become detached from the plunger.	<p>Tested in accordance with Annex B, complied. Complied with the requirement.</p> <p>Length of the plunger from the surface of the barrel flanges nearer to the push-button:</p> <p>16.19mm 16.10mm 16.66mm 16.27mm 16.14mm</p>
		<p>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.</p> <p>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 3, shall be at least 8 mm.</p>	
Nozzle	12.1	<p>The male conical fitting of the syringe nozzle shall be in accordance with ISO 80369-7.</p> <p>If the syringe has a locking fitting, it shall be in accordance with ISO 80369-7.</p>	See appendix 1 Complied with the requirement
			See appendix 1 Complied with the requirement
			See appendix 1 Complied with the requirement
			See appendix 1 Complied with the requirement
			See appendix 1 Complied with the requirement
	12.2.1	<p>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.</p>	N/A



Test Item(s)	Clause	Standard Requirement(s)	Test Result(s)
Nozzle	12.2.2	On syringes of nominal capacity of 5 ml and greater, the syringe nozzle shall be situated either centrally or eccentrically.	Complied with the requirement
			Complied with the requirement
			Complied with the requirement
			Complied with the requirement
	12.2.3	If the syringe nozzle is eccentric, its axis shall be vertically below the axis of the barrel when the syringe is lying on a flat surface with the scale uppermost. The distance between the axis of the nozzle and the nearest point on the internal surface of the bore of the barrel shall be not greater than 4,5 mm.	N/A
12.3	The nozzle lumen shall have a diameter of not less than 1,2 mm.	2.15 mm 2.13 mm 2.19 mm 2.13 mm 2.16 mm	
Dead space	13.1	When tested in accordance with Annex C, the maximum volume of liquid contained in the barrel and the nozzle when the plunger stopper is fully inserted shall be as given in Table 1.	0.054 mL 0.055 mL 0.068 mL 0.053 mL 0.063 mL
Freedom from air and liquid leakage past plunger stopper	13.2	When tested in accordance with Annex D, there shall be no leakage of water past the plunger stopper or seal(s). Small droplets between the seals are not considered failure.	Tested with reference to Annex D, applying a sideways force of 2.0N and an axial force of 300kPa to the syringe. Maintain the pressure for 30s. No leakage of water past the plunger stopper or seal. No leakage of water past the plunger stopper or seal. No leakage of water past the plunger stopper or seal. No leakage of water past the plunger stopper or seal. No leakage of water past the plunger stopper or seal.





Test Item(s)	Clause	Standard Requirement(s)	Test Result(s)
Freedom from air and liquid leakage past plunger stopper	13.2	When tested in accordance with Annex B, there shall be no leakage of air past the plunger stopper or seal(s), and there shall be no fall in the manometer reading.	Tested with reference to Annex B, drew 2.0 mL water into the syringe, under 88kPa below ambient atmospheric pressure, observe the manometer reading for 60s, no leakage of air past the plunger stopper or seal.
			No leakage of air past the plunger stopper or seal.
			No leakage of air past the plunger stopper or seal.
			No leakage of air past the plunger stopper or seal.
Force to operate the piston	13.3	It is recommended to measure the force to operate the piston. A suggested test method and performance criteria for the forces requirement to move the plunger stopper is given in Annex E.	Initiate force
			1.47 N
			1.55 N
			1.69 N
			1.86 N
			1.35 N
			Mean force
			0.96 N
			1.03 N
			0.92 N
1.33 N			
1.02 N			
Fit of plunger stopper / plunger in barrel	13.4	When the syringe is filled with water to the nominal capacity and held vertically with first one end and then the other end uppermost, the piston shall not move by reason of its own mass and the water contained.	Complied with the requirement
			Complied with the requirement
			Complied with the requirement
			Complied with the requirement
			Complied with the requirement
			Complied with the requirement





Appendix 1

Test Item(s)	Clause	Standard Requirement(s)	Test Result(s)	
Conical fitting	12.1	Accordance with ISO 80369-7	Positive pressure liquid leakage	No leakage
				No leakage
			Leakage by pressure decay	Leakage rate was 0.0011 Pa.m ³ /s
				Leakage rate was 0.0019 Pa.m ³ /s
				Leakage rate was 0.0012 Pa.m ³ /s
				Leakage rate was 0.0010 Pa.m ³ /s
				Leakage rate was 0.0016 Pa.m ³ /s
			Sub-atmospheric pressure air leakage	Leakage rate was 0.0001 Pa.m ³ /s
				Leakage rate was 0.0002 Pa.m ³ /s
				Leakage rate was 0.0002 Pa.m ³ /s
				Leakage rate was 0.0001 Pa.m ³ /s
				Leakage rate was 0.0004 Pa.m ³ /s
			Stress cracking	No stress cracking. No leakage by pressure decay or the positive pressure liquid leakage rate was 0.0014 Pa.m ³ /s after 48h
				No stress cracking. No leakage by pressure decay or the positive pressure liquid leakage rate was 0.0020 Pa.m ³ /s after 48h
				No stress cracking. No leakage by pressure decay or the positive pressure liquid leakage rate was 0.0012 Pa.m ³ /s after 48h
				No stress cracking. No leakage by pressure decay or the positive pressure liquid leakage rate was 0.0018 Pa.m ³ /s after 48h
				No stress cracking. No leakage by pressure decay or the positive pressure liquid leakage rate was 0.0015 Pa.m ³ /s after 48h





Test Item(s)	Clause	Standard Requirement(s)	Test Result(s)	Test Item(s)
Conical fitting	12.1	Accordance with ISO 80369-7	Resistance to separation from axial load	No separate from the reference connector
				No separate from the reference connector
				No separate from the reference connector
				No separate from the reference connector
				No separate from the reference connector

Note: This report is for internal use only such as internal scientific research, education, quality control, product R&D.

-END OF THE TEST REPORT-



SHANGHAI CO.