REVi

GUOYU GLOBAL,INC.

DISPOSABLE HYPODERMIC SYRINGE AND NEEDLE

FDA U.S. FOOD & DRUG ADMINISTRATION TÜV SGS CE

REVI
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GUOYU GLOBAL,INC.

DISPOSABLE HYPODERMIC SYRINGE AND NEEDLE

1mL Luer Slip Syringe with/without Needle

Capacity	1 mL/cc
Description	Luer Slip with/without Needle
Scale Graduation	0.01ml
Package	Blister
Box (Units)	200
Case (units)	3000
Sterilization	Ethylene Oxide
Shelf Life	3 years

Needle Size: 23G-27G* 16-38mm (1/2"-1 1/2")

*Other specifications are available according to customer requests.

3 mL Luer Lock/Luer Slip Syringe with/without Needle

Capacity	3 mL/cc
Description	Luer Lock/Luer Slip with/without Needle
Scale Graduation	0.1ml
Package	Blister
Box (Units)	100
Case (units)	1800
Sterilization	Ethylene Oxide
Shelf Life	3 years

Needle Size: 21G-27G* 16-38mm (1/2"-1 1/2")

*Other specifications are available according to customer requests.

5 mL Luer Lock/Luer Slip Syringe with/without Needle

Capacity	5 mL/cc
Description	Luer Lock/Luer Slip with/without Needle
Scale Graduation	0.2ml
Package	Blister
Box (Units)	100
Case (units)	1600
Sterilization	Ethylene Oxide
Shelf Life	3 years

Needle Size: 21G-25G* 16-38mm(1/2"-1 1/2")

*Other specifications are available according to customer requests.

REVI
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GUOYU GLOBAL,INC.

DISPOSABLE HYPODERMIC SYRINGE AND NEEDLE

10 mL Luer Lock/Luer Slip Syringe with/without Needle

Capacity	10 mL/cc
Description	Luer Lock/Luer Slip with/without Needle
Scale Graduation	0.2ml
Package	Blister
Box (Units)	100
Case (units)	1200
Sterilization	Ethylene Oxide
Shelf Life	3 years

Needle Size: 21G-25G* 16-38mm(1/2"-1 1/2")

*Other specifications are available according to customer requests.

20 mL Luer Lock/Luer Slip Syringe with/without Needle

Capacity	20 mL/cc
Description	Luer Lock/Luer Slip with/without Needle
Scale Graduation	1 ml
Package	Blister
Box (Units)	100
Case (units)	600
Sterilization	Ethylene Oxide
Shelf Life	3 years

Needle Size: 21G-23G* 16-38mm(1/2"-1 1/2")

*Other specifications are available according to customer requests.

25/30 mL Luer Lock/Luer Slip Syringe with/without Needle

Capacity	25/30 mL/cc
Description	Luer Lock/Luer Slip with/without Needle
Scale Graduation	1 ml
Package	Blister
Box (Units)	50
Case (units)	400
Sterilization	Ethylene Oxide

Needle Size: 21G-23G* 16-38mm(1/2"-1 1/2")

*Other specifications are available according to customer requests.

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GUOYU GLOBAL,INC.

DISPOSABLE HYPODERMIC SYRINGE AND NEEDLE

50/60 mL Luer Lock/Luer Slip Syringe with/without Needle

Capacity	50/60 mL/cc
Description	Luer Lock/Luer Slip/Catheter Tip with/without Needle
Scale Graduation	1 ml
Package	Blister
Box (Units)	20
Case (units)	200
Sterilization	Ethylene Oxide

Needle Size: According to customer requests.

Hypodermic Needle

SIZE		COLOR		LENGTH OF REGULAR NEEDLES					
				13mm	16mm	19mm	25mm	32mm	38mm
O.D (mm)	GUAGE	COLOR CODE		1/2″	5/8″	3/4″	1″	1 1/4″	1 1/2″
1.60	16G		White						
1.20	18G		Pink						
1.00	19G		Beige						
0.90	20G		Yellow						
0.80	21G		Green						
0.70	22G		Black						
0.60	23G		Blue						
0.55	24G		Purple						
0.50	25G		Orange						
0.45	26G		Brown						
0.40	27G		Grey						
0.36	28G		Blue-Green						
0.33	29G		Red						
0.30	30G		Light Yellow						

*Other specifications are available according to customer requests.

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GUOYU GLOBAL,INC.

DISPOSABLE HYPODERMIC SYRINGE AND NEEDLE

Disposable Hypodermic Syringe With Safety Needle

- Material: Polypropylene+Stainless Steel
- Parts: Needle+Cap
- Packing: Blister
- Sterilization: EO
- Needle Size: 18G-27G

Box： 210x180x135 mm
Quantity： 100 Pcs

Carton :570x445x585 mm
Quantity： 1800 Pcs

DISPOSABLE HYPODERMIC SYRINGE AND NEEDLE

New Search | Back To Search Results

Device Classification Name	Syringe, Antistick
510(K) Number	K072739
Device Name	JIERUI SYRINGES AND NEEDLES
Applicant	SHANDONG WEIGAO GROUP MEDICAL POLYMER CO.,LTD. SUITE 8D, NO.19, LANE 999 ZHONGSHAN NO.2 ROAD(S) Shanghai, CN 200030
Applicant Contact	Diana Hong
Correspondent	SHANDONG WEIGAO GROUP MEDICAL POLYMER CO.,LTD. SUITE 8D, NO.19, LANE 999 ZHONGSHAN NO.2 ROAD(S) Shanghai, CN 200030
Correspondent Contact	Diana Hong
Regulation Number	880.5860
Classification Product Code	MEG
Date Received	09/27/2007
Decision Date	03/21/2008
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

K072739
1 of 5

510(k) Summary

MAR 21 2008

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 9807.92.

The Assigned 510(k) Number is: _____

1. Applicant Device Information

Trade/Proprietary Name: Jierui Syringes and Needle
Classification Information:

a. Sterile Hypodermic Syringe for single use, with/without needle
(1) Classification Name: Syringe, Piston
(2) Regulation Number: 880.5860
(3) Product Code: FMF
(4) Class: II
(5) Review Panel: General Hospital

b. Retractable Auto-Disable Syringe for single use, with/without needle
(1) Classification Name: Syringe, Antistick
(2) Regulation Number: 880.5860
(3) Product Code: MEG
(4) Class: II
(5) Review Panel: General Hospital

c. Sterile Insulin Syringe for single use, with fixed needle
(1) Classification Name: Syringe, Piston
(2) Regulation Number: 880.5860
(3) Product Code: FMF
(4) Class: II
(5) Review Panel: General Hospital

d. Sterile Hypodermic Needle for single use
(1) Classification Name: Needle, Hypodermic, Single Lumen
(2) Regulation Number: 880.5570
(3) Product Code: FMI
(4) Class: II
(5) Review Panel: General Hospital

2. Submitter Information

Manufacturer Name:

ShanDong WeiGao Group Medical Polymer Products Co., LTD
No.312, Shichang Road
Weihai, Shandong, China, 264209

Contact Person of the Submission:

Ms. Diana. Hong
Mr. Eric. Chen
Suite 8D, Zhongxin Zhongshan Mansion,
No.19, Lane 999, Zhongshan No.2 Road(S)
Shanghai, China 20030
Phone: +86-21-64264467 x 152
Fax: +86-21-64264468 x 809
Email: Diana.hong@mid-link.net
Eric.chen@mid-link.net

3. Predicate Device

a. **K number: K070936**
Trade Name: Welmed Hypodermic Syringe (various sizes)
Common Name: Syringes, Hypodermic
Classification Name: Piston Syringe
Product Code: FMF

b. **K number: K071630**
Trade Name: TERUMO 31G ThinPro Insulin Syringe
Classification Name: Piston syringe with fixed hypodermic single lumen needle
Product Code: FMF

c. **K number: K053519**
Trade Name: Safety Syringe
Common Name: Syringe
Classification Name: Syringe,Antistick
Product Code: MEG

d. **K number: K070440**
Trade Name: BD Hypoint
Common Name: Hypodermic Needle
Classification Name: Single Lumen Hypodermic Needle
Product Code: FMI

4. Device Description

Device Name	Intended Use	Nozzel	Volume	Material	Remark
Sterile Hypodermic Syringe for single use	The Sterile Hypodermic Syringe for Single Use With/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.	Luer Slip	1,2,3,5,10,20,30,50,100 (ml)	PP	With or Without Needle
		Luer Lock	3,5,10,20,50,100 (ml)		
Sterile Insulin Syringe for single use	The sterile Insulin Syringe for single use with needle is a device intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface skin.	Fixed	0.5,1 (ml)	PP	With Fixed Needle
Retractable Auto-Disable Syringe for single use	The Retractable Auto-Disable Syringe for single use with/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body. Its secondary intended use is to retract inside the safety barrel, contain the contaminated needle and aid in the prevention of accidental needle stick injuries.	Luer Lock	3,5,10 (ml)	PP	With or Without Needle
Sterile Hypodermic Needle for single use	The Sterile Hypodermic Needle for single use is intended for use with syringes and injection devices for general purpose fluid injection/aspiration	Luer Slip Luer Lock	16G,18G,19G,20G, 21G,22G,23G,24G, 25G,26G,27G,29G	Stainless Steel	--

K073739

5. Substantially Equivalence Determination

Comparison Analysis:

The Applicant device has the same classification information, intended use, sterilization specifications, performance, biocompatibility, chemical specifications and similar physical and mechanical specifications with the predicate device. The only difference between applicant device and predicate device is some physical specifications variant which is too slight to influence the effectiveness and safety.

Conclusion:

The applicant device is **Substantially Equivalent (SE)** to the predicate device in terms of Effectiveness and Safety.

K072737
5 of 5

6. Effectiveness and Safety Considerations

Effectiveness:

All the variant models of the applicant device are evaluated regarding the performance.

Safety Considerations:

With accordance with the Table 1 Initial Evaluation Tests for Consideration and Table 2 Supplementary Evaluation Tests for Consideration in ISO 10993-1:2003(E), Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing, the necessary tests for Biocompatibility Testing includes: Cytotoxicity, Sensitization, Irritation or Intracutaneous Reactivity, Systemic Toxicity (Acute), Haemo-compatibility.

Conclusion: The all conducted Biological Evaluation Tests are in compliance with the standards of ISO 10993, "Biological Evaluation of Medical Devices". The compatibility of all the possible skin-contact component material in the finished product meets the requirement of Biocompatibility

The applicant device is **Substantially Equivalent (SE)** to the predicate device which is US legally market device. Therefore, the applicant device is determined as safe and effectiveness.

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2008

ShanDong WeiGao Group Medical Polymer Products Company, Limited
C/O Ms. Diana Hong
General Manager
Shanghai Mid-Link Business Consulting Company, Limited
Suite 8D, No. 19, Lane 999
Zhongshan No. 2 Road (S)
Shanghai 200030
CHINA

Re: K072739
Trade/Device Name: Sterile Hypodermic Syringe for Single Use With/Without Needle
Retractable Auto-Disable Syringe for Single Use With/Without Needle
Sterile Insulin Syringe for Single Use With Fixed Needle
Sterile Hypodermic Needle for Single Use
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF, MEG, FMI
Dated: March 11, 2008
Received: March 11, 2008

Dear Ms. Hong:

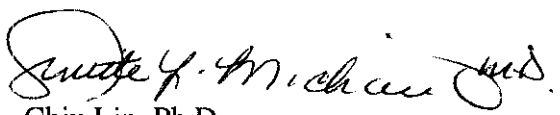
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Indications for Use

510(k) Number: K072739

Device Name: Sterile Hypodermic Syringe for Single Use With/without needle

Indications for Use:

The Sterile Hypodermic Syringe for Single Use With/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072739

Indications for Use

510(k) Number: K072739

Device Name: Retractable Auto-Disable Syringe for single use With/without needle

Indications for Use:

The Retractable Auto-Disable Syringe for single use with/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body. Its secondary intended use is to retract inside the safety barrel, contain the contaminated needle and aid in the prevention of accidental needle stick injuries.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072739

Indications for Use

510(k) Number: K072739

Device Name: Sterile Insulin Syringe for single use with fixed needle

Indications for Use:

The sterile Insulin Syringe for single use with fixed needle is a device intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface skin.

Prescription Use _____ AND/OR Over-The-Counter Use ___√___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072739

Indications for Use

510(k) Number: K072739

Device Name: Sterile Hypodermic Needle for single use

Indications for Use:

The Sterile Hypodermic Needle for single use is intended for use with syringes and injection devices for general purpose fluid injection/aspiration.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K072739

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TESTING
CNAS L0604

scan to see the report

QDHL2104501757MD

Test Report

Report No.: QDHL2104501757MD

Sample Description:	STERILE HYPODERMIC SYRINGES FOR SINGLE USE
Applicant:	WEIGAO MEDICAL INTERNATIONAL CO., LTD.
Test Type:	SUBMITTED BY CLIENT

Report No.: QDHL2104501757MD

Test Report

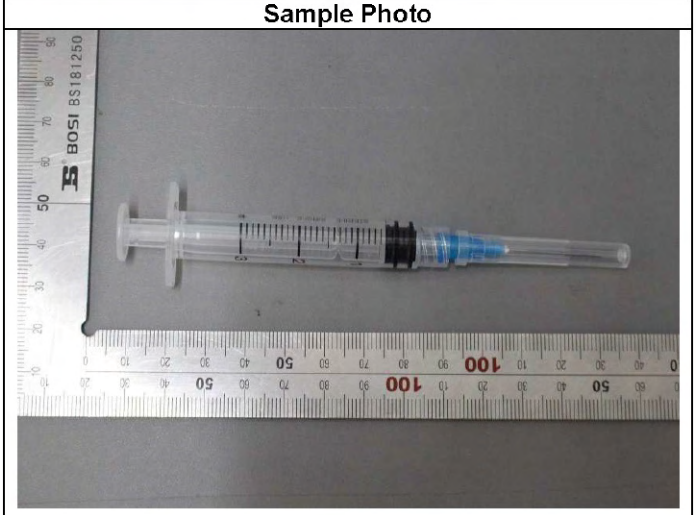
Sample information	Sample Description	STERILE HYPODERMIC SYRINGES FOR SINGLE USE	Color	DARK BLUE NEEDLE HOLDER, TRANSPARENT SYRINGE
	Received sample quantity/ Tested sample quantity	160PCS/ 50PCS	Type/ Specifications	3mL LUER LOCK 23GX1
	Lot No.	20210305	Lot Quantity	NOT PROVIDED
	Manufacture Date	2021-03-05	Expiration Date	2024-03-04
	Material/ Appearance	POLYPROPYLENE	Storage Condition	NOT PROVIDED
	Manufacturer	NOT PROVIDED		
	Others	/		
Client information	Applicant	WEIGAO MEDICAL INTERNATIONAL CO., LTD.		
	Applicant address	NO.1 WEIGAO ROAD, HIGH-TECH INDUSTRIAL DEVELOPMENT ZONE, WEIHAI, SHANDONG PROVINCE, PEOPLE'S REPUBLIC OF CHINA		

Report No.: QDHL2104501757MD

Test information	Sample Receiving Date	APR.09,2021	Test Period Date	APR.09,2021 TO APR.21,2021
	Sample No.	QDHL2104501757MD (TAOHG2101610601) (SHIN2104022967MR)	Test environment	Meet requirement
	Test items	General, Limits for acidity or alkalinity, Limits for extractable metals, Tolerance on graduated capacity, Graduated scale, Barrel, Plunger stopper/plunger assembly, Nozzle, Performance, Information supplied by the manufacturer*		
	Testing Accordance	ISO 7886-1:2017 Sterile hypodermic syringes for single use-Part 1: Syringes for manual use clause 6.1, 6.2, 6.3, 8, 9, 10, 11, 12, 13, 15*		
Test conclusion	This report only provides the test results and individual judgment, conclusion please see follow pages. Issue date: APR.21,2021			
Remark	THE NEEDLE PART FOR PHOTO ONLY.			

Approver: Jessica Co Auditor: Jessica Co Compiler: Lillian Diao

Date: APR.21,2021 Date: APR.21,2021 Date: APR.21,2021

Sample Photo



Report No.: QDHL2104501757MD

Packaging (Artwork-Overall)

Packaging (Artwork-Detail)

Shandong Weigao Group Medical Polymer Co., Ltd.
No.18 Xingshan Road,Torch Hi-tech Science Park, 264210 Weihai,
Shandong Province,PEOPLE'S REPUBLIC OF CHINA

EC REP MedNet EC-REP GmbH
Borkstrasse 10, 48163 Muenster, GERMANY

Product information is provided by applicant without verification of authentication of the brand.

Report No.: QDHL2104501757MD

Test Results

Test Items	Unit	Test Method	Requirement		Test Result		Assessment
ISO 7886-1:2017 Sterile hypodermic syringes for single use-Part 1: Syringes for manual use							
Cleanliness (General)	/	ISO 7886-1:2017 Clause 6.1	The surfaces of the syringe that come in contact with injection fluids during normal use shall be free from particles and extraneous matter.		No particles and extraneous matter		Pass
pH value (Limits for acidity or alkalinity)	/	ISO 7886-1:2017 Clause 6.2	The pH value of an extract shall be within one unit of pH of that the control fluid.		ΔpH: 0.22		Pass
Heavy metals: Pb, Zn, Sn, Fe, Cd (Limits for extractable metals)	mg/kg	ISO 7886-1:2017 Clause 6.3	Total (Pb + Sn + Zn+Fe)	/	Lead (Pb)	< 0.1	Pass
					Tin(Sn)	< 0.1	
					Zinc (Zn)	0.2	
					Iron(Fe)	< 0.1	
				≤5	Total (Pb + Sn + Zn+Fe)	0.2	
			Cadmium (Cd)	<0.1	Cadmium (Cd)	< 0.05	
Tolerance on graduated capacity	mL	ISO 7886-1:2017 Clause 8	The tolerances on the graduated capacity shall be: less than half nominal capacity: ±(1.5% of V + 2% of expelled volume): 0.07mL equal to or greater than half nominal capacity: ±5% of expelled volume: 0.10mL		Tolerance on 1mL: 0.007 Tolerance on 2mL: 0.006		Pass

Test Items	Unit	Test Method	Requirement	Test Result	Assessment
Graduated scale					
Scale	mL	ISO 7886-1:2017 Clause 9.1	The syringe shall have either only one scale or more than one identical scales, the unit of volume shall be marked on the barrel. scale interval: ≤0.2mL	one scale scale interval: 0.1 The unit of volume: 3	Pass
	/		If the scale is extended beyond the nominal capacity, the extended portion shall be differentiated from the rest of the scale.	/	Not applicable
	/		The graduation lines shall be of uniform thickness. They shall lie in planes at right angles to the axis of the barrel.	The thicknesses of the graduation lines are uniform. They lie in planes at right angles to the axis of the barrel.	Pass
	/		The graduation lines shall be evenly spaced along the longitudinal axis between the zero graduation line and the line for the total graduated capacity.	The graduation lines are evenly spaced along the longitudinal axis between the zero graduation line and the line for the total graduated capacity.	Pass
	mm		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 shall be approximately half the length of the long lines.	The ends of all graduation lines of similar length are vertically beneath each other. Short graduation lines length: 4 Long graduation lines length: 8	Pass

Report No.: QDHL2104501757MD

Test Items	Unit	Test Method	Requirement	Test Result	Assessment
Number of scale	mL	ISO 7886-1:2017 Clause 9.2	The line denoting the nominal capacity or the lines denoting the nominal capacity and the total graduated capacity, if these differ, shall be numbered. Increment between graduation lines to be numbered: ≤1mL	Increment between graduation lines to be numbered: 1 The nominal capacity line: 3 The total graduated capacity line: 3	Pass
	/		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.	The numbers are vertical on the scale and are approximately centred on the graduation lines to which they relate. The numbers are close to, but not touch, the ends of the graduation lines to which they relate.	Pass
Overall length of scale to nominal capacity line	mm	ISO 7886-1:2017 Clause 9.3	Minimum overall length of scale to nominal capacity mark: 27mm	Overall length of the scale: 44.2	Pass
Position of scale	/	ISO 7886-1:2017 Clause 9.4	When the plunger stopper is fully inserted, the zero-graduation line of the scale shall coincide with the fiducial line on the plunger stopper	The zero-graduation line coincides with the fiducial line	Pass

Test Items	Unit	Test Method	Requirement	Test Result	Assessment
Barrel					
Dimensions	mm	ISO 7886-1:2017 Clause 10.1	Maximum capacity shall be determined by risk assessment with consideration of, for example, removal of air bubbles or risk of overdose.	Maximum capacity length: 50.1 can remove air bubbles	Pass
Barrel flanges	/	ISO 7886-1:2017 Clause 10.2	The open end of the barrel shall be provided with barrel flanges. The syringe design 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.	No rolling No flash and sharp edges	Pass
Piston/plunger assembly (Plunger stopper/plunger assembly)					
Design	/	ISO 7886-1:2017 Clause 11.1	The plunger stopper shall not become detached from the plunger.	Not detached	Pass
	/		The plunger should be of a length adequate to allow the plunger stopper to traverse the full length of the barrel, but it should not be possible easily to withdraw the piston completely from the barrel.	The plunger stopper can traverse the full length of the barrel, and it was not easily completely from the barrel.	Pass
	/		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,should be at least 8mm.	It can be operated without difficulty The length of the plunger from the surface of the barrel flanges grips nearer to the push-button: 11.0mm	Pass

Report No.: QDHL2104501757MD

Test Items	Unit	Test Method	Requirement	Test Result	Assessment
Nozzle					
Conical fitting	/	ISO 80369-7	Conical fitting shall be in accordance with ISO 80369-7.	Details see ISO 80369-7	Details see ISO 80369-7
Position of nozzle on end of barrel	/	ISO 7886-1:2017 Clause 12.2	On syringes of nominal capacity of less than 5ml, the syringe nozzle shall be situated centrally, i.e. it shall be coaxial with the barrel.	The syringe nozzle is situated centrally	Pass
			On syringes of nominal capacity of 5mL and greater, the syringe nozzle shall be situated either centrally or eccentrically.	/	Not applicable
			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 nearest point on the internal surface of the bore of the barrel shall be not greater than 4.5mm.	/	Not applicable
Nozzle lumen	mm	ISO 7886-1:2017 Clause 12.3	The nozzle lumen shall have a diameter of not less than 1.2mm.	Diameter of the nozzle lumen: 2.0	Pass
Performance					
Dead space	mL	ISO 7886-1:2017 Clause 13.1	Maximum dead space: 0.07mL	Dead space: 0.04	Pass
Freedom from air and liquid leakage past plunger stopper	/	ISO 7886-1:2017 Clause 13.2	No leakage of water past the plunger stopper or seal(s).	No leakage of water	Pass
			No leakage of air past the plunger stopper or seal(s), and there shall be no fall in the manometer reading.	No leakage of air No fall in the manometer reading	Pass

<table>
<tr><th>Test Items</th><th>Unit</th><th>Test Method</th><th>Requirement</th><th>Test Result</th><th>Assessment</th></tr>
<tr><td>Force to operate the piston</td><td>N</td><td>ISO 7886-1:2017 Clause 13.3</td><td>Table E.1 — Proposed values for forces required to operate plunger<table><tr><th>Nominal capacityof syringe (V)mL</th><th>Initial force (Fs)Nmax.</th><th>Mean force (F)Nmax.</th><th>Maximum force (Fmax)N</th></tr><tr><td>2 ≤ V < 50</td><td>25</td><td>10</td><td>< (2,0 × measured F) or (measured F + 1,5 N),whichever is higher</td></tr></table></td><td>Fs: 3.6
F: 2.0
Fmax: 2.7</td><td>Pass</td></tr>
<tr><td>Fit of plunger stopper/plunger in barrel</td><td>/</td><td>ISO 7886-1:2017 Clause 13.4</td><td>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 reaon of its own mass and the water contained.</td><td>Not moved</td><td>Pass</td></tr>
<tr><td colspan="6">Information supplied by the manufacturer*</td></tr>
<tr><td>General*</td><td>/</td><td>ISO 7886-1:2017 Clause 15.1</td><td>The syringe shall be accompanied by the information that is sufficient for its safe use, taking account of the training and knowledge of potential users.
The information shall include the identity of the manufacturer.</td><td>No instruction for safe use.

Shandong Weigao Group Medical Polymer Co.,Ltd.</td><td>/</td></tr>
<tr><td>General-Syringes*</td><td>/</td><td>ISO 7886-1:2017 Clause 15.2.1</td><td>The barrels of syringes shall be marked with the following information:
a) appropriate graduated scale in accordance with Clauses 8 and 9;
b) total graduated capacity in millilitres</td><td>a) Graduated scale was found.
b) 3mL</td><td>Pass</td></tr>
</table>

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Test Items	Unit	Test Method	Requirement	Test Result	Assessment
Additional marking for self-contained syringe units*	/	ISO 7886-1:2017 Clause 15.2.2	The syringe or unit shall additionally be marked with the following information: a) the words “For single use” or equivalent, such as the symbol for “Do not re-use” (see ISO 15223-1:2016, Table 1, symbol number 5.4.2); the term “disposable” shall not be used; b) name and/or registered trademark of the manufacturer and, where applicable, reference to its authorized representative.	/	Not applicable
			A warning to check the integrity of the seals of the self-contained syringe unit before use may be given. All information appearing on the barrel should be marked in such a position as to interfere as little as possible with the reading of the graduated scale.	/	Not applicable
User packaging*	/	ISO 7886-1:2017 Clause 15.3	See appendix 1 for details	See appendix 1 for details	See appendix 1 for details

Test Items	Unit	Test Method	Requirement	Test Result	Assessment
General-Multiple unit packs*	/	ISO 7886-1:2017 Clause 15.4.1	The multiple unit packs for syringes shall be marked with the following information: a) "the words "For single use" or equivalent, such as the symbol for "Do not re-use" (see ISO 15223-1:2016, Table 1, symbol number 5.4.2); the term "disposable" shall not be used; b) name and/or trademark and address of the manufacturer and/or his authorized representative, unless the product bears this information and is visible through the multiple unit pack; c) an identification reference to the batch code or lot number, prefixed by the symbol "Batch code" (see ISO 15223-1:2016, Table 1, symbol number 5.1.5); or the word "LOT". d) the external diameter and length of the needle in millimetres, if included; the gauge size of the needle may also be marked; e) identity of the contents, including the capacity of the syringe to be used unless the information is visible through the multiple unit pack. f) "the words "EXP" or equivalent, such as the symbol for "Use-by date" (see ISO 15223-1:2016, Table 1, symbol number 5.1.4).	Not Provided	Not Conducted
Multiple unit packs with self-contained syringes*	/	ISO 7886-1:2017 Clause 15.4.2	The multiple unit packs for self-contained syringes shall be marked with the following information: a) the words "Syringe interior sterile" or equivalent, such as the symbol for "Sterile fluid path" (see ISO 15223-1:2016, Table 1, symbol number 5.2.9); b) a warning to check the integrity of the seals of the self-contained syringe units before use, unless this warning is given on the syringe unit.	/	Not applicable

Test Items	Unit	Test Method	Requirement	Test Result	Assessment
User packaging*	/	ISO 7886-1:2017 Clause 15.5	The user packaging shall be marked with the following information: a) the word "STERILE" or equivalent, such as the symbol for "Sterile" (see ISO 15223-1:2016, Table 1, symbol number 5.2.9); b) for self-contained syringes, the words "Syringe interior sterile" or equivalent, such as the symbol for "Sterile fluid path" (see ISO 15223-1:2016, Table 1, symbol number 5.2.9); c) "the words "For single use" or equivalent, such as the symbol for "Do not reuse" (see ISO 15223-1:2016, Table 1, symbol number 5.4.2); the term "disposable" shall not be used; d) an identification reference to the batch code or lot number, prefixed by the symbol "Batch code"(see ISO 15223-1:2016, Table 1, symbol number 5.1.5);or the word "LOT". e) name and/or trademark and address of the manufacturer and/or his authorized representative; f) description of contents; g) the words "EXP" or equivalent, such as the symbol for "Use-by date" (see ISO 15223-1:2016, Table 1, symbol number 5.1.4).	Not Provided	Not Conducted

Test Items	Unit	Test Method	Requirement	Test Result	Assessment
Storage container*	/	ISO 7886-1:2017 Clause 15.6	If user packaging comes in a storage container, the storage container shall be marked with at least the following information a) identity of the contents, including the capacity of the syringe; b) an identification reference to the batch code or lot number, prefixed by the symbol "Batch code" (see ISO 15223-1:2016, Table 1, symbol number 5.1.5); or the word "LOT"; c) the word "STERILE or equivalent, such as the symbol for " sterile" (see ISO 15223-1:2016, Table 1, symbol number 5.2.1); d) the name and address of the manufacturer and where applicable reference to its authorized representative; e) information for handling, storage and transportation of the contents f) the word "EXP" or equivalent, such as the symbol for "Use-by date (see ISO 15223-1:2016, Table 1, symbol number 5.1.4). Symbols that indicate the sterilization method may also be used. See ISO 15223-1:2016, Table 1, symbol numbers 5.2.2 to 5.2.5. An indication to keep the storage container away from sunlight and keep dry may be given. See ISO 15223-1:2016, Table 1, symbol numbers 5.3.2 and 5.3.4.	Not Provided	Not Conducted
Transport wrapping*	/	ISO 7886-1:2017 Clause 15.7	If a storage container is not used but the secondary containers are wrapped for transportation, the information required by 15.6 shall either be marked on the wrapping or shall be visible through the wrapping.	Not Provided	Not Conducted

Test Items		Unit	Test Method	Requirement	Test Result	Assessment
ISO 80369-7: 2016 Small-bore connectors for liquids and gases in healthcare applications —Part 7: Connectors for intravascular or hypodermic applications						
Material used for luer connectors*		/	ISO 80369-7:2016 Clause 4.2 ASTM D638-14	Luer connectors shall be made of materials with a nominal modulus of elasticity either in flexure or in tension greater than 700MPa.	See appendix 2 for details	Pass
liquid leakage (Fluid leakage)	Positive pressure liquid leakage	$Pa \cdot m^3/s$	ISO 80369-20:2015 Annex C	No signs of leakage	No leakage	Pass
Air leakage (Sub-atmospheric pressure air leakage)		$Pa \cdot m^3/s$	ISO 80369-20:2015 Annex D	Not leak by more than 0.005 $Pa \cdot m^3/s$	Leak: $4.77x10^{-6}$	Pass
Stress cracking		/	ISO 80369-20:2015 Annex E	No signs of leakage	No leakage	Pass
Resistance to separation from axial load		/	ISO 80369-20:2015 Annex F	Luer connectors shall not separate from the reference connector.	No separation	Pass
Resistance to separation from unscrewing		/	ISO 80369-20:2015 Annex G	Luer lock connectors shall not separate from the reference connector.	No separation	Pass
Resistance to overriding		/	ISO 80369-20:2015 Annex G	Luer lock connectors shall not override the threads or lugs of the reference connector	No overriding	Pass

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Appendix 1: Unit packaging*

Clause	Requirement	Result	Rating
15.3 Unit packaging	The unit packaging shall be marked with the following information: a) the word “STERILE” or equivalent, such as the symbol for “Sterile” (see ISO 15223-1:2016, Table 1, symbol number 5.2.1); b)the words “For single use” or equivalent, such as the symbol for “Do not re-use” (see ISO 15223-1:2016, Table 1, symbol number 5.4.2); the term “disposable” shall not be used; c) an identification reference to the batch code or lot number, prefixed by the symbol “Batch code” (see ISO 15223-1:2016, Table 1, symbol number 5.1.5), or the word “LOT”; d) the external diameter and length of the needle in millimetres, if included; the gauge size of the needle may also be marked.	a) The word “STERILE” was found b) The words “For single use only” were found. Symbol 5.4.2 was found. c) Symbol 5.1.5 was found: 20210305 d) 23Gx1” 0.6x25mm	Pass
	A warning to check the integrity of the unit packaging before use may be given; such as using the symbol for “Do not use if package is damaged”. See ISO 15223-1:2016, Table 1, symbol number 5.2.8.	“Do not use it if the package is opended or damaged”	Pass
	Symbols that indicate the sterilization method may also be used. See ISO 15223-1:2016, Table 1, symbol numbers 5.2.2 to 5.2.5.	Symbol 5.2.3 was found.	Pass
	The unit packaging shall also be marked with the following information unless the product bears the information and is visible through the unit packaging: a) identity of the contents, including the capacity of the syringe; b) name and/or trademark and address of the manufacturer and/or his authorized representative; c) the words “EXP” or equivalent, such as the symbol for “Use-by date” (see ISO 15223-1:2016, Table 1, symbol number 5.1.4).	a) DISPOSABLE SYRINGE: 3mL b) Shandong Weigao Group Medical Polymer Co.,Ltd. No.18 Xingshan Road,Torch Hi-tech Science Park, 264210 Weihai,Shandong Province,PEOPLE’S REPUBLIC OF CHINA c) Symbol 5.1.4 was found: 2024-03-04	Pass

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Appendix 2：Material used for luer connectors*

Test Item: Tensile Test

Sample Description: Resin

Test Method: ASTM D638-14

Test Condition:

Pretreatment conditions: 23 ± 2 ℃, 50 ± 5 % RH, 48 h

Specimen: Type I

Quantities of Specimens: 5

Specimen width at narrow portion: 12.866 mm

Specimen thickness: 3.146 mm

Testing speed: 5 mm/min

Gauge length: 50 mm

Initial distance between grips: 115 mm

Lab Environmental Condition: 23 ± 2 ℃, 50 ± 5 % RH

Test Result:

Test Item	Test Result
Tensile Modulus	1310 MPa
Standard Deviation	4.95

Note:

1. Test specimens were injection molded.
2. The extensometer accuracy is Class 0.5, The extensometer system which both defines gauge length and senses extension, for example, a clip-on strain gauge type with conditioning electronics.
3. The test was carried out by SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd. (CMA No. 170900340938; CNAS No. L0599).

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Remark:

1. Type of fitting: male
2. The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.
3. * Test items were not included in the CNAS accredited schedule for our laboratory.
4. Packaging and Package Marking was based on the information provided by the customer, excluding the verification of the authenticity of the content. SGS is not responsible for verifying the accuracy of the information provided by customers.
5. Only evaluate the contents of the labelling required by this standard.

End of Report

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No. G1 094273 0003 Rev. 03

Manufacturer:

Shandong Weigao Group Medical Polymer Co., Ltd.
No.18 Xingshan Road
Torch Hi-tech Science Park
264210 Weihai, Shandong Province
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Sterile 'Infusion Sets, Transfusion Sets, Hypodermic Syringes, Plastic Blood Bag, Intravenous Needles, Blood Collection Needles, High Pressure Angiographic Syringes, Retractable Auto-Disable Syringe, Oral / Enteral Syringe' for Single Use, Sterile Micro-Filter Syringes for Single Use, Infusion Sets with Precision Filters for Single Use, Light-resistant Infusion Sets for Single Use, Flow Rate-setting and Adjustable Infusion Sets with Precision Filters for Single Use, Sterile Light-resistant Syringe with Needle for Single Use, Ultra-low Density Polyethylene Infusion Set for Single Use.

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Report No.: BJ19884031

Valid from: 2020-02-18
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Date, 2020-02-18

Christoph Dicks
Head of Certification/Notified Body

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