ISO 11608-2 (2012)

COMPARISON TEST REPORT

[BD and Shina INSULIN SYRINGES]

1. PURPOSE

The purpose of this report is to verify the performance and design of the **W.L. MED INSULIN PEN NEEDLE**.

Product Name	Insulin Syringe		Model Name	31Gx8mm
Lot No.			Manufactured Date	Jan. 2022 ~ Oct. 2022
Manufacturer	Company Name	Shina Med and BD		
	Company Country	REPUBLIC OF KOREA and USA		
	Company address	455-30, Bogaewonsam-ro, Bogae-myeon, Anseong-si, Gyeonggi-do, Republic of Korea & 1 Becton Drive, Franklin Lakes, NJ 07417 USA		
Testing Location	Company Name	Shina Med Corporation		
	Company address	455-30, Bogaewonsam-ro, Bogae-myeon, Anseong-si, Gyeonggi-do, Republic of Korea		
Test Method	ISO8537:2016 Sterile single-use syringes, with or without needle, for insulin			
	ISO7864:1993 Sterile hypodermic needles for single use			
	IEC60068-2-30:2005 Environmental testing-Part2: Test Db and guidance: Damp heat, cyclic (12+12-hour cycle)			
	ISO9626:1991/Amd1 2001 Stainless steel needle tubing for the manufacture of medical Devices.			
Sampling Method	According to ISO 11608-2(2012), Claus 5, sampling Select 350 Needles			

The purpose of this report is to verify the performance and design of the W.L. MED insulin pen-needle.

Functional area representatives

Division	Department	Name	Date	Signature
Prepared by	QA Engineer	Kang-Uk Jin	Feb. 20, 2023	
Reviewed by	Q.M.R	Tae-Joo Ha	Feb. 20, 2023	
Approved by	CEO	Sang-Hyuk Bang	Feb. 20, 2023	

2. SCOPE

This report is applicable to the below product.

Trade Name: Sure Comfort and Ultra-Fine™ Insulin Syringes	
Common Name	Sterile single use Insulin Syringe
Model name	1cc 31G x 8mm 0.5cc 31G x 8mm 0.3cc 31G x 8mm

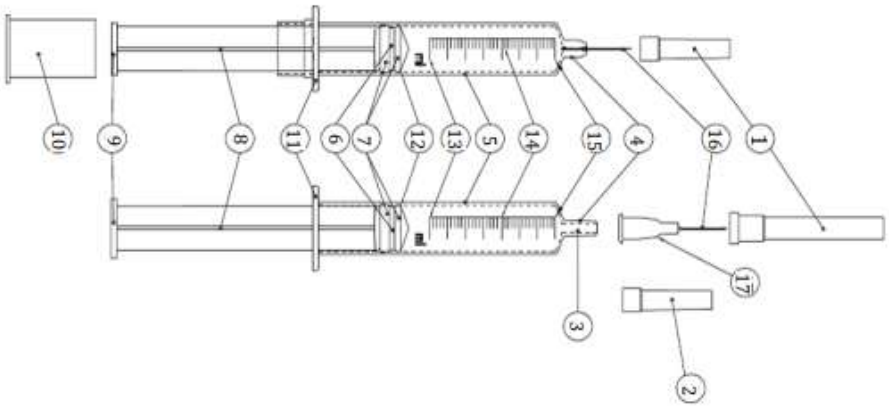
The model selected for the test is defined in each test item.

3. TERMS AND DEFINITIONS

For the purposes of this part of ISO 8537, the following terms and definitions apply. The nomenclature used for some components of syringes intended for single use is shown in Figure below.

3.1 Sterile single-use syringes, with or without needle, for Insulin

Insulin Syringes are hypodermic insulin syringes for subcutaneous injection of insulin



1	needle cap	10	plunger cap
2	nozzle cap	11	finger grips
3	nozzle lumen	12	fiducial line
4	nozzle	13	nominal capacity
5	barrel	14	graduation lines
6	plunger stopper	15	zero line
7	seals	16	needle tube
8	plunger	17	hub
9	push-button		

3.2 Plunger Stopper
Component connected to the leading end of the plunger and seals the open end of the syringe barrel.

3.3 Plunger cap
Cover intended to maintain the sterility of the syringe and enclose the projecting portion of the plunger and push button, if present.

3.4 Total graduated capacity
Capacity of the syringe at the graduation line farthest from the zero graduation line. (the total graduated capacity may be equal to, or greater than, the nominal capacity.)

3.5 Piston
Assembled component of plunger and plunger stopper.

3.6 Unit packaging
Packaging of an individual device, intended to maintain its sterility.

3.7 User packaging
Packaging, which contains one or more items of unit packaging, designed to provide labelling information to the user.

4. QUALITY MANAGEMENT SYSTEM

4.1 Documentation

4.1.1 The documentation of transit validation is performed according to Quality document control procedure

4.1.2 The review and approval is approved according to the followings.

Division	Authored by	Reviewed by	Approved by
Test report	Quality assurance team	QMR	CEO

4.2 Record

4.2.1 The records of transit validation are performed according to Quality record control procedure

4.3 Design and development of the Performance and design verification

4.3.1 The report design of the performance and design verification is performed according to ISO837:2016.

4.4 Qualification and training

4.4.1 Qualification and training of responsibility that is assigned are performed in accordance with the clause 5 of this report.

4.4.2 Qualification and training of responsibility that is assigned are performed in accordance with Qualification and Training procedure.

4.5 Calibration

4.5.1 Measurement equipment's to be used for transit validation are calibrated according to testing, measurement

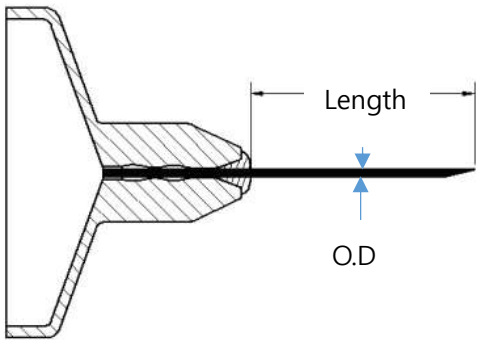
And testing equipment control procedure.

5. TESTING EQUIPMENT

Micormeter		Figure	Vernier Calipers		Figure
Manufacturer	Mitutoyo	 Calibration : 1year	**Manufacturer**	Mitutoyo	 Calibration : 1years
Product name	Micrometer		**Product name**	Vernier Calipers	
Model name	MDC-25MX		**Model name**	A19069711	
Specification	Measuring range : 0~25mm		**Specification**	Measuring range : 0~150mm	
Projector		**Figure**	**Electronic scale**		**Figure**
Manufacturer	Mitutoyo	 Calibration : 1year	**Manufacturer**	AND	 Calibration : 1year
Product name	Projector		**Product name**	ELECTRONIC SCALE	
Model name	PJ-A3000		**Model name**	GF-200	
Specification	Magnification : 20x		**Specification**	Measuring range :0~210g	
UTM		**Figure**	**Push-Pull gauge**		**Figure**
Manufacturer	QMESYS	 Calibration : 1year	**Manufacturer**	HANDPI	 Calibration :1year
Product name	Tensile tester		**Product name**	Push-Pull Gauge	
Model name	QM100S		**Model name**	NK-200	
Specification	Maximum speed : 300mm/min, Tensile : 50kgf		**Specification**	Measuring range : 0~200N	

6. TESTING METHOD

6.1 Dimension testing

EQUIPMENT	PROJECTOR	VERNIER CALIPERS	MICROMETER	-
				
REQUIREMENT	ISO 8537:2016 (5.9 Needle tubing and needles / 5.9.2 Needle tubing for syringe type 5,6,7,and 8) Needle tubing for syringe type 5,6,7 and 8 shall be in accordance with ISO 9626. The needle length shall be measured as shown in figure below and the tolerance of the needle length shall be Within ±1.25㎜. 			
METHOD	**Needle length is measured by a projector.** **Needle outer diameter is measured by a micrometer.** **SAMPLING : AQL 1.0% (n=10, c=0)**			
Testing sample	1cc 31G x 8mm 0.5cc 31G x 8mm 0.3cc 31G x 8mm			

RESULTS

SHINA MED			BD		
1cc 31G x 8mm	0.5cc 31G x 8mm	0.3cc 31G x 8mm	1cc 31G x 8mm	0.5cc 31G x 8mm	0.3cc 31G x 8mm
O.D: 0.254 ~ 0.267mm			O.D: 0.254 ~ 0.267mm		
0.259	0.259	0.260	0.259	0.259	0.261
Pass	Pass	Pass	Pass	Pass	Pass

SHINA MED			BD		
1cc 31G x 8mm	0.5cc 31G x 8mm	0.3cc 31G x 8mm	1cc 31G x 8mm	0.5cc 31G x 8mm	0.3cc 31G x 8mm
Length: 8 ± 1.25 mm			Length: 8 ± 1.25 mm		
8.162	8.358	8.428	7.914	7.399	7.386
Pass	Pass	Pass	Pass	Pass	Pass

6.1.1 Outer Diameter Result:

No.	SHINA MED			BD		
	1cc 31G	0.5cc 31G	0.3cc 31G	1cc 31G	0.5cc 31G	0.3cc 31G
	O.D: 0.254 ~ 0.267mm			O.D: 0.254 ~ 0.267mm		
1	0.256	0.230	0.261	0.262	0.257	0.263
2	0.261	0.259	0.262	0.260	0.262	0.259
3	0.259	0.258	0.258	0.258	0.259	0.256
4	0.257	0.256	0.258	0.259	0.255	0.264
5	0.261	0.256	0..257	0.257	0.261	0.264
6	0.258	0.263	0.258	0.258	0.261	0.263
7	0.259	0.259	0.258	0.261	0.260	0.259
8	0.260	0.258	0.263	0.259	0.260	0.262
9	0.259	0.257	0.260	0.259	0.259	0.261
10	0.260	0.260	0.262	0.255	0.257	0.262
Ave.	0.259	0.259	0.260	0.259	0.259	0.261

6.1.2 Length Result:

No.	SHINA MED			BD		
	1cc 31G	0.5cc 31G	0.3cc 31G	1cc 31G	0.5cc 31G	0.3cc 31G
	Length: 8 ± 1.25 mm			Length: 8 ± 1.25 mm		
1	7.898	8.289	8.431	7.531	7.530	7.379
2	8.244	8.224	8.390	7.821	7.313	7.151
3	8.142	8.256	8.625	8.005	7.627	7.248
4	8.252	8.420	8.598	8.138	7.372	7.580
5	8.157	8.100	8.492	8.213	7.408	7.209
6	8.328	8.409	8.617	7.934	7.304	7.473
7	8.159	8.414	8.362	7.694	7.164	7.547

8	8.135	8.478	8.137	7.926	7.371	7.449
9	7.934	8.452	8.300	7.638	7.486	7.433
10	8.368	8.533	8.325	8.235	7.410	7.394
Ave.	8.162	8.358	8.428	7.914	7.399	7.386

6. TESTING METHOD

6.2 Bond between hub and needle tube testing

EQUIPMENT

UTM

REQUIREMENT

□ ISO8537:2016 (5.9.3 Bond between hub and needle tube)

The bond between hub and needle tube shall be withstand at least minimum shearing strength

PRE-CONDITIONING

□ The products are stored on the following conditions

Temperature: 18 ~ 28℃ / Relative humidity: 25 ~ 75%RH

Testing shall be performed after samples have been stored under these conditions for at least 4hours.

METHOD

①Attach the needle to the test gauge which It is intended. in both cases, the needle shall be attached in accordance With the instructions for use. Verify that the needle is completely attached.

②Pull the needle tube with the test equipment under the100mm/min speed.

□ **SAMPLING: AQL 1.0% (n=10, c=0)**

Testing sample

1cc 31G x 8mm

0.5cc 31G x 8mm

0.3cc 31G x 8mm

CRITERIA

□ **Minimum strength of bond between hub and needle tube**

Nominal outside diameter of needle (mm)	Force min. (N)	Nominal outside diameter of needle (N)	Force min. (N)
0.25 (31G)	11	0.33 (29G)	22

RESULTS

SHINA MED			BD		
1cc 31G x 8mm	0.5cc 31G x 8mm	0.3cc 31G x 8mm	1cc 31G x 8mm	0.5cc 31G x 8mm	0.3cc 31G x 8mm
Minimum force 11N			Minimum force 11N		
48.86	55.74	54.61	52.96	57.57	50.42
Pass	Pass	Pass	Pass	Pass	Pass

6.2.1 Bond between hub and needle tube test Result

No.	SHINA MED			BD		
	1cc 31G	0.5cc 31G	0.3cc 31G	1cc 31G	0.5cc 31G	0.3cc 31G
	Minimum force 11N			Minimum force 11N		
1	43.35	59.00	49.27	39.83	57.96	49.37
2	50.58	58.66	54.60	55.66	54.33	51.07
3	42.66	57.00	56.37	54.09	54.86	46.93
4	52.72	52.62	43.54	52.58	58.25	58.39
5	43.74	45.16	54.56	54.86	58.92	43.29
6	56.05	55.78	57.92	52.35	55.64	47.41
7	49.60	57.86	57.27	52.45	58.94	59.84
8	52.96	55.58	57.00	56.07	59.90	53.09
9	47.72	57.66	60.25	55.76	55.17	44.03
10	49.21	58.06	55.35	55.94	61.68	50.78
Ave.	48.86	55.74	54.61	52.96	57.57	50.42

6. TESTING METHOD

6.3 Pull force of Needle cap and Plunger cap

EQUIPMENT	UTM				
					
REQUIREMENT	□ ISO8537:2016 The force between cap and syringe shall be withstand in a proper strength (※ Pull force of plunger and needle cap is SHINAMED's own regulation)				
PRE-CONDITIONING	□ The products are stored on the following conditions Temperature: 18 ~ 28℃ / Relative humidity: 25 ~ 75%RH Testing shall be performed after samples have been stored under these conditions for at least 4hours.				
METHOD	①Attach the cap to the test gauge which It is intended. in both cases, the cap shall be assembled in accordance With the instructions for use. Verify that the cap is completely assembled. ②Pull the cap with the test equipment under the100mm/min speed.				
	□ **SAMPLING: AQL 1.0% (n=10, c=0)**				
Testing sample	1cc 31G x 8mm 0.5cc 31G x 8mm 0.3cc 31G x 8mm				
CRITERIA	□ **Pull force**				

Name	Pull force (N)	Name	Force min. (N)
Plunger cap	5 ~ 20	Needle Cap	5 ~ 20

RESULTS

SHINA MED			BD		
1cc 31G x 8mm	0.5cc 31G x 8mm	0.3cc 31G x 8mm	1cc 31G x 8mm	0.5cc 31G x 8mm	0.3cc 31G x 8mm
Pull force of Plunger cap: 5 ~ 20N			Pull force of Plunger cap: 5 ~ 20N		
10.80	10.94	13.49	13.94	24.06	18.56
Pass	Pass	Pass	Pass	Reject	Pass

SHINA MED			BD		
1cc 31G x 8mm	0.5cc 31G x 8mm	0.3cc 31G x 8mm	1cc 31G x 8mm	0.5cc 31G x 8mm	0.3cc 31G x 8mm
Pull force of Needle cap: 5 ~ 20N			Pull force of Needle cap: 5 ~ 20N		
10.90	12.50	9.23	8.07	22.07	16.47
Pass	Pass	Pass	Pass	Reject	Pass

6.3.1 Pull force of Plunger cap

No.	SHINA MED			BD		
	1cc 31G	0.5cc 31G	0.3cc 31G	1cc 31G	0.5cc 31G	0.3cc 31G
	Pull force of plunger cap: 5 ~ 20N			Pull force of plunger cap: 5 ~ 20N		
1	15.04	11.04	12.96	20.18	17.83	19.75
2	16.51	8.90	12.79	11.75	23.69	17.93
3	10.08	8.16	16.87	10.02	17.32	17.40
4	7.14	11.57	11.75	10.22	24.56	17.06
5	10.00	10.94	14.14	12.02	22.81	22.79
6	11.22	9.77	12.36	10.36	26.16	15.79
7	7.45	17.14	12.83	14.10	29.03	20.32
8	9.36	10.45	8.90	18.16	29.28	14.20
9	7.90	12.61	17.36	17.24	21.89	21.12
10	13.30	8.81	14.96	15.34	28.05	19.22
Ave.	10.80	10.94	13.49	13.94	24.06	18.56

6.3.2 Pull force of Needle cap

No.	SHINA MED			BD		
	1cc 31G	0.5cc 31G	0.3cc 31G	1cc 31G	0.5cc 31G	0.3cc 31G
	Pull force of needle cap: 5 ~ 20N			Pull force of needle cap: 5 ~ 20N		
1	11.24	12.00	7.10	8.34	25.07	19.24
2	9.00	12.20	9.92	7.04	21.61	18.85
3	11.71	12.10	9.32	6.47	21.30	11.43
4	8.94	13.87	9.36	8.26	15.08	17.71
5	9.26	12.10	9.59	8.32	25.93	18.06
6	11.71	10.02	10.41	6.98	24.91	14.79

7	11.89	10.81	8.47	6.92	21.83	16.55
8	11.22	13.49	10.43	11.18	20.99	19.08
9	10.53	15.73	8.75	6.90	20.04	12.91
10	13.45	12.67	8.96	10.30	23.95	16.04
Ave.	10.90	12.50	9.23	8.07	22.07	16.47

6. TESTING METHOD

6.4 Penetration force for needle

EQUIPMENT	**UTM**				
					
REQUIREMENT	□ ISO7864:2016 (4.11 Needle Point) Penetration testing can provide an indication of the needle point sharpness and lubrication. An example of a test method for determining the needle penetration performance is given in Annex D				
PRE-CONDITIONING	□ The products are stored on the following conditions Temperature: 18 ~ 28℃ / Relative humidity: 25 ~ 75%RH Testing shall be performed after samples have been stored under these conditions for at least 24hours.				
METHOD	① The needle should be mounted onto the force measurement apparatus ② The substrate should be secured inside the substrate holder, such that it is visible in the target penetration area ③ The axis of motion of the needle is aligned perpendicular with the circular target area for substrate insertion ④ The needle should be moved towards the substrate at the 100mm/min speed ⑤ The needle should be retreated from the substrate to complete the testing				
	□ **SAMPLING: AQL 1.0% (n=10, c=0)**				
Testing sample	1cc 31G x 8mm 0.5cc 31G x 8mm 0.3cc 31G x 8mm				
CRITERIA	□ **Maximum force** **31G ~ 32G : Below 50gf**				

RESULTS	SHINA MED			BD		
	1cc 31G x 8mm	0.5cc 31G x 8mm	0.3cc 31G x 8mm	1cc 31G x 8mm	0.5cc 31G x 8mm	0.3cc 31G x 8mm
	Below 50gf			Below 50gf		
	30.5	32.5	35.3	42.7	43.7	38.5
	Pass	Pass	Pass	Pass	Pass	Pass

6.4.1 Penetration force for needle

No.	SHINA MED			BD		
	1cc 31G	0.5cc 31G	0.3cc 31G	1cc 31G	0.5cc 31G	0.3cc 31G
	Below 50gf			Below 50gf		
1	29.6	32.8	31.4	40.0	47.4	40.6
2	24.4	40.0	34.6	46.8	45.8	35.8
3	28.8	30.0	33.2	48.2	35.4	37.0
4	29.4	30.4	29.6	41.2	44.6	45.4
5	40.8	35.4	41.6	38.6	48.8	36.6
6	27.4	33.6	47.8	45.0	40.4	40.0
7	25.0	33.6	31.2	32.4	44.2	38.0
8	37.0	28.0	36.8	45.6	44.4	36.6
9	26.6	32.0	33.6	47.2	44.2	32.4
10	35.8	29.0	33.2	42.4	41.6	42.8
Ave.	30.5	32.5	35.3	42.7	43.7	38.5

6. TESTING METHOD

6.5 Plunger stopper movement

EQUIPMENT	UTM				
					
REQUREMENT	□ ISO8537:2016 (5.7.2 Fit of plunger stopper in barrel) The fit of plunger stopper in the barrel should be such that the plunger stopper slides smoothly throughout full range of its travel within the barrel.				
PRE-CONDITIONING	□ The products are stored on the following conditions Temperature: 18 ~ 28℃ / Relative humidity: 25 ~ 75%RH Testing shall be performed after samples have been stored under these conditions for at least 4hours.				
METHOD	① fix the barrel and plunger stopper onto the force measurement apparatus ② Pull and push the plunger stopper at the 100mm/min speed ③ Measure the initial movement force				

	SAMPLING: AQL 1.0% (n=10, c=0)					
Testing sample	1cc 31G x 8mm 0.5cc 31G x 8mm 0.3cc 31G x 8mm					
CRITERIA	**The force to initiate movement of the plunger stopper shall not be exceed 15N**					
RESULTS	**SHINA MED**			**BD**		
	1cc 31G x 8mm	0.5cc 31G x 8mm	0.3cc 31G x 8mm	1cc 31G x 8mm	0.5cc 31G x 8mm	0.3cc 31G x 8mm
	Maximum force 15N			Maximum force 15N		
	5.58	7.13	5.84	8.64	3.91	3.63
	Pass	Pass	Pass	Pass	Pass	Pass

6.5.1 Plunger stopper movement force

No.	SHINA MED			BD		
	1cc 31G	0.5cc 31G	0.3cc 31G	1cc 31G	0.5cc 31G	0.3cc 31G
	Maximum force 15N			Maximum force 15N		
1	3.63	3.61	7.92	11.36	3.30	4.08
2	5.59	10.26	5.75	8.94	3.67	3.14
3	7.24	6.96	4.69	9.16	6.22	5.32
4	5.39	7.35	4.10	5.84	6.57	3.02
5	5.65	5.57	6.65	10.85	5.55	3.82
6	6.16	8.53	4.47	6.94	2.18	2.35
7	8.34	7.83	8.24	10.77	3.00	4.10
8	2.69	6.49	5.24	10.90	4.18	3.37
9	4.53	4.98	6.61	7.43	2.20	3.71
10	6.53	9.73	4.77	4.22	2.26	3.41
Ave.	5.58	7.13	5.84	8.64	3.91	3.63

6. TESTING METHOD

6.6 Dead space

EQUIPMENT	**Electronic scale**				
					
REQUIREMENT	ISO8537:2016 (5.11.1 Dead space) Dead space should be minimized to reduce waste and transmission of infectious agents.				
PRE-CONDITIONING	The products are stored on the following conditions Temperature: 18 ~ 28℃ / Relative humidity: 25 ~ 75%RH Testing shall be performed after samples have been stored under these conditions for at least 4hours.				
METHOD	① Weigh the empty syringe, including needle if appropriate, prepared in accordance with an accuracy of 0.001 g. ② Fill the syringe to the total graduated capacity with distilled water, taking care to expel all air bubbles. ③ Expel the water by fully depressing the plunger, and wipe dry the outer surface of the syringe. ④ Reweigh the syringe. ⑤ Determine the mass of water, in grams, remaining in the syringe by subtracting the mass of the empty syringe from the mass of the syringe after expulsion of the water.				
	SAMPLING: AQL 1.0% (n=10, c=0)				
Testing sample	1cc 31G x 8mm 0.5cc 31G x 8mm 0.3cc 31G x 8mm				
CRITERIA	**Maximum dead space**				

Type of syringe	Maximum dead space (ml)
1 and 2	0.07
3 and 4	0.10
5 and 6	0.02
7 and 8	0.01

RESULTS	SHINA MED			BD		
	1cc 31G x 8mm	0.5cc 31G x 8mm	0.3cc 31G x 8mm	1cc 31G x 8mm	0.5cc 31G x 8mm	0.3cc 31G x 8mm
	Maximum dead space 0.01ml			Maximum dead space 0.01ml		
	0.003	0.003	0.002	0.002	0.002	0.002
	Pass	Pass	Pass	Pass	Pass	Pass

6.5.1 Dead space

No.	SHINA MED			BD		
	1cc 31G	0.5cc 31G	0.3cc 31G	1cc 31G	0.5cc 31G	0.3cc 31G
	Maximum dead space 0.07ml			Maximum dead space 0.07ml		
1	0.002	0.003	0.002	0.002	0.003	0.002
2	0.002	0.003	0.002	0.002	0.003	0.001
3	0.003	0.004	0.001	0.002	0.001	0.001
4	0.004	0.002	0.002	0.003	0.004	0.001
5	0.003	0.003	0.002	0.002	0.002	0.003
6	0.003	0.001	0.003	0.003	0.001	0.001
7	0.004	0.004	0.001	0.004	0.004	0.001
8	0.002	0.002	0.001	0.001	0.002	0.002
9	0.001	0.001	0.001	0.002	0.002	0.003
10	0.003	0.003	0.002	0.002	0.002	0.002
Ave.	0.003	0.003	0.002	0.002	0.002	0.002

6. TESTING METHOD

6.7 Tolerance on graduated capacity

EQUIPMENT	Electronic scale				
					
REQUIREMENT	ISO8537:2016 (Annex H, Syringe sizes and graduated scales) Table H.1 provides examples of syringe graduation specifications for U-40 and U-100 syringes				
PRE-CONDITIONING	The products are stored on the following conditions Temperature: 18 ~ 28℃ / Relative humidity: 25 ~ 75%RH Testing shall be performed after samples have been stored under these conditions for at least 4hours.				
METHOD	① Fill the syringe with water according to the maximum capacity scale, taking care to expel all air bubbles. ② After draining the water completely, weigh the water to an accuracy of 0.001g.				

SAMPLING: AQL 1.0% (n=10, c=0)

Testing sample

1cc 31G x 8mm
0.5cc 31G x 8mm
0.3cc 31G x 8mm

CRITERIA

Table H.1 – Insulin syringes, range of sizes, graduated scale and tolerance on graduated capacity.

Unit scale	Nominal capacity ml	Minimum length of scale mm	Scale interval units	Tolerance on graduated capacity	
				Volumes less than half the nominal capacity	Volumes equal to or greater than half the nominal capacity
U-100	0,3	41	0,5	±1,5 % of the nominal capacity +2 % of the expelled volume	±5 % of the expelled volume
	0,3	41	1		
	0,5	43	1		
	1,0	57	1		
	1,0	57	2		
U-40	0,5	43	0,5		
	0,5	43	1		
	1,0	50	1		
	2,0	60	1		
	2,0	60	2		

RESULTS

SHINA MED			BD		
1cc 31G x 8mm	0.5cc 31G x 8mm	0.3cc 31G x 8mm	1cc 31G x 8mm	0.5cc 31G x 8mm	0.3cc 31G x 8mm
±5 % of the expelled volume			±5 % of the expelled volume		
0.989	0.493	0.299	0.990	0.490	0.298
Pass	Pass	Pass	Pass	Pass	Pass

6.7.1 Tolerance on graduated capacity

No.	SHINA MED			BD		
	1cc 31G	0.5cc 31G	0.3cc 31G	1cc 31G	0.5cc 31G	0.3cc 31G
	±5 % of the expelled volume			±5 % of the expelled volume		
1	0.988	0.496	0.298	0.988	0.490	0.297
2	0.997	0.493	0.303	0.997	0.492	0.298
3	0.986	0.491	0.296	0.992	0.491	0.297
4	0.982	0.490	0.301	0.993	0.490	0.299
5	0.986	0.491	0.301	0.990	0.488	0.298
6	0.993	0.503	0.299	0.991	0.492	0.299
7	0.997	0.491	0.300	0.987	0.487	0.295
8	0.990	0.489	0.297	0.989	0.488	0.299
9	0.986	0.494	0.296	0.982	0.491	0.298
10	0.988	0.493	0.302	0.993	0.490	0.297
Ave.	0.989	0.493	0.299	0.990	0.490	0.298

7. Summary and Conclusion

Test items	Criteria	SHINA MED			BD		
		1cc 31G	0.5cc 31G	0.3cc 31G	1cc 31G	0.5cc 31G	0.3cc 31G
Outer Diameter	**0.254~0.267mm**	0.259	0.259	0.260	0.259	0.259	0.261
Length	**6.75~8.12mm**	8.162	8.358	8.428	7.914	7.399	7.386
Minimum strength of bond	**Min. 11N**	48.86	55.74	54.61	52.96	57.57	50.42
Pull force of plunger cap	**5 ~ 20N**	10.80	10.94	13.49	13.94	24.06	18.56
Pull force of needle cap	**5 ~ 20N**	10.90	12.50	9.23	8.07	22.07	16.47
Penetration force for needle	**Below 50gf**	30.5	32.5	35.3	42.7	43.7	38.5
Plunger stopper movement	**Max. 15N**	5.58	7.13	5.84	8.64	3.91	3.63
Dead space	**Max 0.01ml**	0.003	0.003	0.002	0.002	0.002	0.002
Graduated capacity	**± 5%**	0.989	0.493	0.299	0.990	0.490	0.298

(※ Pull force of plunger and needle cap is SHINAMED's own regulation)

The comparison test results of Shina Med and BD Insulin Syringe are mostly similar, but the patient's pain is likely to be lower due to the low force of Shina Med product in the penetration force for needle. In the pull force of plunger cap and needle cap, it is judged that there will be difficulties in cap separation when the BD product is used out of the standard.

In conclusion, the SHINAMED product was judged to be superior because it had less pain and easier Cap separation compared to the BD product.