

Brief Introduction Disposable Latex Surgical Gloves			Prepared by	Wang Yitong
			Checked by	Tao Zheng huan.
Doc. No.	HS/CE01-02		Approved by	Zhang Xiansheng
Effective date	2019.05.12	Ver. A/2	Page No.	Page 1 of 3

Product introduction

1. Introduction of the company

Tianchang Hengsheng Medical Devices Co.,Ltd. is located in Tianchang City, Anhui Province, is a professional latex gloves manufacture which focus on global market.

Contact information:

Tianchang Hengsheng Medical Devices Co.,Ltd.

Qinlan Industrial Park, 239341, Tianchang City, Anhui Province, People's Republic of China Tel: 0086-550-7811946

Fax: 0086-550-781 6946

The authorized representative of European Union:

Zoustech S.L.

Pso. Castellana, 141-Planta 19, 28046-Madrid, Spain

Tel:0550-7811946

Post code:239341

Web site: www.tcweicai.com

2. Product brief introduction

Product name: Disposable Latex Surgical Gloves

Intended use: The surgical glove acts as a protective barrier between the user's hand or hands and the external environment. This will typically be, e.g. an infection barrier between patient and healthcare provider or as an overall protection of the skin of the hand and fingers. The device may also provide therapeutic protection. Sterile, for single-use.

Materials: Natural latex

Product Name	Disposable Latex Surgical Gloves
UMDNS code	11883
Models	6#, 6.5#, 7#, 7.5#, 8#, 8.5#
Validity	5 years
Sterilization	Gamma Radiation
Manual	IFU-LSG, A/2

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Physical Dimension:

Widths and length:

Size	Length(mm)	Width(mm)	Weight(gm)
6.0	≥ 265	77 ± 5	$7.0g \pm 0.3g$
6.5	≥ 265	83 ± 5	$7.5g \pm 0.3g$
7.0	≥ 275	89 ± 5	$8.0g \pm 0.3g$
7.5	≥ 275	95 ± 5	$8.5g \pm 0.3g$
8.0	≥ 275	102 ± 6	$9.0g \pm 0.3g$
8.5	≥ 285	108 ± 6	$9.5g \pm 0.3g$

2.2 Thickness(double wall):

Location of thickness measurement	Double wall thickness(mm)
Palm (at centre of palm)	0.26
Fingertip(at 13mm from the extreme tip)	0.28
Cuff(at 25mm from the cuff)	0.21

3.Physical Properties:

Characteristic	Reference Standard	Before Ageing	After Ageing 7days@70°C ± 2 hours
Tensile strength(MPa)	ASTM D 3577	Min 24	Min18
Elongation at Break(%)	ASTM D 3577	Min700	Min500

3 Classification of the product

According to the requirements of the intended use of the product and MDD 93/42/EEC:

Product name: Disposable Latex Surgical Gloves

Classification: The above product belongs to Class IIa medical devices according to Rule 6 of Classification in Annex IX of MDD 93/42/EEC.

According to Rule 6: - All surgically invasive devices intended for transient use are in Class IIa unless they are:

- *intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III,*
- *reusable surgical instruments, in which case they are in Class I,*
- *intended to supply energy in the form of ionizing radiation in which case they are in Class IIb,*
- *intended to have a biological effect or to be wholly or mainly absorbed in which case they are in Class IIb,*
- *intended to administer medicines by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which they are in Class IIb.*

The Disposable Latex Surgical Gloves is a invasive device, transient use. According to the 1st paragraph of Rule 6, the Disposable Latex Surgical Gloves belongs to Class IIa.

4 Application method

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The product concerned has been manufactured under a quality management system according to Annex V.3 of Directive 93/42/EEC as amended by 2007/47/EC and the product apply CE certification following the instruction from Annex V.3.

5 Notified body

TÜV SÜD Product Service GmbH,
Ridlerstr. 65, 80339 München, Germany



Test Report

Name		POWDER FREE STERILE SURGICAL GLOVES						
Standard		ASTM D3577		Sampling procedures		ISO2859-1:1999		
Size		6"	Finished classified	Powder Free, Textured	Lot		2023-01	
Hand Forms		curved fingers	Quantity	20000		C.No.	MEDS-0027PF	
No.	inspection item		Standard Requirements		Inspection Level & AQL	Sample quantity	Inspection Result	Ac/Re
1	visual inspections		Gloves should be clean and no stains,single pouch should be sealed and clean		I AQL1.5	125pcs	Meet request	Ac
2	Length		Min length 260mm		S-2 4.0	13pcs	Length :266mm	Ac
3	Width		Width77±5mm				Width:77mm	Ac
4	Thickness (Single ply)		thickness on Finger ≥0.1mm				0.14mm	Ac
			thickness on Palm ≥0.1mm				0.13mm	
			thickness on Cuff ≥0.1mm		0.12mm			
5	Water tightness		Introduce 1000 cm³± 50 cm³ of water at a maximum temperature of 36 °C,check leak		I AQL1.5	125pcs	2 pcs is leaky	Ac
6	Tensile Strength before accelerated ageing		the tore minimum is 24MPa		S-2 AQL4.0	13pcs	the tore minimum is 25.4MPa	Ac
7	elongation before accelerated ageing		elongation of minimum value is 750%				elongation of minimum value is 820%	Ac
8	Tensile Strength after accelerated ageing		the tore minimum is 18MPa		S-2 AQL4.0	13pcs	the tore minimum is 19.2MPa	Ac
9	Elongation after accelerated ageing		elongation of minimum value is 560%				elongation of minimum value is 691%	Ac
10	Protein content		≤200 μg /dm²				124.2 μg /dm²	Ac
11	Powder content		≤2mg/pc				1.38mg/pc	Ac
12	Packing		Sealed		I AQL1.5	125pcs	100% sealed	Ac
13	Sterile		Final goods must be sterile				sterile	Ac
Conclusion			The product conforms to the requirements of ASTM D3577 and customers request					
			Date: 2023.5.9					

Inspector: Wang yue

Reviewed by: Wu chuan hua



Test Report

Name		POWDER FREE STERILE SURGICAL GLOVES						
Standard		ASTM D3577		Sampling procedures		ISO2859-1:1999		
Size		6.5"	Finished classified	Powder Free, Textured	Lot	2023-01		
Hand Forms		curved fingers	Quantity	15000	C.No.	MEDS-0027PF		
No.	inspection item		Standard Requirements		Inspection Level & AQL	Sample quantity	Inspection Result	Ac/Re
1	visual inspections		Gloves should be clean and no stains,single pouch should be sealed and clean		I AQL1.5	125pcs	Meet request	Ac
2	Length		Min length 260mm		S-2 4.0	13pcs	Length :269mm	Ac
3	Width		Width 83±6mm				Width:83mm	Ac
4	Thickness (Single ply)		thickness on Finger ≥0.1mm				0.14mm	Ac
			thickness on Palm ≥0.1mm				0.13mm	
			thickness on Cuff ≥0.1mm		0.12mm			
5	Water tightness		Introduce 1000 cm³± 50 cm³ of water at a maximum temperature of 36 °C,check leak		I AQL1.5	125pcs	2 pcs is leaky	Ac
6	Tensile Strength before accelerated ageing		the tore minimum is 24MPa		S-2 AQL4.0	13pcs	the tore minimum is 25.6MPa	Ac
7	elongation before accelerated ageing		elongation of minimum value is 750%				elongation of minimum value is 825%	Ac
8	Tensile Strength after accelerated ageing		the tore minimum is 18MPa		S-2 AQL4.0	13pcs	the tore minimum is 19.1MPa	Ac
9	Elongation after accelerated ageing		elongation of minimum value is 560%				elongation of minimum value is 693%	Ac
10	Protein content		≤200 μ g /dm²				124.1 μ g /dm²	Ac
11	Powder content		≤2mg/pc				1.36mg/pc	Ac
12	Packing		Sealed		I AQL1.5	125pcs	100% sealed	Ac
13	Sterile		Final goods must be sterile				sterile	Ac
Conclusion			The product conforms to the requirements of ASTM D3577 and customer's request					
			Date: 2023.5.9					

Inspector: Wang yue

Reviewed by: Wu chuan hua



Test Report

Name		POWDER FREE STERILE SURGICAL GLOVES					
Standard		ASTM D3577		Sampling procedures		ISO2859-1:1999	
Size		7"	Finished classified	Powder Free, Textured	Lot	2023-01	
Hand Forms		curved fingers	Quantity	60000	C.No.	MEDS-0027PF	
No.	inspection item	Standard Requirements		Inspection Level & AQL	Sample quantity	Inspection Result	Ac/Re
1	visual inspections	Gloves should be clean and no stains,single pouch should be sealed and clean		I AQL1.5	200pcs	Meet request	Ac
2	Length	Min length 265mm		S-2 4.0	13pcs	Length :275mm	Ac
3	Width	Width 89±6mm				Width:89mm	Ac
4	Thickness (Single ply)	thickness on Finger ≥0.1mm				0.14mm	Ac
		thickness on Palm ≥0.1mm				0.12mm	
		thickness on Cuff ≥0.1mm		0.12mm			
5	Water tightness	Introduce 1000 cm³ ± 50 cm³ of water at a maximum temperature of 36 °C,check leak		I AQL1.5	200pcs	3 pcs is leaky	Ac
6	Tensile Strength before accelerated ageing	the tore minimum is 24MPa		S-2 AQL4.0	13pcs	the tore minimum is 26.2MPa	Ac
7	elongation before accelerated ageing	elongation of minimum value is 750%				elongation of minimum value is 841%	Ac
8	Tensile Strength after accelerated ageing	the tore minimum is 18MPa		S-2 AQL4.0	13pcs	the tore minimum is 19.7MPa	Ac
9	Elongation after accelerated ageing	elongation of minimum value is 560%				elongation of minimum value is 667%	Ac
10	Protein content	≤200 μg /dm²				138.2g /dm²	Ac
11	Powder content	≤2mg/pc				1.34mg/pc	Ac
12	Packing	Sealed		I AQL1.5	200pcs	100% sealed	Ac
13	Sterile	Final goods must be sterile				steriled	Ac
Conclusion		The product conforms to the requirements of ASTM D3577 and customer's request					
		Date: 2023.5.9 检验专用章					

Date: 2023.5.9

Inspector: Wang yue

Reviewed by: Wu chuan hua



Test Report

Name		POWDER FREE STERILE SURGICAL GLOVES										
Standard		ASTM D3577		Sampling procedures		ISO2859-1:1999						
Size		7.5"		Finished classified		Powder Free, Textured		Lot		2023-01		
Hand Forms		curved fingers		Quantity		230000		C.No.		MEDS-0027PF		
No.	inspection item		Standard Requirements		Inspection Level & AQL		Sample quantity		Inspection Result		Ac/Re	
1	visual inspections		Gloves should be clean and no stains,single pouch should be sealed and clean		I AQL1.5		315pcs		Meet request		Ac	
2	Length		Min length 265mm		S-2 4.0		13pcs		Length : 280mm		Ac	
3	Width		Width 95±6mm						Width:95mm		Ac	
4	Thickness (Single ply)		thickness on Finger ≥0.1mm						0.14mm		Ac	
			thickness on Palm ≥0.1mm						0.13mm			
			thickness on Cuff ≥0.1mm		0.12mm							
5	Watertightness		Introduce 1000 cm ³ ± 50 cm ³ of water at a maximum temperature of 36 °C,check leak		I AQL1.5		315pcs		5 pcs is leaky		Ac	
6	Tensile Strength before accelerated ageing		the tore minimum is 24MPa		S-2 AQL4.0		13pcs		the tore minimum is 25.9MPa		Ac	
7	elongation before accelerated ageing		elongation of minimum value is 750%						elongation of minimum value is 811%		Ac	
8	Tensile Strength after accelerated ageing		the tore minimum is 18MPa		S-2 AQL4.0		13pcs		the tore minimum is 19.3MPa		Ac	
9	Elongation after accelerated ageing		elongation of minimum value is 560%						elongation of minimum value is 623%		Ac	
10	Protein content		≤200 μg /dm ²						136.3 μg /dm ²		Ac	
11	Powder content		≤2mg/pc						1.34mg/pc		Ac	
12	Packing		Sealed		I AQL1.5		315pcs		100% sealed		Ac	
13	Sterile		Final goods must be sterile						steriled		Ac	
Conclusion			The product conforms to the requirements of ASTM D3577 and customer's request									
			Date: 2023.5.9									

Inspector: Wang yue

Reviewed by: Wu chuan hua



Test Report

Name		POWDER FREE STERILE SURGICAL GLOVES						
Standard		ASTM D3577		Sampling procedures		ISO2859-1:1999		
Size		8"		Finished classified	Powder Free, Textured	Lot	2023-01	
Hand Forms		curved fingers		Quantity	80000	C.No.	MEDS-0027PF	
No.	inspection item		Standard Requirements		Inspection Level & AQL	Sample quantity	Inspection Result	Ac/Re
1	visual inspections		Gloves should be clean and no stains,single pouch should be sealed and clean		I AQL1.5	200pcs	Meet request	Ac
2	Length		Min length 265mm		S-2 4.0	13pcs	Length :278mm	Ac
3	Width		Width 102±6mm				Width:102mm	Ac
4	Thickness (Single ply)	thickness on Finger ≥0.1mm		0.13mm			Ac	
		thickness on Palm ≥0.1mm		0.12mm				
		thickness on Cuff ≥0.1mm		0.11mm				
5	Watertightness		Introduce 1000 cm ³ ± 50 cm ³ of water at a maximum temperature of 36 °C,check leak		I AQL1.5	200pcs	3 pcs is leaky	Ac
6	Tensile Strength before accelerated ageing		the tore minimum is 24MPa		S-2 AQL4.0	13pcs	the tore minimum is 24.8MPa	Ac
7	elongation before accelerated ageing		elongation of minimum value is 750%				elongation of minimum value is 811%	Ac
8	Tensile Strength after accelerated ageing		the tore minimum is 18MPa		S-2 AQL4.0	13pcs	the tore minimum is 19.3MPa	Ac
9	Elongation after accelerated ageing		elongation of minimum value is 560%				elongation of minimum value is 672%	Ac
10	Protein content		≤200 μ g /dm ²				142.2 μ g /dm ²	Ac
11	Powder content		≤2mg/pc				1.41mg/pc	Ac
12	Packing		Sealed		I AQL1.5	200pcs	100% sealed	Ac
13	Sterile		Final goods must be sterile				sterile	Ac
Conclusion			The product conforms to the requirements of ASTM D3577 and customer's request					
			Date: 2023.5.9					

Inspector: Wang yue

Reviewed by: Wu chuan hua



Test Report

Name		POWDER FREE STERILE SURGICAL GLOVES						
Standard		ASTM D3577		Sampling procedures		ISO2859-1:1999		
Size		8.5"	Finished classified	Powder Free, Textured	Lot	2023-01		
Hand Forms		curved fingers	Quantity	40000	C.No.	MEDS-0027PF		
No.	inspection item		Standard Requirements	Inspection Level & AQL	Sample quantity	Inspection Result	Ac/Re	
1	visual inspections		Gloves should be clean and no stains,single pouch should be sealed and clean	I AQL1.5	200pcs	Meet request	Ac	
2	Length		Min length 265mm	S-2 4.0	13pcs	Length :285mm	Ac	
3	Width		Width 108±6mm			Width:108mm	Ac	
4	Thickness (Single ply)		thickness on Finger ≥0.1mm			0.13mm	Ac	
			thickness on Palm ≥0.1mm			0.12mm		
			thickness on Cuff ≥0.1mm	0.11mm				
5	Watertightness		Introduce 1000 cm ³ ± 50 cm ³ of water at a maximum temperature of 36 °C,check leak	I AQL1.5	200pcs	3 pcs is leaky	Ac	
6	Tensile Strength before accelerated ageing		the tore minimum is 24MPa	S-2 AQL4.0	13pcs	the tore minimum is 24.4MPa	Ac	
7	elongation before accelerated ageing		elongation of minimum value is 750%			elongation of minimum value is 822%	Ac	
8	Tensile Strength after accelerated ageing		the tore minimum is 18MPa	S-2 AQL4.0	13pcs	the tore minimum is 18.6MPa	Ac	
9	Elongation after accelerated ageing		elongation of minimum value is 560%			elongation of minimum value is 633%	Ac	
10	Protein content		≤200 μ g /dm ²				146.9 μ g /dm ²	Ac
11	Powder content		≤2mg/pc				1.56mg/pc	Ac
12	Packing		Sealed		I AQL1.5	200pcs	100% sealed	Ac
13	Sterile		Final goods must be sterile				sterile	Ac
Conclusion			The product conforms to the requirements of ASTM D3577 and customer's request					
			Date: 2023.5.9					

Inspector: Wang yue

Reviewed by: Wu chuan hua



Test Report

Name		POWDERED STERILE LATEX SURGICAL GLOVES				
Standard		ASTM D3577		Sampling procedures		ISO2859-1:1999
Size	6"	Finished classified	Powder Textured	Lot	00323PW	
Hand Forms	curved fingers	Quantity	100000	C.No.	THS003-23SGPW	
No.	inspection item	Standard Requirements	Inspection Level & AQL	Sample quantity	Inspection Result	Ac/Re
1	visual inspections	Gloves should be clean and no stains, single pouch should be sealed and clean	I AQL1.5	200pcs	Meet request	Ac
2	Length	Min length 260mm	S-2 4.0	13pcs	Length :265	Ac
3	Width	Width 77±5mm			Width:78	Ac
4	Thickness (Single ply)	thickness on Finger ≥0.1mm			0.14	Ac
		thickness on Palm ≥0.1mm			0.13	
		thickness on Cuff ≥0.1mm			0.12	
5	Water tightness	Introduce 1000 cm ³ ± 50 cm ³ of water at a maximum temperature of 36 °C, check leak	I AQL1.5	200pcs	3 pcs is leaky	Ac
6	Tensile Strength before accelerated ageing	the tore minimum is 24MPa	S-2 AQL4.0	13pcs	the tore minimum is 26MPa	Ac
7	elongation before accelerated ageing	elongation of minimum value is 750%			elongation of minimum value is 771%	Ac
8	Tensile Strength after accelerated ageing	the tore minimum is 18MPa	S-2 AQL4.0	13pcs	the tore minimum is 19MPa	Ac
9	Elongation after accelerated ageing	elongation of minimum value is 560%			elongation of minimum value is 581%	Ac
10	Protein content	≤200 μg /dm ²			180	Ac
11	Powder content	≤10mg/dm ²			7.6	Ac
12	Packing	Sealed	I AQL1.5	200pcs	100% sealed	Ac
13	Sterile	Final goods must be sterile			steriled	Ac
Conclusion		The product conforms to the requirements of ASTM D3577 and customer's request Date: 2023.6.2				

Inspector: Wang yue

Reviewed by: Wu chuan hua

Test Report

Name		POWDERED STERILE LATEX SURGICAL GLOVES				
Standard		ASTM D3577		Sampling procedures		ISO2859-1:1999
Size	6.5"	Finished classified	Powder Textured	Lot	00323PW	
Hand Forms	curved fingers	Quantity	104000	C.No.	THS003-23SGPW	
No.	inspection item	Standard Requirements	Inspection Level & AQL	Sample quantity	Inspection Result	Ac/Re
1	visual inspections	Gloves should be clean and no stains, single pouch should be sealed and clean	I AQL1.5	200pcs	Meet request	Ac
2	Length	Min length 260mm	S-2 4.0	13pcs	Length :270	Ac
3	Width	Width 83±6mm			Width:84	Ac
4	Thickness (Single ply)	thickness on Finger ≥0.1mm			0.14	Ac
		thickness on Palm ≥0.1mm			0.13	
		thickness on Cuff ≥0.1mm			0.12	
5	Water tightness	Introduce 1000 cm ³ ± 50 cm ³ of water at a maximum temperature of 36 °C, check leak	I AQL1.5	200pcs	3 pcs is leaky	Ac
6	Tensile Strength before accelerated ageing	the tore minimum is 24MPa	S-2 AQL4.0	13pcs	the tore minimum is 26MPa	Ac
7	elongation before accelerated ageing	elongation of minimum value is 750%			elongation of minimum value is 774%	Ac
8	Tensile Strength after accelerated ageing	the tore minimum is 18MPa	S-2 AQL4.0	13pcs	the tore minimum is 19MPa	Ac
9	Elongation after accelerated ageing	elongation of minimum value is 560%			elongation of minimum value is 581%	Ac
10	Protein content	≤200 μg /dm ²			180	Ac
11	Powder content	≤10mg/dm ²			7.6	Ac
12	Packing	Sealed	I AQL1.5	200pcs	100% sealed	Ac
13	Sterile	Final goods must be sterile			steriled	Ac
Conclusion		The product conforms to the requirements of ASTM D3577 and customer's request Date: 2023.6.2				

Inspector: Wang yue

Reviewed by: Wu chuan hua

Test Report

Name		POWDERED STERILE LATEX SURGICAL GLOVES				
Standard		ASTM D3577-09	Sampling procedures		ISO2859-1:1999	
Size		7"	Finished classified	Powder , Textured	Lot	00323PW
Hand Forms		curved fingers	Quantity	156000	C.No.	THS003-23SGPW
No.	inspection item	Standard Requirements	Inspection Level & AQL	Sample quantity	Inspection Result	Ac/Re
1	visual inspections	Gloves should be clean and no stains, single pouch should be sealed and clean	I AQL1.5	315pcs	Meet request	Ac
2	Length	Min length 265mm	S-2 4.0	13pcs	Length :275	Ac
3	Width	Width 89±6mm			Width:89	Ac
4	Thickness (Single ply)	thickness on Finger ≥0.1mm			0.13	Ac
		thickness on Palm ≥0.1mm			0.13	
		thickness on Cuff ≥0.1mm			0.12	
5	Water tightness	Introduce 1000 cm ³ ± 50 cm ³ of water at a maximum temperature of 36 °C, check leak	I AQL1.5	315pcs	5 pcs is leaky	Ac
6	Tensile Strength before accelerated ageing	the tore minimum is 24MPa	S-2 AQL4.0	13pcs	the tore minimum is 25MPa	Ac
7	elongation before accelerated ageing	elongation of minimum value is 750%			elongation of minimum value is 772%	Ac
8	Tensile Strength after accelerated ageing	the tore minimum is 18MPa	S-2 AQL4.0	13pcs	the tore minimum is 20MPa	Ac
9	Elongation after accelerated ageing	elongation of minimum value is 560%			elongation of minimum value is 587%	Ac
10	Protein content	≤200 μg /dm ²			165	Ac
11	Powder content	≤10mg/dm ²			6.9	Ac
12	Packing	Sealed	I AQL1.5	315pcs	100% sealed	Ac
13	Sterile	Final goods must be sterile			steriled	Ac
Conclusion		The product conforms to the requirements of ASTM D3577 and customer's request Date: 2023.6.2				

Inspector: Wang yue

Reviewed by: Wu chuan hua

Test Report

Name		POWDERED STERILE LATEX SURGICAL GLOVES						
Standard		ASTM D3577-09		Sampling procedures		ISO2859-1:1999		
Size		7.5"		Finished classified	Powder , Textured	Lot	00323PW	
Hand Forms		curved fingers		Quantity	223500	C.No.	THS003-23SGPW	
No.	inspection item		Standard Requirements		Inspection Level & AQL	Sample quantity	Inspection Result	Ac/Re
1	visual inspections		Gloves should be clean and no stains,single pouch should be sealed and clean		I AQL1.5	315pcs	Meet reques	Ac
2	Length		Min length 265mm		S-2 4.0	13pcs	Length :273	Ac
3	Width		Width 95±6mm				Width: 96	Ac
4	Thickness (Single ply)		thickness on Finger ≥0.1mm				0.14	Ac
			thickness on Palm ≥0.1mm				0.13	
			thickness on Cuff ≥0.1mm		0.12			
5	Watertightness		Introduce 1000 cm3 ± 50 cm3 of water at a maximum temperature of 36 °C,check leak		I AQL1.5	315pcs	5 pcs is leaky	Ac
6	Tensile Strength before accelerated ageing		the tore minimum is 24MPa		S-2 AQL4.0	13pcs	the tore minimum is 25MPa	Ac
7	elongation before accelerated ageing		elongation of minimum value is 750%				elongation of minimum value is 794%	Ac
8	Tensile Strength after accelerated ageing		the tore minimum is 18MPa		S-2 AQL4.0	13pcs	the tore minimum is 19MPa	Ac
9	Elongation after accelerated ageing		elongation of minimum value is 560%				elongation of minimum value is 612%	Ac
10	Protein content		≤200 μ g /dm²				183	Ac
11	Powder content		≤10mg/dm²				7.7	Ac
12	Packing		Sealed		I AQL1.5	315pcs	100% sealed	Ac
13	Sterile		Final goods must be sterile				steriled	Ac
Conclusion			The product conforms to the requirements of ASTM D3577 and customer's request					
			Date: 2023.6.2					

Inspector: Wang yue

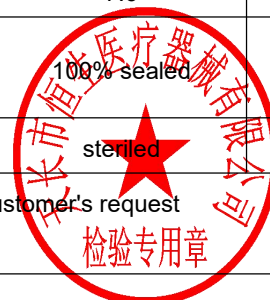
Reviewed by: Wu chuan hua

Test Report

Name		POWDERED STERILE LATEX SURGICAL GLOVES						
Standard		ASTM D3577-09		Sampling procedures		ISO2859-1:1999		
Size		8"		Finished classified	Powder Textured	Lot	00323PW	
Hand Forms		curved fingers		Quantity	26000	C.No.	THS003-23SGPW	
No.	inspection item		Standard Requirements		Inspection Level & AQL	Sample quantity	Inspection Result	Ac/Re
1	visual inspections		Gloves should be clean and no stains,single pouch should be sealed and clean		I AQL1.5	125pcs	Meet request	Ac
2	Length		Min length 265mm		S-2 4.0	13pcs	Length :280	Ac
3	Width		Width 102±6mm				Width:103	Ac
4	Thickness (Single ply)		thickness on Finger ≥0.1mm				0.12	Ac
			thickness on Palm ≥0.1mm				0.12	
			thickness on Cuff ≥0.1mm		0.12			
5	Watertightness		Introduce 1000 cm3 ± 50 cm3 of water at a maximum temperature of 36 °C,check leak		I AQL1.5	125pcs	2 pcs is leaky	Ac
6	Tensile Strength before accelerated ageing		the tore minimum is 24MPa		S-2 AQL4.0	13pcs	the tore minimum is 25MPa	Ac
7	elongation before accelerated ageing		elongation of minimum value is 750%				elongation of minimum value is 760%	Ac
8	Tensile Strength after accelerated ageing		the tore minimum is 18MPa		S-2 AQL4.0	13pcs	the tore minimum is 20MPa	Ac
9	Elongation after accelerated ageing		elongation of minimum value is 560%				elongation of minimum value is 587%	Ac
10	Protein content		≤200 μg /dm²				156	Ac
11	Powder content		≤10mg/dm²				7.6	Ac
12	Packing		Sealed		I AQL1.5	125pcs	100% sealed	Ac
13	Sterile		Final goods must be sterile				steriled	Ac
Conclusion			The product conforms to the requirements of ASTM D3577 and customer's request					
			Date: 2023.6.2					

Inspector: Wang yue

Reviewed by: Wu chuan hua



Test Report

Name		POWDERED STERILE LATEX SURGICAL GLOVES						
Standard		ASTM D3577-09		Sampling procedures		ISO2859-1:1999		
Size		8.5"		Finished classified	Powder Textured	Lot	00323PW	
Hand Forms		curved fingers		Quantity	10500	C.No.	THS003-23SGPW	
No.	inspection item		Standard Requirements		Inspection Level & AQL	Sample quantity	Inspection Result	Ac/Re
1	visual inspections		Gloves should be clean and no stains,single pouch should be sealed and clean		I AQL1.5	125pcs	Meet request	Ac
2	Length		Min length 280mm		S-2 4.0	13pcs	Length :285	Ac
3	Width		Width 108±6mm				Width:108	Ac
4	Thickness (Single ply)		thickness on Finger ≥0.1mm				0.12	Ac
			thickness on Palm ≥0.1mm				0.13	
			thickness on Cuff ≥0.1mm				0.12	
5	Watertightness		Introduce 1000 cm3 ± 50 cm3 of water at a maximum temperature of 36 °C,check leak		I AQL1.5	125pcs	1 pcs is leaky	Ac
6	Tensile Strength before accelerated ageing		the tore minimum is 24MPa		S-2 AQL4.0	13pcs	the tore minimum is 25MPa	Ac
7	elongation before accelerated ageing		elongation of minimum value is 750%				elongation of minimum value is 760%	Ac
8	Tensile Strength after accelerated ageing		the tore minimum is 18MPa		S-2 AQL4.0	13pcs	the tore minimum is 20MPa	Ac
9	Elongation after accelerated ageing		elongation of minimum value is 560%				elongation of minimum value is 587%	Ac
10	Protein content		≤200 μ g /dm²				156	Ac
11	Powder content		≤10mg/dm²				7.6	Ac
12	Packing		Sealed		I AQL1.5	125pcs	100% sealed	Ac
13	Sterile		Final goods must be sterile				steriled	Ac
Conclusion			The product conforms to the requirements of ASTM D3577 and customer's request					
			Date: 2023.6.2					

Inspector: Wang yue

Reviewed by: Wu chuan hua

