	Brief Introduction	Prepared by	Wong futing	
Dispos	able Latex Surgical Glo	Checked by	Tao Zhong hum,	
Doc. No.	HS/CE01-0	2	Approved by	Zhang xino shang
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

	Brief Introduction	Prepared by	Wond JuTing	
Dispos	able Latex Surgical Gl	Checked by	Tao Zhong hum,	
Doc. No.	HS/CE01-0	2	Approved by	Zhang xino shang
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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	$83 \pm 5$	$7.5g \pm 0.3g$
7.0	≥275	89±5	$8.0g \pm 0.3g$
7.5	≥275	95±5	$8.5g \pm 0.3g$
8.0	≥275	$102 \pm 6$	$9.0g \pm 0.3g$
8.5	≥285	108±6	$9.5g \pm 0.3g$

#### 2.2Thickness(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 Ilb,
- 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 Ilb.

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

	Brief Introduction	Prepared by	Wond JuTing	
Dispos	able Latex Surgical Gl	Checked by	Tao Zhong hum,	
Doc. No.	HS/CE01-0	2	Approved by	Zhang xino shang
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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





TIANCHANG HENGSHENG MEDICAL DEVICES CO., LTD. add: qinlan industrial park, tianchang city, anhui province, China. tel:+86-550-7811946 fax: +86-550-7816946

**Test Report** 

Nam	ne	POWDER	R FREE ST	ΓERI	LE SURG	ilC	AL GLOV	ES				
Sta	ndard	ASTM D35	577		Sampling	g p	rocedures				ISO2859-1:19	99
Size		6"			shed sified		owder Free, extured	,	Lot		2023-01	
Han	d Forms	curved fir	ngers	Qua	intity	2	0000		C.No		MEDS-0027P	F
No.	inspect	tion item	Standard Requirements			Inspection Level & AQL		Sample Ins		pection Result	Ac/Re	
1	visual in	spections	Gloves should be clean and no stains, single pouch should be sealed and clean				I AQL1.5	1:	25pcs	Meet	request	Ac
2	Lei	ngth	Min length	260m	m					Leng	th :266mm	Ac
3	W	idth	Width77±5m	nm						Widtl	n:77mm	Ac
			thickness or	n Finge	er ≥0.1mm		S-2	1	3pcs	0.141	mm	
4	Thickness (Single ply)		thickness or	n Palm	≥0.1mm		4.0			0.131	mm	Ac
			thickness on Cuff ≥0.1mm							0.121	mm	
5	Water t	iightness	water at	t a	000 cm³± 50 cm³ of a maximum of 36 °C,check leak		I AQL1.5	1:	25pcs	2	pcs is leaky	Ac
6		ength before ted ageing	the tore min	imum is 24MPa		S-2			the t	ore minimum is 25.4MPa	Ac	
7	_	on before ted ageing	elongation	of mini 750%	mum value i	s	AQL4.0	13pcs			elongation of nimum value is 820%	Ac
8		rength after ted ageing	the tore min	imum i	is 18MPa		S-2			the t	ore minimum is 19.2MPa	Ac
9		gation erated ageing	elongation	of mini 560%	mum value i	S	AQL4.0	1	3pcs		elongation of nimum value is 691%	Ac
10	Protein	content	≤2	200 µ g	/dm²					12	24.2 µ g /dm²	Ac
11	Powde	r content	:	≤2mg/	/рс						1.38mg/pc	Ac
12	Pad	cking	Sealed				I AQL1.5		1	00% sealed	Ac	
13	Ste	erile	Final goo	ds mu	st be sterile						steriled The	Ac
	Conclusion	The	product confo	orms to	the requirer	mei	nts of ASTM D			custome	request	順公母





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**Test Report** 

Nam	ne .	POWDER	R FREE ST	ΓERII	LE SURG	IC	AL GLOV	ES	3			
Sta	ndard	ASTM D35	577		Sampling	j p	rocedures				ISO2859-1:19	99
Size	ı	6.5"			shed sified		owder Free, extured	,	Lot		2023-01	
Han	d Forms	curved fir	ngers	Qua	intity		15000		C.No		MEDS-0027P	F
No.	inspect	tion item	Standard Requirements			Inspection Level & AQL		Sample Ins		pection Result	Ac/Re	
1	visual in	spections	Gloves should be clean and no stains, single pouch should be sealed and clean			I AQL1.5	1	25pcs	Meet	request	Ac	
2	Lei	ngth	Min length	260m	m					Leng	th :269mm	Ac
3	W	idth	Width 83±6r	mm						Widt	h:83mm	Ac
			thickness or	n Finge	er ≥0.1mm		S-2		13pcs	0.14	mm	
4	Thickness 4		thickness or	n Palm	≥0.1mm		4.0			0.13	mm	Ac
	(Sing	thickness on Cuff ≥0.1mm							0.12	mm		
5	Water t	iightness	water at	t a	000 cm³± 50 cm³ of a maximum of 36 °C,check leak		I AQL1.5	1	25pcs	2	pcs is leaky	Ac
6		ength before ted ageing	the tore min	imum is 24MPa		S-2			the t	ore minimum is 25.6MPa	Ac	
7	_	on before ted ageing	elongation	of mini 750%	mum value i	S	AQL4.0	•	13pcs		elongation of nimum value is 825%	Ac
8		rength after ted ageing	the tore min	imum i	is 18MPa		S-2			the t	ore minimum is 19.1MPa	Ac
9		gation erated ageing	elongation	of mini 560%	mum value i	S	AQL4.0	•	13pcs		elongation of nimum value is 693%	Ac
10	Protein	content	≤2	200 µ g	/dm²					12	24.1 µ g /dm²	Ac
11	Powde	r content	:	≤2mg/	/рс						1.36mg/pc	Ac
12	Pad	cking		ed		I 125pcs		1	00% sealed	Ac		
13	Ste	erile	Final goo	ds mu	st be sterile						steriled The A	Ac
	Conclusion	The	product confo	orms to	the requirer	nei	nts of ASTM D			custom	request	順公母





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# **Test Report**

Nam	ne	POWDER	R FREE ST	ΓERI	LE SURG	ICAL GLO	۷E	S			
Sta	ndard	ASTM D35	577		Sampling	procedures	•			ISO2859-1:199	99
Size	1	7"			ished ssified	Powder Free Textured	е,	Lot		2023-01	
Han	d Forms	curved fir	curved fingers		antity	60000	0 0			MEDS-0027PF	
No.	inspect	ion item	Standar	d Req	uirements	Inspection Level & AQL		Sample quantity	Ins	Inspection Result	
1	visual in	spections		pou	clean and no			200pcs	Meet	request	Ac
2	Lei	ngth	Min length 265mm						Leng	th :275mm	Ac
3	W	idth	Width 89±6r	nm					Width	n:89mm	Ac
	Thickness		thickness or	Finge	er ≥0.1mm	S-2		13pcs	0.14r	nm	
4			thickness on Palm ≥0.1mm			4.0			0.12mm		Ac
	(Sing	(Single ply)		thickness on Cuff ≥0.1mm					0.12r	nm	1
5	Water t	ightness	а	m³ ± 50 cm³ c maximur °C,check leal	n   1		200pcs	3 pcs is leaky		Ac	
6		ength before ed ageing	the tore mini	imum	is 24MPa	S-2			the tore minimum is 26.2MPa		Ac
7	_	on before ted ageing	elongation of minimum value is 750%		10140		13pcs	elongation of minimum value is 841%		Ac	
8		rength after ted ageing	the tore mini	imum is 18MPa		S-2			the tore minimum is 19.7MPa		Ac
9		gation rated ageing	elongation o	of min 560%	imum value is %	10140		13pcs	elongation of minimum value is 667%		Ac
10	Protein	content	≤2	00 μ g	ı /dm²				1	38.2g /dm²	Ac
11	Powde	content		≤2mg	/pc					1.34mg/pc	Ac
12	Pad	cking		Seale	ed	I AQL1.5		200pcs	1	00% sealed	Ac
13	Ste	erile	Final goo	ds mu	st be sterile				4	Steriled	₩ Ac
	Conclusion		product confo	orms t	o the requirer	nents of ASTM  Date: 20				rs request 检验专用章	THE STATE OF THE S





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# **Test Report**

Nam	те	POWD	ER FREE ST	ΓERI	LE SURG	ICA	L GLOV	ΈS	3			
Sta	ndard	ASTM D	3577		Sampling	pro	cedures				ISO2859-1:19	99
Size	•	7.5"			shed ssified		wder Free tured	,	Lot		2023-01	
Han	d Forms	curved	fingers	Qua	Quantity 2		230000		C.No		MEDS-0027	PF
No.	inspect	ion item	Standard	d Req	uirements	lı	nspection Level & AQL		Sample uantity	l Ins	pection Result	Ac/Re
1	visual in:	spections	stains,single	Gloves should be clean and no stains, single pouch should be sealed and clean					315pcs	Meet	Ac	
2	Ler	ngth	Min length	265m	m					Leng	th : 280mm	Ac
3	Wi	dth	Width 95±6m	nm						Widtl	n:95mm	Ac
	Thickness 4 (Single ply)		thickness on	Finge	er ≥0.1mm		5-2		13pcs	0.14r	nm	
4			thickness on	thickness on Palm ≥0.1mm			.0			0.13r	nm	Ac
			thickness on	thickness on Cuff ≥0.1mm						0.12r	nm	
5	Waterti	atertightness water a			n ³± 50 cm³c maximur °C,check leal	n   '	QL1.5	3	315pcs	5	pcs is leaky	Ac
6	Tensile Stre	ength before	e the tore mini	the tore minimum is 24MPa			S-2			the t	ore minimum is 25.9MPa	Ac
7	1	on before ed ageing	elongation o	of mini 750%	mum value is	١,	AQL4.0		13pcs		longation of imum value is 811%	Ac
8		ength after ed ageing	the tore mini	mum i	s 18MPa	S	i-2			the t	ore minimum is 19.3MPa	Ac
9	Elono after accele	gation rated agein		of mini 560%	mum value is	١,	AQL4.0		13pcs		longation of iimum value is 623%	Ac
10	Protein	content	≤20	00 μ g	/dm²					13	36.3 μ g /dm²	Ac
11	Powder	content	<u> </u>	≤2mg/	/pc						1.34mg/pc	Ac
12	Pac	king		Seale	Sealed		QL1.5	3	315pcs 100%		sealed	Ac
13	Ste	erile	Final goods must be sterile								steriled The	Ac
	Conclusion	Т	The product confo	orms to	o the requirer			)35 )23.		custom	request +	<b>順公</b>





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**Test Report** 

Nam	Name POWDER FREE STERILE SURGICAL GLOVES											
Sta	ndard	ASTM D	3577	Sampling	gp	rocedures				ISO2859-1:199	99	
Size		8"		Finished classified		Powder Free, extured		Lot		2023-01		
Han	d Forms	curved f	ingers	Quantity	8	0000	C.No.			MEDS-00271	PF	
No.	inspect	ion item	Standar	Standard Requirements				Sample Ins		pection Result	Ac/Re	
1	visual in	spections	stains,single	Gloves should be clean and no stains, single pouch should be sealed and clean			20	00pcs	Meet	request	Ac	
2	Lei	ngth	Min length	265mm					Leng	th :278mm	Ac	
3	W	idth	Width 102±6	Smm					Width	n:102mm	Ac	
			thickness or	Finger ≥0.1mm		S-2 4.0	1	3pcs	0.13r	nm		
4			thickness or	thickness on Palm ≥0.1mm					0.12r	nm	Ac	
	(Single ply)			thickness on Cuff ≥0.1mm					0.11mm			
5	Waterti	ghtness	000 cm <sup>3</sup> ± 50 cm <sup>3</sup> a maximu of 36 °C,check lea	I AQL1.5	20	00pcs	3 pcs is leaky		Ac			
6		ength before ted ageing	the tore mini	tore minimum is 24MPa ongation of minimum value is 750%		S-2			the t	ore minimum is 24.8MPa	Ac	
7	_	on before ted ageing	elongation			AQL4.0	13pcs		elongation of minimum value is 811%		Ac	
8		rength after ted ageing	the tore min	mum is 18MPa		S-2			the t	ore minimum is 19.3MPa	Ac	
9		gation rated ageing		of minimum value i 560%	s	AQL4.0	1	3pcs		longation of imum value is 672%	Ac	
10	Protein	content	≪2	00 µ g /dm²					14	l2.2 μ g /dm²	Ac	
11	Powde	content	\$	≤2mg/pc						1.41mg/pc	Ac	
12	Pad	cking		Sealed		I AQL1.5	200pcs		1	00% sealed	Ac	
13	Ste	erile	Final goo	Final goods must be sterile						steriled The	Ac	
	Conclusion	TI	ne product confo	orms to the require	me	nts of ASTM D			ustome	request	過公司	





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**Test Report** 

Nam	ne	POW	DER FREE ST	ΓERI	LE SURG	ÎC/	AL GLOV	ES	S				
Sta	ndard	ASTM	D3577		Sampling	g pr	ocedures					ISO2859-1:1999	
Size	ı	8.5"		Finished classified			owder Free, extured	,	Lot			2023-01	
Han	d Forms	curve	d fingers	Quantity 4			0000		C.No.			MEDS-0027PF	
No.	inspect	ion item	Standar	Standard Requirements					Sample Ins quantity			ection Result	Ac/Re
1 visual inspections				pou	clean and no	e	I AQL1.5	2	200pcs	s Me	et	request	Ac
2	Ler	ngth	Min length	265m	m					Ler	ngt	h :285mm	Ac
3	Wi	dth	Width 108±6	mm						Width		:108mm	Ac
			thickness on	Finge	er ≥0.1mm		S-2 4.0		13pcs	0.1	0.13mm		
4		kness	thickness on	thickness on Palm ≥0.1mm					0.12n		2n	ım	Ac
	(Sing	le ply)	thickness on	thickness on Cuff ≥0.1mm						0.1	1m	ım	
5	Waterti	ghtness	water at a ma	Introduce 1000 cm water at a maximum of 36 °C,check leak			I AQL1.5		200pcs	5	3	pcs is leaky	Ac
6	Tensile Stre	-	the fore mini	the tore minimum is 24MPa			S-2 AQL4.0			the	the tore minimum is 24.4MPa		Ac
7	elongatio accelerat	on before ed ageinç		elongation of minimum value is 750%					13pcs		elongation of minimum value is 822%		Ac
8	Tensile Str accelerat	-	the fore mini	mum i	is 18MPa		S-2 AQL4.0			pcs e		ore minimum is 18.6MPa	Ac
9	after acc	gation celerated eing	elongation o	of min	imum value is %				13pcs			ongation of mum value is 633%	Ac
10	Protein	content	≤2	≤200 µ g /dm²							14	6.9 µ g /dm²	Ac
11	Powder	content	<u> </u>	≤2mg/pc								1.56mg/pc	Ac
12	Pac	king		Sealed			I AQL1.5	2	200pcs	3	10	00% sealed	Ac
13	Ste	erile	Final good	ds mu	st be sterile							steriled了器分	Ac
	Conclusion	ı	The product confo	orms t	o the requirer	ment	ts of ASTM D			d custor	闸	's request	眼公





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**Test Report** 

Nam	ne	POWD	ERED STER	RILE	LATEX SU	_		0	VES			
Sta	ndard	ASTM D	3577		Sampling	g p	rocedures				ISO2859-1:19	99
Size	•	6"			ished ssified		owder extured		Lot		00323PW	
Han	d Forms	curved	fingers	Quantity 10		00000		C.No.		THS003-23SGPW		
No.	No. inspection item		Standar	Standard Requirements					Sample quantity	Ins	pection Result	Ac/Re
1	visual in	spections		pou	clean and r ch should b		I AQL1.5	2	200pcs	Meet	Ac	
2	Lei	ngth	Min length	260m	nm					Leng	th :265	Ac
3	W	idth	Width 77±5n	mm						Widtl	า:78	Ac
			thickness on	n Fing	er ≥0.1mm		S-2		13pcs	0.14		
4		kness	thickness on	thickness on Palm ≥0.1mm			4.0			0.13		Ac
	(Sing	le ply)	thickness on	thickness on Cuff ≥0.1mm						0.12		
5	Untroduce water			ce 1000 cm3 ± 50 cm3 of at a maximum rature of 36 °C,check leak			I AQL1.5	2	200pcs	3	pcs is leaky	Ac
6	Tensile Stre	ength befor ted ageing	the tore mini	the tore minimum is 24MPa			S-2			the tore minimum is 26MPa		Ac
7		on before ted ageing	elongation	elongation of minimum value is 750%			AQL4.0		13pcs	elongation of minimum value is 771%		Ac
8		rength afte	r the tore mini	imum	is 18MPa		S-2			the tore minimum is		Ac
9	Elon	gation erated ageir		n of minimum value is 560%			AQL4.0		13pcs		longation of imum value is 581%	Ac
10	Protein	content	≤2	200 ր 6	g /dm²						180	Ac
11	Powde	r content	<	10mg	ı/dm²						7.6	Ac
12	Pad	Packing			ed	I AQL1.5	2	200pcs	100% Sealed		Ac	
13	Ste	erile	Final goo	ods must be sterile					#	steriled	Ac	
	Conclusion	1	The product confo	orms t	o the requirer	ner	nts of ASTM Date: 20			ustome	r's request 检验专用章	





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**Test Report** 

Nam	10	DO\\\/	DERED STE	DII E	I ATEY SI			$\overline{}$	VES				
	ndard		DEKED 316 D3577	INILE			rocedures	ISO2859-1:199	ISO2850_1·1000				
Size		6.5"			nished essified	P	owder extured		Lot	00323PW			
Han	d Forms	curve	d fingers	Qu	Quantity 1		104000		C.No.		THS003-23S0	GPW	
No.	inspect	Stan	Standard Requirements			Inspection Level & AQL		Sample quantity	Inspection Result		Ac/Re		
1	visual in	spections		gle pou	e clean and n uch should b		I AQL1.5	2	200pcs	Opcs Meet request			
2	Lei	ngth	Min lengt	h 260r	mm					Leng	th :270	Ac	
3	W	idth	Width 83:	±6mm						Width	า:84	Ac	
			thickness	on Fing	ger ≥0.1mm		S-2		13pcs	0.14			
4		kness	thickness	thickness on Palm ≥0.1mm			4.0			0.13		Ac	
	(Sing	le ply)	thickness	thickness on Cuff ≥0.1mm						0.12			
5	Water t	Water tightness water a			m3 ± 50 cm3 o a maximul 6 °C,check lea	I AQL1.5	2	200pcs	3 pcs is leaky		Ac		
6	Tensile Stre	-	the tore n	the tore minimum is 24MPa			S-2			the tore minimum is 26MPa		Ac	
7	elongati accelerat	on before	1	elongation of minimum value is 750%			AQL4.0		13pcs	elongation of minimum value is 774%		Ac	
8	Tensile St	-	the tore n	ninimum	n is 18MPa		S-2			the tore minimum is		Ac	
9	Elon	gation rated age	_	on of mi	nimum value is	S	AQL4.0		13pcs	elongation of minimum value is 581%		Ac	
10	Protein	content	:	≤200 μ	g /dm²						180	Ac	
11	Powde	rcontent		≤10mg	g/dm²						7.6	Ac	
12	Pad	Packing			Sealed I AQL			2	200pcs	1	000 sealed	Ac	
13	Ste	erile	Final g	oods m	ust be sterile					出と	steriled	Ac	
	Conclusion	l	The product co	nforms	to the requirer	nei	nts of ASTM Date: 20			ustome	tr's request 检验专用章		





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# **Test Report**

Nam	16	POWE	POWDERED STERILE LATEX SURGICAL GLOVES												
Sta	ndard	ASTM	D3577-09	Samp	oling <sub> </sub>	procedures			ISO2859-1:19	99					
Size		7"		Finished classified		Powder , Textured	Lot		00323PW						
Han	d Forms	curve	d fingers	Quantity		156000	C.No.		THS003-23S	23SGPW					
No.	No. inspection item		Standar	Standard Requirements			Sample quantity	Ins	pection Result	Ac/Re					
1	visual in	spections		uld be clean a pouch shou clean	I AQL1.5	315pcs	Meet	request	Ac						
2	Lei	ngth	Min length	265mm				Leng	th :275	Ac					
3	W	idth	Width 89±6n	nm				Width	า:89	Ac					
			thickness on	Finger ≥0.1ı	mm	S-2 4.0	13pcs	0.13							
4		kness	thickness on	thickness on Palm ≥0.1mm				0.13		Ac					
	(Sing	le ply)	thickness on	Cuff ≥0.1mr			0.12								
5	Water t	ightness	water at	Introduce 1000 cm3 ± 50 cm3 of water at a maximum temperature of 36 °C,check leak			315pcs	5	pcs is leaky	Ac					
6	Tensile Stre	ength befo ted ageing	the tore mini	the tore minimum is 24MPa				the t	ore minimum is 25MPa	Ac					
7	1	on before ted ageing		elongation of minimum value is 750%			13pcs		longation of imum value is 772%	Ac					
8	Tensile St	rength afto ted ageing	the fore mini	mum is 18MPa	а	S-2		the t	ore minimum is 20MPa	Ac					
9	Elon	gation erated age	"	of minimum va 560%	lue is	AQL4.0	13pcs		longation of iimum value is 587%	Ac					
10	Protein	content	≤2	00 µ g /dm²					165	Ac					
11	Powder	r content		10mg/dm²					6.9	Ac					
12	Pad	cking		Sealed		I AQL1.5	315pcs	1	00% sealed	Ac					
13	Ste	erile	Final goo	ds must be ste	erile			大	steriled	Ac					
	Conclusion	1	The product confo	orms to the rec	quireme	ents of ASTM Date: 20		custom	tr's request 检验专用章						





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# **Test Report**

Nan	ne	POWE	POWDERED STERILE LATEX SURGICAL GLOVES											
Sta	ndard	ASTM [	D3577-09		Sampling	g pro	cedures				ISO2859-1:199	99		
Size	1	7.5"			ished ssified		der , ured		Lot		00323PW			
Han	d Forms	curved	fingers	Quantity 2			500	C.No.		THS003-23S	GPW			
No.	No. inspection item		Standard	Standard Requirements					Sample luantity	Ins	Ac/Re			
1	visual ins	spections	stains,single	Gloves should be clean and no stains, single pouch should be sealed and clean				3	315pcs	Meet	Ac			
2	Ler	ngth	Min length	265m	m					Leng	th :273	Ac		
3	Wi	dth	Width 95±6m	nm						Width	n: 96	Ac		
			thickness on	Finge	er ≥0.1mm	S- - 4.			13pcs	0.14				
4		(ness	thickness on	thickness on Palm ≥0.1mm thickness on Cuff ≥0.1mm						0.13		Ac		
	(Sing	le ply)	thickness on							0.12				
5	Waterti	water at	Introduce 1000 cm3 ± 50 cm3 of water at a maximum temperature of 36 °C,check leak				3	315pcs	5	pcs is leaky	Ac			
6	Tensile Stre	ength befored	the fore mini	the tore minimum is 24MPa			S-2			the t	ore minimum is 25MPa	Ac		
7	_	on before ed ageing	elongation o	elongation of minimum value is 750%					13pcs	elongation of minimum value is 794%		Ac		
8	Tensile Str accelerat	ength afte ed ageing	the tore mini	ninimum is 18MPa			- S-2 AQL4.0			the tore minimum is		Ac		
9	Elonç after accele	gation rated agei		elongation of minimum value is 560%					13pcs		longation of imum value is 612%	Ac		
10	Protein	content	≤20	00 µ g	ı /dm²						183	Ac		
11	Powder	content	<b>\leq</b>	≤10mg/dm²							7.7	Ac		
12	Pac	Packing			Sealed			3	315pcs	11/4	our sealed	Ac		
13	Ste	erile	Final good	ds mu	s must be sterile					世代	steriled	Ac		
	Conclusion	ı	The product confo	orms t	o the requirer	ments	of ASTM [ Date: 20			custome	r's request 检验专用章			





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**Test Report** 

Nam	ne	POWE	ERED STER	RILE	LATEX SU	_		0	VES			
Sta	ndard	ASTM [	D3577-09		Sampling	jр	rocedures				ISO2859-1:199	99
Size	1	8"			ished ssified		owder extured		Lot	00323PW		
Han	d Forms	curved fingers		Quantity 2		2	26000		C.No.		THS003-23S	GPW
No.	No. inspection item		Standar	Standard Requirements			Inspection Level & AQL		Sample luantity	Inspection Result		
1	visual in	spections		pou	clean and n ch should b	- 1	I AQL1.5	,	125pcs Meet request			Ac
2	Lei	ngth	Min length	265m	nm					Leng	th :280	Ac
3	W	idth	Width 102±6	Smm						Width	n:103	Ac
			thickness on	Fing	er ≥0.1mm		S-2		13pcs	0.12		
4		kness	thickness on	thickness on Palm ≥0.1mm			4.0			0.12		Ac
	(Sing	le ply)	thickness on	thickness on Cuff ≥0.1mm						0.12		
5	Waterti	water at	Introduce 1000 cm3 ± 50 cm3 of water at a maximum temperature of 36 °C,check leak			I AQL1.5	,	125pcs	2	Ac		
6	Tensile Stre	ength befo ted ageing	the fore mini	the tore minimum is 24MPa			S-2			the tore minimum is 25MPa		Ac
7	_	on before ted ageing	_	elongation of minimum value is 750%			AQL4.0		13pcs	elongation of minimum value is 760%		Ac
8	Tensile Str	rength afte	the tore mini	imum	is 18MPa		S-2			the tore minimum is 20MPa		Ac
9	Elone	gation rated agei		elongation of minimum value is 560%			AQL4.0		13pcs		longation of imum value is 587%	Ac
10	Protein	content	≪2	00 μ g	J /dm²						156	Ac
11	Powder	content	€	10mg	/dm²						7.6	Ac
12	Pac	cking		Sealed			I AQL1.5	,	125pcs	1000% sealed		Ac
13	Ste	erile	Final good	ds must be sterile					たた	steriled	Ac	
	Conclusion	ı	The product confo	orms t	to the requirer	ner	nts of ASTM Date: 2			ustome	r's request 检验专用章	





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**Test Report** 

Nam	ne	POWE	ERED STER	RILE	LATEX SU	_		0	VES				
Sta	ndard	ASTM [	D3577-09		Sampling	j p	rocedures				ISO2859-1:199	D2859-1:1999	
Size	1	8.5"			ished ssified		owder extured		Lot	00323PW			
Han	d Forms	curved fingers		Quantity 1		1	0500		C.No.		THS003-23S	GPW	
No.	No. inspection item		Standar	Standard Requirements			Inspection Level & AQL		Sample quantity	Inspection Result			
1	visual in	spections		pou	clean and no		I AQL1.5		125pcs Meet request			Ac	
2	Lei	ngth	Min length	280m	nm					Leng	th :285	Ac	
3	W	idth	Width 108±6	3mm						Width	า:108	Ac	
			thickness on	Fing	er ≥0.1mm		S-2		13pcs	0.12			
4		kness	thickness on	thickness on Palm ≥0.1mm			4.0			0.13		Ac	
	(Sing	le ply)	thickness on	thickness on Cuff ≥0.1mm						0.12			
5	Untrodu Watertightness water			Introduce 1000 cm3 ± 50 cm3 of water at a maximum temperature of 36 °C,check leak			I AQL1.5		125pcs	1	Ac		
6	Tensile Stre	ength befo ted ageing	the fore mini	the tore minimum is 24MPa			S-2			the tore minimum is 25MPa		Ac	
7	_	on before ted ageing	_	elongation of minimum value is 750%			AQL4.0		13pcs	elongation of minimum value is 760%		Ac	
8	Tensile Sti accelerat	rength afte	the tore mini	imum	is 18MPa		S-2			the tore minimum is 20MPa		Ac	
9	Elon	gation rated agei		elongation of minimum value is 560%			AQL4.0		13pcs		longation of imum value is 587%	Ac	
10	Protein	content	≤2	00 μ g	ر /dm²						156	Ac	
11	Powder	content	€	10mg	/dm²						7.6	Ac	
12	Pad	cking		Sealed			I AQL1.5		125pcs	1000 sealed		Ac	
13	Ste	erile	Final good	ds must be sterile						走と	steriled	Ac	
	Conclusion	ı	The product confo	orms t	o the requirer	nei	nts of ASTM [ Date: 2			ustome	r's request 检验专用章		