



GUANTE QUIRÚRGICO

NITRILO

**PRODUCTO
IMPORTADO****Descripción:**

Guante de nitrilo, no estéril, ambidiestro, peso : 3.20 +0.2 gramos.

Características:

- Confortable. Ofrece protección frente a riesgos químicos específicos y disolventes en contacto esporádico.
- Presentación : cajón de 10 cajas, y cada caja contiene 50 pares.
- No almacenar los guantes en áreas con temperaturas extremas ni cerca de calentadores, o directamente a la luz solar.

Usos:

- Son perfectos para mantener las manos a salvo de bacterias, virus o sustancias contaminantes y nocivas para la piel al mismo tiempo que proporcionan alta comodidad y precisión.
- Otra de las propiedades de estos guantes es que son impermeables, de ahí su gran uso en industrias, laboratorios químicos, etc.



NAME (Nombre)		SPECIFICATION(Especificación)	TEST
Length(Longitud) Width(Anchura)	Small(S)	240mm(+/-5mm)	240mm(+/-5mm)
	Medium(M)	240mm(+/-5mm)	240mm(+/-5mm)
	Large(L)	240mm(+/-5mm)	240mm(+/-5mm)
Weight(Peso)	Small(S)	3.0g(+/-0.3g)	3.0g(+/-0.3g)
	Medium(M)	3.5g(+/-0.3g)	3.5g(+/-0.3g)
	Large(L)	4.0g(+/-0.3g)	4.0g(+/-0.3g)
Packing(Embalaje)		1,000 units per master box (1,000 unidades por caja master)	1,000 units (1,000 unidades)





FILE NO.QBE-16-01-01

PRODUCTS INSPECTION REPORT BEFORE PACKING

Sep.18.2021

Customer name		Eficiencia Laboral S.A.				Invoice No		ZH2109CB03	
Color/Level		LIGHT BLUE/AQL1.5			Description		Powder Free Gloves		
Size		XS	S		M	L	XL	Total	
Quantity			1,720		4,300	2,580		8,600	
Lot number		20210901							
Production Date		09-2021				Expiration Date		09-2026	
Physical Parameter Inspection (L: S-2 AQL 4.0 AC: 1 RE: 2)									
Size S	Weight (g)	Length(mm)	Width (mm)	Thickness(mm)		Tensile strength(Mpa)		Elongation(%)	
				Palm	Finger	Before aging	After aging	Before aging	After aging
1	3.1	244	85	0.07	0.10	26	28	543	531
2	3.1	241	85	0.07	0.10	25	26	551	533
3	3.2	245	85	0.07	0.10	27	27	576	542
4	3.2	243	85	0.07	0.10	25	28	568	536
5	3.1	242	85	0.07	0.11	25	28	556	531
6	3.0	244	85	0.07	0.11	24	27	560	532
7	3.2	244	85	0.07	0.10	26	29	538	528
8	3.2	245	85	0.07	0.11	26	28	545	524
9	3.1	245	85	0.07	0.10	28	30	551	533
10	3.1	244	85	0.07	0.10	25	27	568	542
11	3.1	241	85	0.07	0.10	25	27	555	531
12	3.1	242	85	0.06	0.11	28	30	561	534
13	3.2	242	85	0.07	0.10	27	30	538	528
Result	3.1	PASS	PASS	PASS	PASS	PASS	PASS	PASS	PASS
Defect Test (L: Multiple sampling inspection AQL: 1.5 AC: 2 RE:9)									
Sampling Frequency	First	Second	Third	Fourth	Fifth	Sixth	Seventh	Total	Result
Sampling No	200							200	PASS
Visual defects	0							0	
Pinhole test	1							1	





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Size		XS	S		M	L	XL	Total	
Quantity			1,720		4,300	2,580		8,600	
Lot number		20210901							
Production Date		09-2021			Expiration Date			09-2026	
Physical Parameter Inspection (L: S-2 AQL 4.0 AC: 1 RE: 2)									
Size M	Weight (g)	Length(mm)	Width (mm)	Thickness(mm)		Tensile strength(Mpa)		Elongation(%)	
				Palm	Finger	Before aging	After aging	Before aging	After aging
1	3.5	244	95	0.07	0.10	25	27	558	532
2	3.5	243	95	0.07	0.10	26	29	564	541
3	3.5	245	95	0.07	0.11	28	31	561	525
4	3.5	245	95	0.07	0.11	27	30	534	511
5	3.5	244	95	0.07	0.10	26	29	563	538
6	3.5	245	95	0.07	0.10	28	30	572	552
7	3.5	243	95	0.07	0.11	25	27	562	544
8	3.5	245	95	0.07	0.10	25	26	560	535
9	3.4	245	95	0.07	0.10	27	29	553	531
10	3.5	244	95	0.07	0.10	28	29	547	528
11	3.5	242	95	0.07	0.10	26	28	556	528
12	3.5	241	95	0.07	0.10	25	28	566	547
13	3.5	245	95	0.06	0.11	27	29	551	530
Result	3.5	PASS	PASS	PASS	PASS	PASS	PASS	PASS	PASS
Defect Test (L: Multiple sampling inspection AQL: 1.5 AC: 2 RE:9)									
Sampling Frequend	First	Second	Third	Fourth	Fifth	Sixth	Seventh	Total	Result
Sampling No	200							200	PASS
Visual defects	0							0	
Pinhole test	1							1	





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Quantity			1,720	4,300	2,580		8,600		
Lot number		20210901							
Production Date		09-2021			Expiration Date		09-2026		
Physical Parameter Inspection (L: S-2 AQL 4.0 AC: 1 RE: 2)									
Size L	Weight (g)	Length(mm)	Width (mm)	Thickness(mm)		Tensile strength(Mpa)		Elongation(%)	
				Palm	Finger	Before aging	After aging	Before aging	After aging
1	3.8	245	105	0.06	0.11	26	28	563	538
2	3.9	244	105	0.07	0.10	25	26	558	541
3	3.8	243	105	0.07	0.10	27	29	539	519
4	3.8	245	105	0.06	0.10	26	29	554	528
5	3.8	245	105	0.07	0.10	29	30	560	537
6	3.8	245	105	0.07	0.11	25	28	559	530
7	3.8	245	105	0.07	0.11	25	27	549	522
8	3.8	241	105	0.07	0.10	28	30	569	538
9	3.8	242	105	0.07	0.10	26	26	548	529
10	3.8	243	105	0.07	0.11	27	28	553	527
11	3.9	245	105	0.07	0.10	24	26	550	519
12	3.8	245	105	0.07	0.11	27	29	572	551
13	3.8	242	105	0.07	0.11	28	31	568	548
Result	3.8	PASS	PASS	PASS	PASS	PASS	PASS	PASS	PASS
Defect Test (L: Multiple sampling inspection AQL: 1.5 AC: 2 RE:9)									
Sampling Frequency	First	Second	Third	Fourth	Fifth	Sixth	Seventh	Total	Result
Sampling No	200							200	PASS
Visual defects	0							0	
Pinhole test	1							1	





Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2059694-1

Organization: Zhonghong Pulin Medical Products Co., Ltd.
West Industrial Park, Luannan County, Tangshan City,
063500 Hebei, P.R. China

Scope: Design and Development, Manufacture and Distribution of Patient
Examination Gloves

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 190131115 110
Effective date: 2021-04-15
Expiry date: 2024-04-14
Issue date: 2021-04-13




Jang Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



Certificate



Quality Management System
EN ISO 13485:2016

Registration No.: SX 2059694-1

Organization: Zhonghong Pulin Medical Products Co., Ltd.
West Industrial Park, Luannan County, Tangshan City,
063500 Hebei, P.R. China

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Zhonghong Pulin Medical Products Co., Ltd. West Industrial Park, Luannan County, Tangshan City, 063500 Hebei, P.R. China	Distribution of Patient Examination Gloves
/02	c/o Minghao Medical Products Co., Ltd. West Industrial Park, Luannan County, Tangshan City, 063500 Hebei, P.R. China	Design and Development, Manufacture of Patient Examination Gloves

Report No.: 190131115 110
Effective date: 2021-04-15
Expiry date: 2024-04-14
Issue date: 2021-04-13




Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



Certificate

**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 2059694-1

Organization: Zhonghong Pulin Medical Products Co., Ltd.
West Industrial Park, Luannan County, Tangshan City,
063500 Hebei, P.R. China

The scope of certification also covers the following:

- | | | |
|-----|---|---|
| /03 | c/o The First Tangshan Branch Company of Zhonghong Pulin Medical Products Co., Ltd.
Pachigang Industrial Park, Luannan County, Tangshan City, 063502 Hebei, P.R. China | Design and Development, Manufacture of Patient Examination Gloves |
| /04 | c/o The Fifth Tangshan Branch Company of Zhonghong Pulin Medical Products Co., Ltd.
South Peituozi Village, Sigezhuang Town, Luannan County, Tangshan City, 063503 Hebei, P.R. China | Design and Development, Manufacture of Patient Examination Gloves |

Report No.: 190131115 110
Effective date: 2021-04-15
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