Test Report No.: 70.418.24.10169.01B
Dated: 2025-01-24

Applicant:	Zhonghong Pulin Medical Products Co.,Ltd.
Address:	West Industrial Park, BDA, Luannan County, 063500 Tangshan City, Hebei Province, PEOPLE'S REPUBLIC OF CHINA
Product Name:	Disposable Nitrile Examination Gloves Powder-Free, Black
Brand:	/
Model No.:	/
Buyer:	/
Manufacturer:	Same as Applicant
Country of Origin:	China
Country of Destination:	/
Receipt Date of Sample:	2024-12-02
Date of Testing:	From 2024-12-02 to 2025-01-23
Sample Submitted:	The sample(s) was (were) submitted by applicant and identified.
Test Result:	Refer to the data listed in following pages

Test Specification(s) or Test Item(s):		**Conclusions:**
1.	**EN 455-1:2020+A2:2024 Medical gloves for single use – Part 1: Requirements and testing for freedom from holes**	**Pass**
2.	**EN 455-2:2024 Medical gloves for single use – Part 2: Requirements and testing for physical properties**	**Pass**
3.	**BS EN 455-3:2023 Medical gloves for single use- Part 3: Requirements and testing for biological evaluation**	**Pass**

Laboratory:
TÜV SÜD Certification and Testing (China) Co., Ltd.
Shanghai Branch, Testing Center
Building B,C, No. 1999 and Building D, No. 2059, Duhui Road, Minhang District, Shanghai

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Hardline laboratory

TÜV SÜD Certification and Testing (China) Co., Ltd. Shanghai Branch
Testing Center

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Youhu Wang
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Note:

(1) The TÜV SÜD Certification and Testing (China) Co., Ltd. "General Terms & Conditions" applied.
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(2) The results relate only to the Items tested.

(3) The test report shall not be reproduced except in full without the written approval of the laboratory

(4) Disclaimer Measurement Uncertainty:
Unless otherwise agreed upon, Pass or Fail verdicts are given based on the measured values without any considerations of measurement uncertainties.
Please note, every test method has a measurement uncertainty which has been evaluated by the laboratory according to ISO/IEC 17025 requirements. By taking measurement uncertainties into account it might happen that measured values can neither be assessed as Pass nor as Fail.

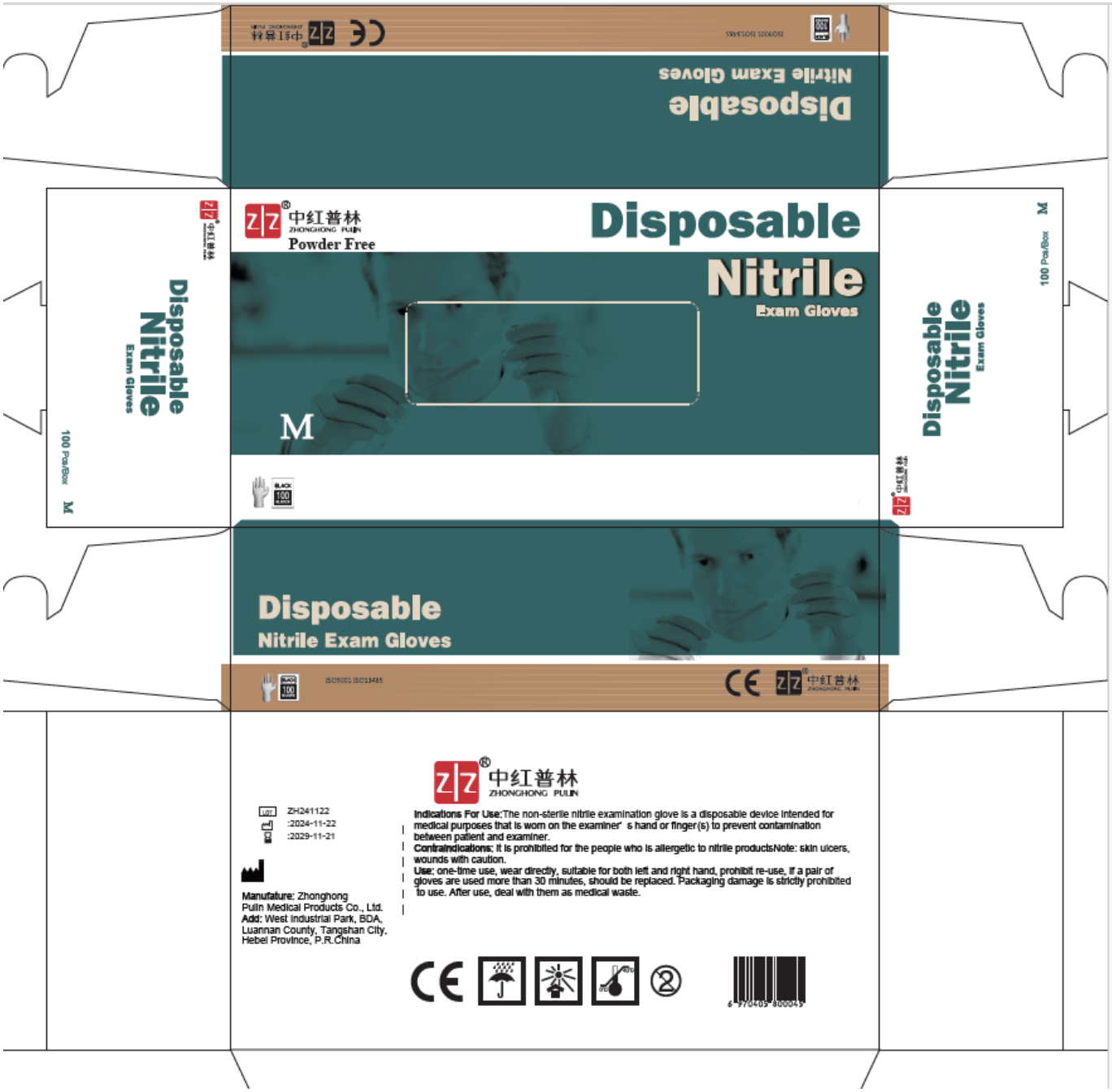
Description of the test subject:

Product Description *Product details*	Disposable Nitrile Examination Gloves Powder-Free, Black

Model No.	Color, Material	Size	Lot No.	Expiry Date	Sample received	Manufacturer
XS	Black, Nitrile	XS	ZH241122	2029-11-21	400pcs	Zhonghong Pulin Medical Products Co.,Ltd.
S		S	ZH241122		400pcs	
M		M	ZH241122		400pcs	
L		L	ZH241122		400pcs	
XL		XL	ZH241122		400pcs	
Lot size: 150,001 to 500,000 pieces per lot as specified by client						

Sample Photo-XS	Sample Photo- S
	
Sample Photo- M	**Sample Photo-L**
	
Sample Photo-XL	/
	/

Artwork


Disposable
Nitrile Exam Gloves
中红普林
ZHONGHONG PULIN
Powder Free
Disposable
Nitrile
Exam Gloves
M
100 Pcs/Box
Disposable
Nitrile Exam Gloves
ZH241122
:2024-11-22
:2029-11-21
Manufature: Zhonghong Pulin Medical Products Co., Ltd.
Add: West Industrial Park, BDA, Luannan County, Tangshan City, Hebei Province, P.R.China
Indications For Use:The non-sterile nitrile examination glove is a disposable device intended for medical purposes that is worn on the examiner' s hand or finger(s) to prevent contamination between patient and examiner.
Contraindications: It is prohibited for the people who is allergetic to nitrile productsNote: skin ulcers, wounds with caution.
Use: one-time use, wear directly, suitable for both left and right hand, prohibit re-use, if a pair of gloves are used more than 30 minutes, should be replaced. Packaging damage is strictly prohibited to use. After use, deal with them as medical waste.

Test Results:

1. EN 455-1:2020+A2:2024 Medical gloves for single use – Part 1: Requirements and testing for freedom from holes

With reference to Clause 6 sampling, inspection level and AQL of EN 455-1:2020/A1:2022 Medical gloves for single use – Part 1: Requirements and testing for freedom from holes:

Sample Plan	Inspection level	AQL	Ac	Re	Sample quantity tested:
Single sample plan	General inspection level I	1.5	10	11	315

Clause	Requirement-test item	Result, Remark		Evaluation
4	**Requirement**			
5	**Water tightness test for detection of holes**			
5.1	Add 1000mL water at temperature of (15~35) °C, into gloves and inspect any leakage at 0 and 2min after filling. (Leakage within 40mm of the cuff are not relevant)	Size:	Non-conformity products	/
		XS	4	P
		S	2	P
		M	1	P
		L	1	P
		XL	2	P

2. EN 455-2:2024 Medical gloves for single use – Part 2: Requirements and testing for physical properties

Clause	Requirement			Result, Remark	Evaluation
4	**Dimensions**			**13 pieces were tested per size**	**P**
4.1	General				
	/	Size:	Req. Dimension, mm	Dimension (median), mm (refer to Table A attached)	/
	Length	XS	≥240	250	P
		S	≥240	252	P
		M	≥240	246	P
		L	≥240	255	P
		XL	≥240	251	
	Width	XS	≤80	79	P
		S	80 ± 10	85	P
		M	95 ± 10	95	P
		L	110 ± 10	105	P
		XL	≥110	113	P

5	**Strength**

5.1	General			13 pieces were tested per size	P
5.2	Force at Break				
	Size:	Tested Sample	Requirement, N	Result(median), N (refer to table B attached)	/
	XS	13pcs	For nitrile examination gloves, median ⩾ 6.0	8.7	P
	S			8.0	P
	M			8.7	P
	L			8.9	P
	XL			8.1	P
5.3	Force at break after challenge testing, 7 days at (70 ± 2) °C				
	Size:	Tested Sample	Requirement, N	Result(median), N (refer to table B attached)	/
	XS	13pcs	For nitrile examination gloves, median ⩾ 6.0	8.9	P
	S			8.6	P
	M			9.6	P
	L			9.1	P
	XL			9.2	P
7	Manufacturer shall label the glove and/ or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN1041:2008+A1:2013.			Symbol and manufacture date are properly printed.	P

3. BS EN 455-3:2023 Medical gloves for single use, Part3: Requirement and testing for biological evaluation.

Clause	Requirement		Result, Remark		Evaluation
4.2	Chemicals	Gloves shall not be dressed with talcum powder (magnesium silicate)	Glove is not dressed with talcum powder, based on client's declaration letter.		P
		Other chemicals	Manufacturer shall disclose upon request a list of chemical ingredients		N/A
4.3 5.1	Endotoxins	<20 EU/pair for gloves labelled with 'low endotoxin content'	Not labelled with 'low endotoxin content'		N/A
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2mg per glove.	XS	0.19 mg per glove	P
			S	0.54 mg per glove	P
			M	0.84 mg per glove	P
			L	0.57 mg per glove	P
			XL	0.79 mg per glove	P
4.5 5.3	Proteins, leachable	The manufacturer shall strive to minimize the leachable protein level for gloves containing natural rubber latex.	Not natural rubber latex glove		N/A

Clause	Requirement		Result, Remark	Evaluation
4.6	Labelling	In addition to the relevant symbols given in EN ISO 15223-1:2021, the following requirements apply:		P
		a) medical gloves shall be labelled for single use on one individual during a single procedure. Note 1 This is in accordance with the Regulation (EU) 2017/745. For any medical glove the product labelling shall not include any term suggesting disinfection, reprocessing or re-use;	Complied	
		b) for any medical glove where chemical ingredients such as accelerators, antioxidants and biocides are either added during manufacturing or already known to be present in the product, and there is a residual risk of causing Type IV allergy, the labelling on at least the dispenser pack shall include the following or equivalent warning statement "Contains potential Type IV chemical allergens." or the symbol in Figure 1;  **Figure 1 — Symbol "Contains or presence of Type IV allergen" (derived from ISO 7000 – 2725)**	N/A	

		c) for any medical glove where chemical ingredients such as accelerators, antioxidants and biocides are either added during manufacturing or already known to be present in the product, and which are known to cause Type IV allergy, the product labelling shall not include: — any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low or reduced content of Type IV allergens; — any unjustified indication or misleading claims of the absence or presence of allergens;	N/A	
		d) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the pouch with the EN ISO 15223-1:2021 symbol for latex (reference number 5.4.5). The labelling shall include the following or equivalent warning statement together with the symbol “(Product) contains natural rubber latex which may cause allergic reactions, including anaphylactic responses.”;	N/A	
		e) the labelling shall state whether the glove is powdered or powder-free;	Complied	
		f) sterile powdered gloves shall be labelled with the following or equivalent: 'CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions'; NOTE 2 This caution statement can be given on the inner wrapping.	N/A	
		g) for any medical glove containing natural rubber latex the product labelling shall not include: — any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein;	N/A	

		— any unjustified indication of the presence of allergens;		
		h) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given. This does not allow a protein labelling claim below 50 µg/g. Lower claims are not considered to be reliable given the expected process variation in manufacture and inter-laboratory testing.	N/A	

Abbreviation: P=Pass; F=Fail; N/A = Not Applicable; N/T=Not Tested; N/R=Not Requested

Table A Dimensions

Size	XS	
No.	**Length, mm**	**Width, mm**
1	250	79
2	251	78
3	250	79
4	251	79
5	250	79
6	250	78
7	249	79
8	250	79
9	249	80
10	250	79
11	250	79
12	250	78
13	250	79
Median Value	250	79

Size	S	
No.	**Length, mm**	**Width, mm**
1	252	85
2	252	84
3	251	84
4	252	85
5	252	85

6	252	85
7	253	85
8	252	86
9	252	85
10	252	85
11	251	85
12	251	84
13	252	85
Median Value	252	85

Size	**M**	
No.	**Length, mm**	**Width, mm**
1	245	96
2	245	95
3	247	95
4	246	95
5	247	96
6	246	95
7	246	95
8	246	95
9	246	94
10	246	95
11	247	95
12	246	95

13	246	94
Median Value	246	95

Size	**L**	
No.	**Length, mm**	**Width, mm**
1	257	105
2	255	104
3	255	105
4	255	105
5	255	106
6	254	104
7	255	105
8	255	105
9	255	105
10	254	105
11	255	104
12	256	105
13	255	105
Median Value	255	105

Size	**XL**	
No.	**Length, mm**	**Width, mm**
1	250	112
2	252	113
3	251	113

4	251	113
5	251	114
6	250	113
7	251	113
8	251	112
9	251	112
10	252	113
11	251	113
12	251	113
13	251	113
Median Value	251	113

Table B

Size		**XS**	
Before Aging		**After Aging**	
No.	**Force at break, N**	**No.**	**Force at break, N**
1	8.7	1	7.7
2	8.3	2	9.3
3	6.7	3	8.9
4	8.0	4	9.9
5	9.0	5	9.3
6	9.0	6	6.7
7	7.2	7	7.6
8	9.3	8	8.4
9	9.5	9	9.4

10	8.4	10	9.2
11	9.0	11	8.7
12	8.5	12	9.3
13	8.9	13	8.5
Median Value	8.7	Median Value	8.9

Size		**S**	
Before Aging		**After Aging**	
No.	**Force at break, N**	**No.**	**Force at break, N**
1	8.7	1	8.6
2	7.9	2	8.9
3	7.9	3	6.6
4	9.4	4	9.4
5	9.3	5	9.0
6	7.0	6	6.9
7	6.2	7	6.8
8	8.0	8	8.8
9	9.6	9	7.6
10	7.7	10	8.4
11	8.4	11	8.7
12	7.8	12	8.2
13	8.1	13	8.8
Median Value	8.0	Median Value	8.6

Size		M	
Before Aging		After Aging	
No.	Force at break, N	No.	Force at break, N
1	8.7	1	7.8
2	8.3	2	7.7
3	9.4	3	7.6
4	8.9	4	9.8
5	8.0	5	9.6
6	10.3	6	9.7
7	8.0	7	10.3
8	9.0	8	9.0
9	8.4	9	10.1
10	8.5	10	9.0
11	8.8	11	9.7
12	8.6	12	9.2
13	8.9	13	9.8
Median Value	8.7	Median Value	9.6

Size		L	
Before Aging		After Aging	
No.	Force at break, N	No.	Force at break, N
1	9.5	1	9.1
2	9.5	2	8.3
3	8.3	3	9.8

4	9.8	4	7.8
5	8.7	5	8.3
6	8.7	6	7.3
7	8.9	7	9.6
8	9.4	8	7.9
9	8.5	9	9.2
10	8.8	10	8.7
11	9.1	11	9.4
12	8.7	12	9.4
13	9.2	13	9.2
Median Value	8.9	Median Value	9.1

Size		**XL**	
Before Aging		**After Aging**	
No.	**Force at break, N**	**No.**	**Force at break, N**
1	7.5	1	9.3
2	7.8	2	8.9
3	8.8	3	9.1
4	8.1	4	8.3
5	8.5	5	9.5
6	8.8	6	9.3
7	8.9	7	9.2
8	7.6	8	10.1
9	7.7	9	8.2
10	8.0	10	8.9

11	8.4	11	9.4
12	8.3	12	9.0
13	7.8	13	9.3
Median Value	8.1	Median Value	9.2

Remark:

1. The sample has been examined according to the client's requirements.

-End of Test Report-