Test Report Dated: 2024-09-19

Applicant:	Shanghai Jessubond International Co., Ltd.
Address:	No.558 Gangye Road, Dagang Songjiang Dist, Shanghai 201614, China PEOPLE'S REPUBLIC OF CHINA
Product Name:	Disposable Nitrile Examination Glove, Blue
Brand:	/
Model No.:	/
Buyer:	/
Manufacturer:	Shanghai Jessubond International Co., Ltd.
Country of Origin:	China
Country of Destination:	/
Receipt Date of Sample:	2024-08-22
Date of Testing:	From 2024-08-22 to 2024-09-19
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/A1:2022 Medical gloves for single use – Part 1: Requirements and testing for freedom from holes**	**Pass**
2.	**EN 455-2:2015 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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Note:

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(2) The results relate only to the Items tested.

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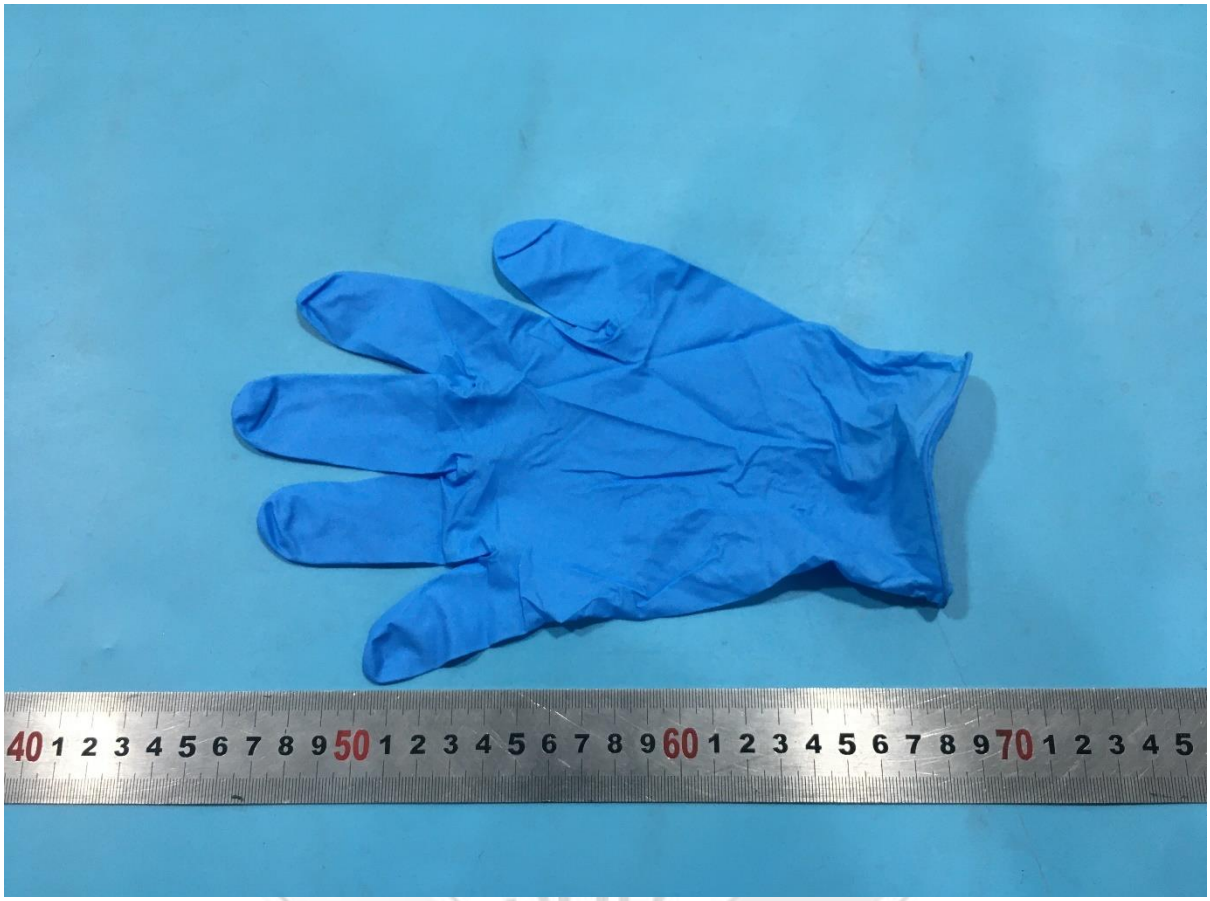
(4) Disclaimer Measurement Uncertainty:
Unless otherwise agreed upon, Pass or Fail verdicts are given based on the measured values without any considerations of measurement uncertainties.
Please note, every test method has a measurement uncertainty which has been evaluated by the laboratory according 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 Glove, Blue
Model No.	Color, Material	Size	Lot No.	Expiry Date	Sample received	Manufacturer
ABC-DG01	Blue, Nitrile	L	20240701DJZ	2029-07-04	400pcs	Shanghai Jessubond International Co., Ltd.
Lot size: 150,001 to 500,000 pieces per lot as specified by client						

Sample Photo-L


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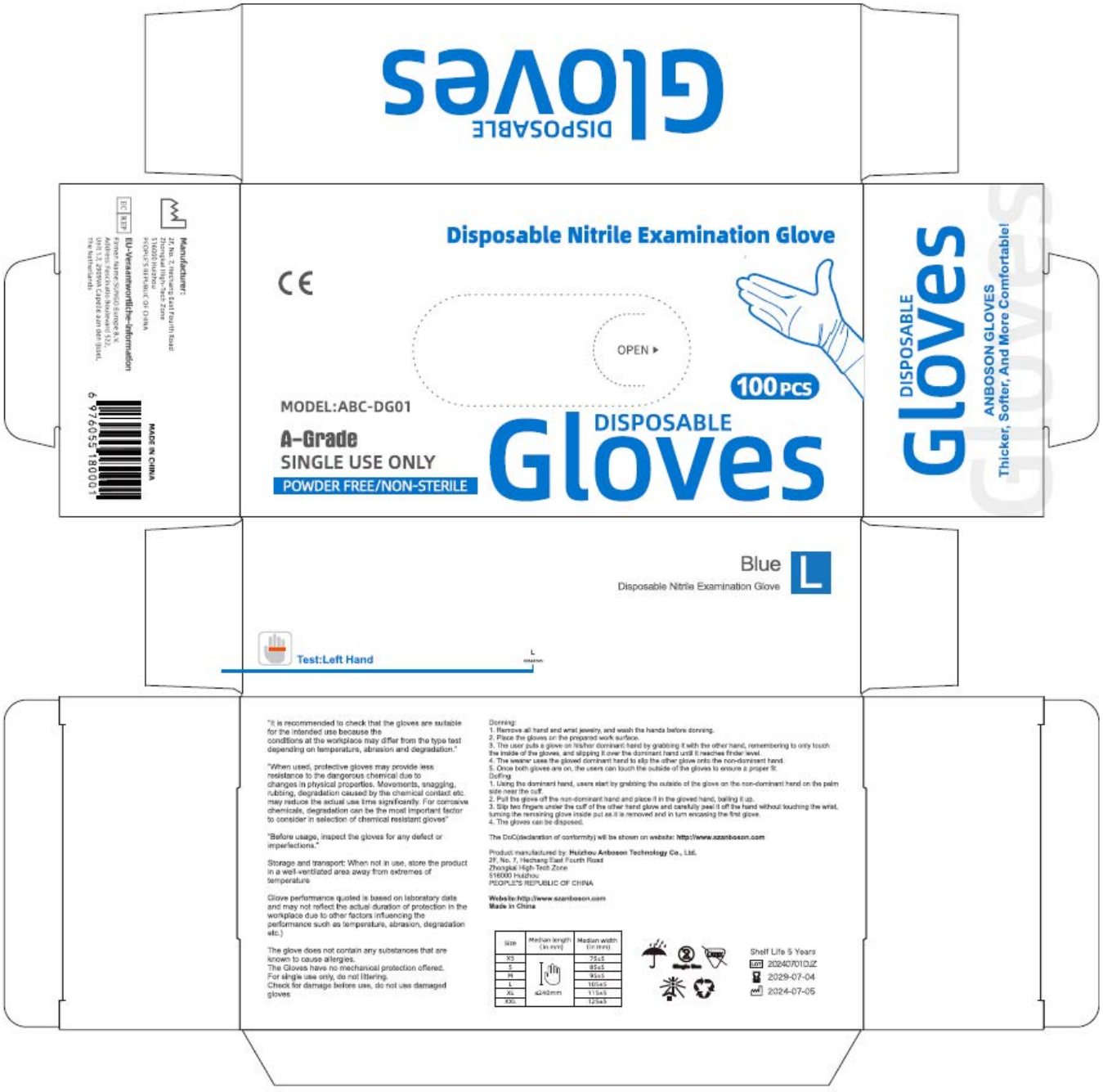
Artwork


Gloves
DISPOSABLE
Disposable Nitrile Examination Glove
CE
OPEN
100 PCS
MODEL:ABC-DG01
A-Grade
SINGLE USE ONLY
POWDER FREE/NON-STERILE
DISPOSABLE
Gloves
DISPOSABLE
Gloves
ANBOSON GLOVES
Thicker, Softer, And More Comfortable!
Blue
L
Disposable Nitrile Examination Glove
Test:Left Hand
Manufacturer:
EU-Verantwortliche-Information
MADE IN CHINA
"It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation."
"When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves"
"Before usage, inspect the gloves for any defect or imperfections."
Storage and transport: When not in use, store the product in a well-ventilated area away from extremes of temperature
Glove performance quoted is based on laboratory data and may not reflect the actual duration of protection in the workplace due to other factors influencing the performance such as temperature, abrasion, degradation etc.)
The glove does not contain any substances that are known to cause allergies.
The Gloves have no mechanical protection offered.
For single use only, do not littering.
Check for damage before use, do not use damaged gloves
Donning:
1. Remove all hand and wrist jewelry, and wash the hands before donning.
2. Place the gloves on the prepared work surface.
3. The user puts a glove on his/her dominant hand by grabbing it with the other hand, remembering to only touch the inside of the gloves, and slipping it over the dominant hand until it reaches finger level.
4. The wearer uses the gloved dominant hand to slip the other glove onto the non-dominant hand.
5. Once both gloves are on, the users can touch the outside of the gloves to ensure a proper fit
Doffing
1. Using the dominant hand, users start by grabbing the outside of the glove on the non-dominant hand on the palm side near the cuff.
2. Pull the glove off the non-dominant hand and place it in the gloved hand, balling it up.
3. Slip two fingers under the cuff of the other hand glove and carefully peel it off the hand without touching the wrist, turning the remaining glove inside out as it is removed and in turn encasing the first glove.
4. The gloves can be disposed.
The DoC(declaration of conformity) will be shown on website: http://www.szanboson.com
Product manufactured by: Huizhou Anboson Technology Co., Ltd.
2F, No. 7, Hechang East Fourth Road
Zhongkai High-Tech Zone
516000 Huizhou
PEOPLE'S REPUBLIC OF CHINA
Website:http://www.szanboson.com
Made in China
Size
Median length (in mm)
Median width (in mm)
XS
S
M
L
XL
XXL
≥240mm
75±5
85±5
95±5
105±5
115±5
125±5
Shelf Life 5 Years
LOT 20240701DJZ
2029-07-04
2024-07-05

Test Results:

1. EN 455-1:2020/A1:2022 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	/
		L	7	P

2. EN 455-2:2015 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	L	≥240	246	P
	Width	L	110 ± 10	110	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)	/
	L	13pcs	For nitrile examination/procedure gloves, median≥ 6.0	7.3	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)	/
	L	13pcs	For nitrile examination/procedure gloves, median≥ 6.0	6.6	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.	L	0.51 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	L	
No.	Length, mm	Width, mm
1	246	110
2	245	110
3	246	109
4	245	110
5	246	110
6	246	111
7	247	110
8	246	110
9	246	111
10	247	110
11	247	110
12	246	109
13	246	110
Median Value	246	110

Table B

Size L			
Before Aging		**After Aging**	
No.	**Force at break, N**	**No.**	**Force at break, N**
1	7.3	1	7.7
2	7.2	2	7.1
3	6.6	3	6.3
4	7.6	4	6.4
5	7.0	5	6.2
6	7.3	6	6.3
7	7.5	7	6.6
8	7.4	8	7.2
9	6.4	9	7.5
10	7.3	10	7.1
11	6.9	11	6.4
12	7.2	12	6.9
13	7.6	13	6.4
Median Value	7.3	Median Value	6.6

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

-End of Test Report