



KICHY VIETNAM CO., LTD.



Products



Specifications of Nitrile Glove

- Superior tensile strength for extraordinary resiliency
- Superior puncture & tear resistance properties
- Protection from unwanted & dangerous substances
- Softness provides superior comfort and natural fit. Fit more comfortably, reduced hand fatigue & respiration
- Beaded cuff makes easy donning and guards against tearing
- Smooth gloves donning surface provides a more natural feel
- Powder free to eliminate powder – induced irritation & dermatitis to user
- Low level of extractable protein & chemical residue, hence lower incidence of allergic reactions.
- Under GMP practice
- Manufactured from 100% nitrile (Acrylonitrile-Butadiene)

DIMENSIONS	STANDARDS	
	SOLIT GLOVES	ASTM D6319
Length	230 min	220 min (XS,S) 230 min (M,L,XL)
Width	75 ± 5 (XS) 85 ± 5 (S) 95 ± 5 (M) 105 ± 5 (L) 115 ± 5 (XL)	70 ± 10 (XS) 80 ± 10 (S) 95 ± 10 (M) 110 ± 10 (L) 120 ± 10 (XL)
Thickness-Single wall	Fingers: 0.08 mm min Palm: 0.06 mm min	Fingers: 0.05 mm min Palm: 0.05 mm min

Tensile	<p>Tensile strength (MPA)</p> <p>Before Aging: 18Mpa min After Aging: 20Mpa min</p>	<p>Tensile strength (MPA)</p> <p>Before Aging : 14Mpa min After Aging 14Mpa min</p>
	<p>Elongation at break (%)</p> <p>Before Aging: 600% min After Aging: 500% min</p>	<p>Elongation at break (%)</p> <p>Before Aging 500% min After Aging 400% min</p>
Powder Content	2 mg/glove maximum	
Protein Content	Protein Free	

CERTIFICATES

FDA Registration number: 3016872430

Certificate of Registration

This certificate of Registration certifies that:

KICHY VIET NAM COMPANY LIMITED

OFFICE 02, 8TH FLOOR, PEARL PLAZA BUILDING, NO.561A DIEN BIEN PHU STREET, WARD 25, BINH THANH DISTRICT, HO CHI MINH, HO CHI MINH, THANH PHO 700000, VIET NAM

has registered with the US Food and Drug Administration pursuant to Title 21 of the United States Code of Federal Regulations.

Owner Operator Number: 10073774

Listed Device

**QKR D402090 Face Mask, N95
OEA D403243 Non-Surgical Isolation Gown
MGS D404392 Medical Gloves**



US Agent: Willow Glen Consultancy LLC

Willow Glen Number: WG2071191

Expiration Date: December 31, 2020

This certificate affirms that the above-named facility is registered with the US FDA pursuant to the regulations required by the US laws. This registration has been verified as effective by Willow Glen Consultancy as of the date below, unless such registration has been terminated after issuance of this Certificate. Willow Glen Consultancy makes no additional representations or warranties, nor does this certificate carry any to any person or entity other than the named certificate holder, for whose sole benefit it is issued. Willow Glen Consultancy assumes no liability to any person or entity in connection with the foregoing, nor does the U.S. FDA recognize a certificate of registration issued by Willow Glen Consultancy.

Willow Glen Consultancy is a private agent not affiliated with the U.S. Food and Drug Administration.

A handwritten signature in blue ink that reads 'Amanda Ou'.

**Amanda Ou, Operation Director
Willow Glen Consultancy LLC
+1-619-869-0249
Date: May 18, 2020**

The logo for Willow Glen, featuring the words 'Willow' and 'Glen' in a green, sans-serif font, with a stylized green leaf graphic between the two words.

**WillowGlenFDA.com
Info@WillowGlenFDA.com
3755 Avocado Blvd, Suite 208
La Mesa, CA 91941, USA**

CERTIFICATES

EU Declaration of Conformity



KICHY VIETNAM COMPANY LIMITED

Address: 8th floor Pearl Plaza Building, 561A Dien Bien Phu Street,
Ward 25, Binh Thanh District, HCMC, Vietnam
www.kichyvn.com

HCMC, 15 October 2020

Declaration of Conformity

Tuyên bố Tuân thủ

The Declaration of Conformity is issued under the sole responsibilities of manufacturer
Tuyên bố Tuân thủ được phát hành và cam kết dưới trách nhiệm của nhà sản xuất

Product: KICHY Nitrile Glove
Sản phẩm: Găng tay Nitrile Kichy

Sizes: S, M, L, XL
Kích cỡ: S, M, L, XL

Classification: PPE Category III
Phân loại: PPE Loại III

Manufacturer: KICHY VIET NAM COMPANY LIMITED
Nhà sản xuất: 8th Floor, Pearl PLAZA Building, 561A Dien Bien Phu, Ward 25, Binh Thanh District, HCM
Tel: 0978 700 800 - 0839 949 393 - 0931 511 898

CÔNG TY TNHH KICHY VIỆT NAM
Lầu 8, Tòa nhà Pearl Plaza, 561A Điện Biên Phủ, P.25, Q. Bình Thạnh, TP.HCM.
Điện thoại: +84 931 511 898 - 0839 949 393 - 0978 700 800

We declare that the product described above, to which this declaration of conformity refers to, is in conformity with the essential requirements of the following legislation:

Chúng tôi tuyên bố rằng sản phẩm được mô tả ở trên, mà tuyên bố về sự phù hợp này để cập đến, phù hợp với các yêu cầu thiết yếu của các luật dưới đây:

Applicable Norms:
Các chuẩn mực áp dụng:

- MDD 93/42/EEC: 2007/47/EC Class I (Non-sterile)
- PPE 2016/425/EU: Personal Protective Equipment
- CE - Certificate Number: CE/016347/0320
- EN ISO 374-1:2016: Protective gloves against dangerous chemicals and micro-organisms — Terminology and performance requirements for chemical risks
- EN 374-2:2014: Protective gloves against dangerous chemicals and micro-organisms — Determination of resistance to penetration
- EN 374-4:2013: Protective gloves against chemicals and micro-organisms -Determination of resistance to degradation by chemicals
- EN 455-1:2000 Medical gloves for single use

CERTIFICATES

EU Declaration of Conformity

- EN 455-2:2015 Requirements and testing for physical properties
 - EN 455-3: 2015 Requirements and testing for biological evaluation
 - EN 16523-1:2015 + A1:2018 test for gloves claimed to protect against permeation by chemicals.
 - ASTM D6319-10 (Reapproved 2015): Standard Specification for Nitrile Examination Gloves for Medical Application
 - ISO 9001:2015 - Certificate Number: 6811/QMS/1020: Quality Management System
 - ISO 14001:2015 - Certificate Number: EMS/018794/1020: Environmental management systems
 - ISO 13485:2016 - Certificate Number: W1208M: Medical devices—Quality management systems
-
- MDD 93/42 / EEC: 2007/47 / EC Class I (Không vô trùng)
 - PPE 2016/425 / EU: Thiết bị Bảo hộ Cá nhân
 - CE - Số chứng chỉ: CE / 016347/0320
 - EN ISO 374-1: 2016: Găng tay bảo vệ chống lại các hóa chất và vi sinh vật nguy hiểm - Các yêu cầu về thuật ngữ và hiệu suất đối với rủi ro về hóa chất
 - EN 374-2: 2014: Găng tay bảo hộ chống lại các hóa chất và vi sinh vật nguy hiểm - Xác định khả năng chống xâm nhập
 - EN 374-4: 2013: Găng tay bảo vệ chống lại hóa chất và vi sinh vật -Xác định khả năng hao mòn bởi hóa chất
 - EN 455-1: 2000 Găng tay y tế sử dụng một lần
 - EN 455-2: 2015 Các yêu cầu và thử nghiệm đối với các đặc tính vật lý
 - EN 455-3: 2015 Các yêu cầu và thử nghiệm để đánh giá sinh học
 - Thử nghiệm EN 16523-1: 2015 + A1: 2018 đối với găng tay được tuyên bố bảo vệ chống lại sự thấm thấu của hóa chất.
 - ASTM D6319-10 (Được phê duyệt lại năm 2015): Đặc điểm kỹ thuật tiêu chuẩn cho Găng tay Nitrile trong hồ sơ y tế
 - ISO 9001: 2015 - Số chứng chỉ: 6811 / QMS / 1020: Hệ thống quản lý chất lượng
 - ISO 14001: 2015 - Số chứng chỉ: EMS / 018794/1020: Hệ thống quản lý môi trường
 - ISO 13485: 2016 - Số chứng chỉ: W1208M: Thiết bị y tế - Hệ thống quản lý chất lượng

On Behalf of KICHY VIET NAM COMPANY LIMITED

Đại diện CÔNG TY TNHH KICHY VIỆT NAM



Đặng Hồng Nam

General Director / Tổng Giám đốc

CERTIFICATES

ISO 21420:2020

Test No. 7191245422-EEC20/01-WBH



Test Report No. 7191245422-EEC20/01-WBH
dated 16 Oct 2020

Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.



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SUBJECT:

Testing of Gloves submitted by KICHY VIET NAM CO., LTD on 01 Oct 2020.

TESTED FOR:

KICHY VIET NAM CO., LTD
8th Floor, Pearl Plaza Building, No. 561A Dien Bien Phu,
Ward 25, Binh Thanh District,
Ho Chi Minh City, Vietnam

TEST DATE:

12 Oct 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Brand/ Model	Size	Colour	Lot No.	Expiry Date	Sample Received (pieces)	Manufacturer
1	Powder Free Nitrile Examination Gloves	KICHY GLOVE	S	Blue	KC010708	08/08/2023	500	KICHY VIET NAM CO., LTD

METHOD OF TEST:

The tests were conducted in accordance with the following test standards:

- BS EN ISO 21420:2020 Protective gloves – General requirements and test methods
- Clause 4.2c pH value
 - Clause 5.1 Sizing and measurement of gloves
 - Clause 5.2 Dexterity



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Co. Reg : 199002667R

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ISO 21420:2020

Test No. 7191245422-EEC20/01-WBH

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dated 16 Oct 2020



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
RESULTS:

Sample: Powder Free Nitrile Examination Gloves, KICHY GLOVE, Blue, Size S

Test	BS EN ISO 21420: 2020 Requirements	Results	Inferred Results	
I. Determination of pH Value, pH value	> 3.5 and < 9.5	7.8	Passed	
II. Sizing, minimum length of glove (mm)	-	250	(see remark 1)	
III. Dexterity, level of performance	Level of performance	Smallest pin diameter fulfilling test conditions (mm)	5	(see remark 2)
	1	11		
	2	9.5		
	3	8		
	4	6.5		
5	5			

REMARKS:

- Sizes of gloves are defined with respect to the sizes of the hands they are to fit. If required for specific use (for example, gloves for welders and firefighters), the minimum glove length shall be defined in the relevant specific standards.
- For Dexterity test, a glove should allow as much dexterity as possible given its purpose.


Lee Banyi
Engineer


Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:



Photo: Powder Free Nitrile Examination Gloves, KICHY GLOVE, Blue, Size S



CERTIFICATES

ISO 21420:2020

Test No. 7191245422-EEC20/01-WBH

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dated 16 Oct 2020

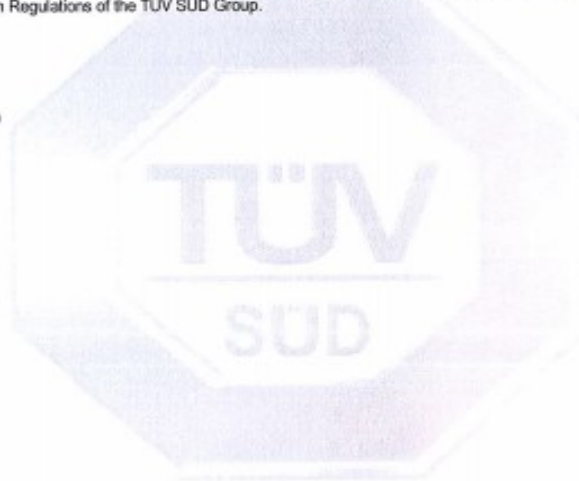


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Please note that this Report is issued under the following terms :

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2. The sample/s mentioned in this report is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.
3. Nothing in this report shall be interpreted to mean that TÜV SÜD PSB has verified or ascertained any endorsement or marks from any other testing authority or bodies that may be found on that sample.
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6. The tests carried out by TÜV SÜD PSB and this report are subject to TÜV SÜD PSB's General Terms and Conditions of Business and the Testing and Certification Regulations of the TÜV SÜD Group.

Effective 01 September 2020



CERTIFICATES

EN 455-1:2000 - EN 455-2:2015 - EN 455-3: 2015

Test Report No. 7191245422-EEC20/02-WBH
dated 22 Oct 2020



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Testing of Gloves submitted by KICHY VIET NAM CO., LTD on 01 Oct 2020.

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TESTED FOR:

KICHY VIET NAM CO., LTD
8th Floor, Pearl Plaza Building, No. 561A Dien Bien Phu,
Ward 25, Binh Thanh District,
Ho Chi Minh City, Vietnam

TEST DATE:

01 Oct 2020 to 22 Oct 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Brand/ Model	Size	Colour	Lot No.	Expiry Date	Sample Received (pieces)	Manufacturer
1	Powder Free Nitrile Examination Gloves	KICHY GLOVE	S	Blue	KC010708	08/08/2023	500	KICHY VIET NAM CO., LTD

Lot size as specified by client: 35,001 to 150,000 pieces

METHOD OF TEST:

- EN 455-1:2020 Medical gloves for single use
Part 1: Requirements and testing for freedom from holes
- EN 455-2:2015 Medical gloves for single use
Part 2: Requirements and testing for physical properties
- EN 455-3:2015 Medical glove for single use
Part 3: Requirements and testing for biological evaluation



TÜV SÜD PSB

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CERTIFICATES

EN 455-1:2000 - EN 455-2:2015 - EN 455-3: 2015

Test Report No. 7191245422-EEC20/02-WBH
dated 22 Oct 2020



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RESULTS:

Sample: Powder Free Nitrile Examination Gloves, KICHY GLOVE, Blue, Size S

Table 1: Results for EN 455-1:2020

Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4	Freedom from holes	Shall not leak	7	200	2	Passed
5						

Table 2: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	a) Length (mm)	≥ 240	13	256	Passed
	b) Width (mm)	For Size S: 80 ± 10	13	84	Passed
5	a) Force at break (N)	For nitrile examination gloves: ≥ 6.0	13	8.2	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	For nitrile examination gloves: ≥ 6.0	13	8.2	Passed

Table 3: Results for EN 455-2:2015 Clause 7

Clause	Tests	Requirements	Results	Inferred results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Comply	Passed

CERTIFICATES

EN 455-1:2000 - EN 455-2:2015 - EN 455-3: 2015

Test Report No. 7191245422-EEC20/02-WBH
dated 22 Oct 2020



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RESULTS (cont'd):

Sample: Powder Free Nitrile Examination Gloves, KICHY GLOVE, Blue, Size S

Table 4: Results for EN 455-3:2015 Clauses 4.2-4.5

Clause	Tests	Requirements	Results / Remarks	Inferred results
4.2	Chemicals	Gloves shall not be dressed with talcum powder (magnesium silicate).	Glove is talcum powder-free glove, based on client's declaration letter on 22 Oct 2020	Passed
		Other chemicals	Manufacturer shall disclose upon request a list of chemical ingredients	NA
4.3 5.1	Endotoxins	< 20 EU/pair for gloves labelled with 'low endotoxin content'.	Not labelled with 'low endotoxin content'	NA
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	0.17 mg per glove	Passed
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	NA

Table 5: Results for EN 455-3:2015 Clause 4.6

Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex;	NA
		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';	NA
		b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free;	Comply
		c) 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';	NA
		d) 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; - any unjustified indication of the presence of allergens;	NA
e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given.	NA		
Inferred results			Passed

CERTIFICATES

EN 455-1:2000 - EN 455-2:2015 - EN 455-3: 2015

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dated 22 Oct 2020



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REMARKS:

1. Labelling requirements are assessed based on the submitted packaging artwork by client.
2. NA: Not applicable for the submitted sample.


Yeo Poh Kwang
Associate Engineer


Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:



Photo 1: Powder Free Nitrile Examination Gloves, KICHY GLOVE, Blue, Size S



Photo 2: Packaging artwork for Powder Free Nitrile Examination Gloves, KICHY GLOVE, Blue, Size S

CERTIFICATES

EN 455-1:2000 - EN 455-2:2015 - EN 455-3: 2015

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Effective 01 September 2020

