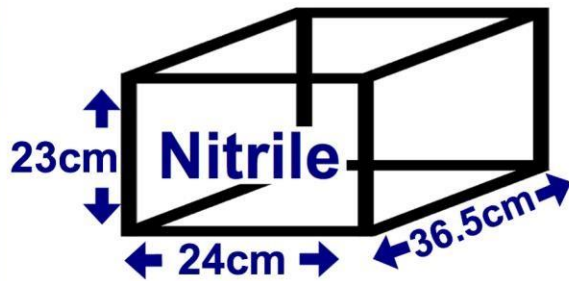




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**size M : 5.6 kg/carton**

**size L : 6.3 kg/carton**

# pure GLOVE

## NITRILE DISPOSABLE GLOVES



Nitrile Powder Free Examination Gloves, 2 Colors: Green and Purple

### Inspection level and AQL

Characteristic	Inspection level	AQL
1) Freedom from holes	GI	1.5
2) Physical dimension (Width, length, thickness)	S-2	4.0
3) Physical properties (before and after accelerated aging)	S-2	4.0
4) Powder Amount	N=2	N/A
5) Powder residue	N=5	N/A
6) Protein content	N=3	N/A

### Dimensions and Tolerances

Size	Width (mm)	Minimum length (mm)	Minimum length (mm)	Thickness (mm)		
				Finger	Palm	Cuff
XS	75±5	290 Min	240 Min	0.12 Min	0.10 Min	0.07 Min
S	85±5	290 Min	240 Min			
M	95±5	290 Min	240 Min			
L	106±5	290 Min	240 Min			
XL	115±5	290 Min	240 Min			

### Feature

- Premium quality
- Full textured surface and finger textured surface
- Ambidextrous
- Single use only



ISO 9001 - 2588  
 ISO 13485 - 2349  
 ISO 2555 - 2333

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**SHUN THAI RUBBER GLOVES INDUSTRY PUBLIC COMPANY LIMITED**

9 Moo-4 Kached, Muang Rayong, RAYONG 21100, THAILAND

Tel : +6625116046-7, +66634481-5 FAX : +6638634001

E- mail : mk@shunthaiglove.com Website : www.shunthaiglove.com Highly Intend To Reply Your

Satisfaction .....

**Nitrile, Powder-Free Examination Gloves**

**Product Code: GTF2409-10Y**

**Product Properties**

- Powder Free —• Textured Surface
- Blue Color • Beaded
- Straight fingers • Shelf life is 3 years
- Hundred (100) gloves per dispenser. Ten (10) dispensers per case.
- Store in a cool, dry place, and avoid excessive heat, store temperature should between 5-40°C. opened box should be shielded from exposure to direct sun or fluorescent lighting.

**Sampling and selection of test pieces**

Characteristic	Inspection level	AQL
Freedom from holes	G I	1.5-2.5
Dimension (width, length, thickness)	S-2	4.0
Physical properties (before and after accelerated aging)	S-2	4.0
Powder residue	N=5	N/A

**Dimensions**

Size	Width (mm)	Minimum length (mm)	Thickness (mm.)		Weight g/pcs.
			Palm	Finger	
XS	75±5	240 Min	0.10± 0.03	0.12± 0.03	3.8±0.20
S	85±5	240 Min	0.10± 0.03	0.12± 0.03	4.0±0.20
M	95±5	240 Min	0.10± 0.03	0.12± 0.03	4.5±0.20
L	106±5	240 Min	0.10± 0.03	0.12± 0.03	5.1±0.20
XL	115±5	240 Min	0.10± 0.03	0.12± 0.03	5.4±0.20

**Physical properties**

ASTM D6319		ISO 11193-1 & TIS 1056		EN 455-2:2015C	
<b>Before accelerated ageing</b>					
Tensile strength (Mpa)	14.0 Min	Force at break (N)	7.0 Min	Force at break (N)	6.0 Min
Elongation at break (%)	500 Min	Elongation at break (%)	500 Min		
<b>After accelerated ageing</b>					
Tensile strength (Mpa)	14.0 Min	Force at break (N)	6.0 Min	Force at break (N)	6.0 Min
Elongation at break (%)	400 Min	Elongation at break (%)	400 Min		

**Powder Content**

<b>Type</b>	<b>ASTM D6124</b>
Powder free gloves	2 mg/ glove Max

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# EC Declaration of Conformity

*Manufacturer:*

Shun Thai Rubber Gloves Industry Public Co., Ltd

We, the manufacturer, herewith declare that the products

## Examination Gloves Non Sterile

**UMDNS-Code: 1182**

Meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex VII of the Directive 93/42/EEC.

It bears the mark



The product concerned has been manufactured under a quality management system according to Annex VII of Directive 93/42/EEC.

Following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release documents for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Shun Thai Rubber Gloves Industry Public Co., Ltd

Address: 9, 14 Moo 4, Paed Sub-District

21100 Rayong-Muang District

Thailand

Rayong-Thailand, 03.01.2020

Place, date

EC Declaration of Conformity

E-D-01, 00 (DOC no., Revision)

A handwritten signature in black ink, appearing to be 'Jong Sittirong', is written over a horizontal line.

Chief Executive Officer

*Legally binding signature, Function*

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**bsi.**



# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Shun Thai Rubber Gloves Industry  
Public Co., Ltd.  
9, 14 Moo 4 Kached Sub-District,  
Muang District,  
Rayong  
21100  
Thailand

Holds Certificate Number:

**FM 724033**

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Manufacturing of Non Sterile Medical Gloves, Non Sterile and Sterile Surgical Gloves.

For and on behalf of BSI:

  
Chris Cheung, Head of Compliance & Risk - Asia Pacific

Original Registration Date: 2006-12-28

Latest Revision Date: 2020-02-01

Effective Date: 2020-02-01

Expiry Date: 2021-12-27

Page: 1 of 1



...making excellence a habit™

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](https://www.bsi-global.com/ClientDirectory)

Printed copies can be validated at [www.bsi-global.com/ClientDirectory](https://www.bsi-global.com/ClientDirectory) or telephone +66(2) 2914889-92.

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization.

This certificate is valid only if provided original copies are in complete set.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.



2020

### CERTIFICATE OF REGISTRATION

*This certifies that:*

**SHUN THAI RUBBER GLOVES INDUSTRY PUBLIC CO., LTD.**  
**9 MOO 4 KACHED MUANG**  
**RAYONG Rayong, THAILAND 21100**

is registered with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Registration:	8040818
Device Classification Name:	POLYMER PATIENT EXAMINATION GLOVE
Product Code:	LZA
Regulation Number:	880.625
Official Correspondent and U.S. Agent:	Registrar Corp 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179


*Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless such registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Registrar Corp assumes no liability to any person or entity in connection with the foregoing.*

*Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."*

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**Registrar Corp**

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info@registrarcorp.com • www.registrarcorp.com

  
\_\_\_\_\_  
Russell K. Statman  
Executive Director  
Registrar Corp

Dated: October 18, 2019

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