

# THAI SON GLOVES

**Nitrile** *Examination*  
**POWDER FREE**



- <http://thaisonmedical.net/>
- Email: [hiep.td@thaisonmedical.net](mailto:hiep.td@thaisonmedical.net)
- Hotline: +84 903995770

# PRODUCT SPECIFICATIONS

<ul style="list-style-type: none"> <li>• <b>Material</b></li> </ul>	<ul style="list-style-type: none"> <li>• Synthetic Nitrile Latex</li> </ul>
<ul style="list-style-type: none"> <li>• <b>Type</b></li> </ul>	<ul style="list-style-type: none"> <li>• Non-Sterile Powder-Free</li> <li>• Ambidextrous, Finger Tip Texture, Beaded Cuff, Blue and Cobalt</li> </ul>
<ul style="list-style-type: none"> <li>• <b>Quality Standards</b></li> </ul>	<ul style="list-style-type: none"> <li>• Conforms to EN455-1/2/3, EN374-1/2/3/4/5, ASTM D6319</li> <li>• Manufactured under ISO:13485:2016, FDA, CE Quality Management System</li> </ul>
<ul style="list-style-type: none"> <li>• <b>Gloves Size</b></li> </ul>	<ul style="list-style-type: none"> <li>• Extra Small ,Small,Medium,Large,Extra Large</li> <li>• Black marked in the check box on the shipping carton</li> </ul>
<ul style="list-style-type: none"> <li>• <b>Storage</b></li> </ul>	<ul style="list-style-type: none"> <li>• Store in a cool and dry place ,temperature is not higher 38*C</li> </ul>
<ul style="list-style-type: none"> <li>• <b>Shelf-life</b></li> </ul>	<ul style="list-style-type: none"> <li>• 3 years from the date of manufacturing</li> </ul>



# PHYSICAL DIMENSIONS

<ul style="list-style-type: none"> <li>• <b>Dimensions</b></li> </ul>	<ul style="list-style-type: none"> <li>• Standards</li> <li>• THAI SON GLOVES</li> </ul>	<ul style="list-style-type: none"> <li>• Standards</li> <li>• ASTM D6319</li> </ul>
<ul style="list-style-type: none"> <li>• <b>Length</b></li> </ul>	<ul style="list-style-type: none"> <li>• 230 min</li> </ul>	<ul style="list-style-type: none"> <li>• 220 min ( XS,S )</li> <li>• 230 min ( M,L,XL )</li> </ul>
<ul style="list-style-type: none"> <li>• <b>Width</b></li> </ul>	<ul style="list-style-type: none"> <li>• 75 ± 5 ( XS )</li> <li>• 85 ± 5 ( S )</li> <li>• 95 ± 5 ( M )</li> <li>• 105 ± 5 ( L )</li> <li>• 115 ± 5 ( XL )</li> </ul>	<ul style="list-style-type: none"> <li>• 70 ± 5 ( XS )</li> <li>• 80 ± 5 ( S )</li> <li>• 95 ± 5 ( M )</li> <li>• 110 ± 5 ( L )</li> <li>• 120 ± 5 ( XL )</li> </ul>
<ul style="list-style-type: none"> <li>• <b>Thickness-Single wall</b></li> </ul>	<ul style="list-style-type: none"> <li>• Fingers : 0.08 mm min</li> <li>• Palm : 0.06 mm min</li> </ul>	<ul style="list-style-type: none"> <li>• Fingers : 0.05 mm min</li> <li>• Palm : 0.05 mm min</li> </ul>



# PHYSICAL PROPERTIES AND BIOCOMPATIBILITY

<ul style="list-style-type: none"> <li>• <b>Tensile</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Tensile strength ( MPA )</b></li> <li>• Before Aging 18Mpa min</li> <li>• After Aging 20Mpa min</li> <li>• <b>Elongation at break (%)</b></li> <li>• Before Aging : 600 % min</li> <li>• After Aging : 500 % min</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Tensile strength ( MPA )</b></li> <li>• Before Aging 14Mpa min</li> <li>• After Aging 14Mpa min</li> <li>• <b>Elongation at break (%)</b></li> <li>• Before Aging : 500 % min</li> <li>• After Aging : 400 % min</li> </ul>
<ul style="list-style-type: none"> <li>• <b>Powder Content</b></li> </ul>	<ul style="list-style-type: none"> <li>• 2 mg/gloves maximum</li> </ul>	
<ul style="list-style-type: none"> <li>• <b>Protein Content</b></li> </ul>	<ul style="list-style-type: none"> <li>• Protein Free</li> </ul>	

## FUNCTIONAL BENEFITS

- Protection from unwanted and dangerous substances
- Beaded cuff ensures easy donning and prevent roll down
- Superior strength with better puncture resistance
- Full textured or Finger Tip textured enhances wet and dry grip
- Thinner gauge improves tactile sensitivity
- Custom design enhances comfort and fit
- Provide an alternative solution for individuals who are allergic to natural rubber latex



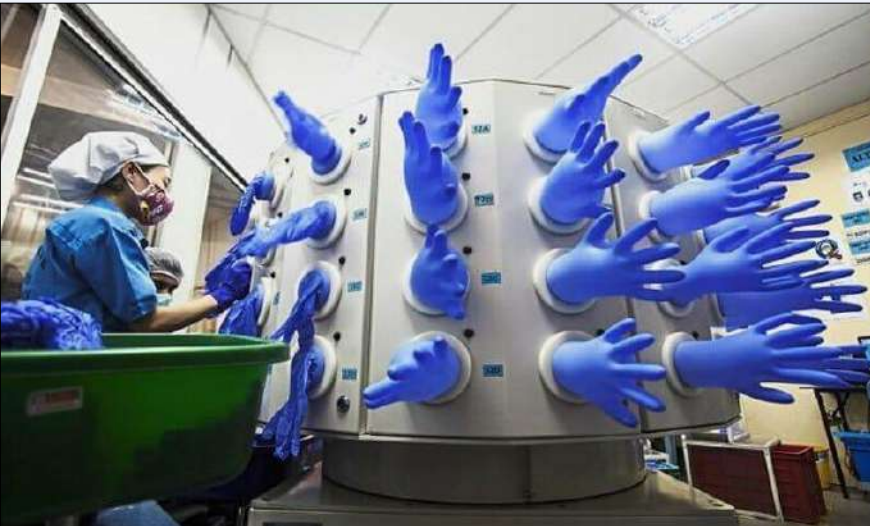
# NITRILE GLOVES



# LATEX GLOVES



# FACTORY SCALE



# CERTIFICATE

  
2021

**CERTIFICATE OF REGISTRATION**

*This certifies that:*  
**THAI SON MEDICAL INVESTMENT JOINT STOCK COMPANY**  
No. 14D, Lane 30, Phan Dinh Giot Street,  
Phuong Liet Ward, Thanh Xuan District  
Hanoi, Vietnam 10000

is registered with the U.S. Food and Drug Administration for FY 2021 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Owner/Operator Number: **10082125**  
Device Classification Name: **POLYMER PATIENT EXAMINATION GLOVE**

Product Code: **LZA**  
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 said 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."*

*The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.*

  
**Registrar Corp**  
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David Lemnarz  
Executive Director  
Registrar Corp  
Dated: *June 15, 2021*

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<http://www.myfda.com/fda-md-reg/36499aaf5>

  
**Certificate of Compliance**

Application for  
Medical Device Directive (MDD) 93/42/EEC.  
This is to certify that the product(s):  
**Medical Face Mask, Medical Gloves.**  
Manufactured by  
**THAI SON MEDICAL INVESTMENT JOINT STOCK COMPANY**  
Office: No.14D, Alley 30, Phan Dinh Giot Street,  
Phuong Liet Ward, Thanh Xuan District, Hanoi City, Vietnam.  
Factory 1: Lot B2-9, Cu Chi Northwest Industrial Park,  
Tan An Hoi Commune, Cu Chi District, Ho Chi Minh City, Vietnam  
Factory 2: Bui Tram Hamlet, Hoa Son Commune,  
Luong Son District, Hoa Binh Province, Vietnam.

Complies with the requirement of the  
"Test Standard: EN 14683:2019 & EN 455/1/2/3"

has been assessed & found in accordance with the requirements of  
**MDD 93/42/EEC as amended by 2007/47/EC Class I (Non-Sterile).**  
QCC is non-notified certification body, issue this  
'compliance certificate' after audit of manufacturer product(s) & technical file(s).  
This certificate applies to the tested sample only not for whole production.  
It's manufacturer sole responsibility to meet all the necessary conformity  
assessment activities according to MDD 93/42/EEC and related standards  
before placing them on the market & CE mark on the product(s).

Certificate No. : **CE/022338/0621**  
Original Certificate Date : 02 - June - 2021  
Issue Date : 02 - June - 2021  
Expiry Date : 01 - June - 2022

To check this certificate status visit:  
"http://uasl.uk.com/certifiedorganization.html"

  
Authorised Signature  
**For Quality Control Certification**  
UK Office: 1929, Chynoweth House,  
Trevissome Park, Truro-TR48UN, Cornwall, UK


Quality Control Certification accredited by UASL, UK.  
This certificate doesn't provide the certified organisation with immunity from its legal obligations.  
This certificate remains the property of QC Certification to whom it must be returned on request.

<https://uasl.uk.com/certifiedorganization/>



# CERTIFICATE

  
**CERTIFICATE**  
No.: **YT 586-21**

**THAI SON MEDICAL INVESTMENT JOINT STOCK COMPANY**  
No. 14D Lane 30, Phan Dinh Giot street, Phuong Liet ward, Thanh Xuan district, Hanoi, Viet Nam

has been assessed and found to conform with the requirements of the following standard:

**ISO 13485:2016**  
Quality Management System

for the following activities:

**Production and trading of medical masks, trading of medical gloves**

This certificate is valid from:  
16 / 6 / 2021 to 15 / 6 / 2024

CERTIFICATION BOARD  
CHAIRMAN  
  
Professor, Dr. Nguyen Hong Son

  
ISO 13485:2016  
535304 700368

ON BEHALF OF DIRECTOR  
VICE DIRECTOR  
  
Dr. Ngo Tat Thang



INSTITUTE FOR STANDARD AND QUALITY DEVELOPMENT STUDIES  
Office: No. 52, lane 46, Lien Mac road, Lien Mac ward, Bac Tu Liem district, Ha Noi city, Vietnam  
Tel: 024 2266 1111 Email: iqvni@issq.org.vn



**GIẤY CHỨNG NHẬN**  
**CERTIFICATE**

Chứng nhận hệ thống quản lý chất lượng cho lĩnh vực trang thiết bị y tế của  
*This is to certify that Medical devices - Quality Management System of*

**CÔNG TY CỔ PHẦN ĐẦU TƯ Y TẾ THÁI SƠN**  
**THAI SON MEDICAL INVESTMENT JOINT STOCK COMPANY**

Địa chỉ/ Address

Trụ sở: Số nhà 14D Ngõ 30, Phố Phan Đình Giót, Phường Phương Liệt, Quận Thanh Xuân, Thành phố Hà Nội, Việt Nam/ Office: No. 14D Lane 30, Phan Dinh Giot Street, Phuong Liet Ward, Thanh Xuan District, Hanoi City, Vietnam  
Địa chỉ sản xuất: Lô B2-9, Khu công nghiệp Tây Bắc Củ Chi, Xã Tân An Hội, Huyện Củ Chi, Thành phố Hồ Chí Minh, Việt Nam/ Production address: Lot B2-9, Cu Chi Northwest Industrial Park, Tan An Hoi Commune, Cu Chi District, Ho Chi Minh City, Vietnam

Đã được đánh giá và phù hợp với các yêu cầu của tiêu chuẩn  
*Has been assessed and found to confirm with the requirements of the following standard*

**ISO 13485:2016**

Cho lĩnh vực/ For the following activities

Sản xuất và kinh doanh găng tay y tế  
*Manufacturing and trading medical gloves*

Chứng chỉ số/ Certification No: **21.10497-MMS/TTP**  
Ngày cấp/ Issue date: .../.../2021  
Ngày hết hạn/ Expiry date: .../.../2024

Đại diện TTP/ On behalf of TTP  
Giám đốc/ Director

  
ISO 13485:2016

**LÊ HOÀNG NHẬT LINH**

CÔNG TY CỔ PHẦN CHỨNG NHẬN VÀ GIÁM ĐỊNH TTP (TTP Certification And Inspection Joint Stock Company)  
Số 208 Phố Mạc Anh Tuấn, Phường Thành Công, Quận Ba Đình, TP. Hà Nội, Việt Nam  
http://tjpcst.com.vn itj@tjpcst.com.vn 024-3229 2616

**Test Report No. 7191265396-EEC21-01-WBH**  
dated 16 Aug 2021



PSB Singapore

Add value.  
Inspire trust.

**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.

**SUBJECT**

Testing of Gloves

**CLIENT**

THAI SON MEDICAL INVESTMENT JOINT STOCK COMPANY  
No.14D, lane 30, Phan Dinh Giot street, Phuong Liet ward,  
Thanh Xuan district, Hanoi,  
Vietnam

**SAMPLE SUBMISSION DATE/ TEST DATE**

28 Jul 2021/ 02 Aug 2021 to 14 Aug 2021

**DESCRIPTION OF SAMPLES**

S/N	Product Description	Brand/ Model	Size	Colour	Lot No.	Expiry Date	Sample Received (pieces)	Manufacturer
1	Nitrile Gloves	THAI SON	M	Blue	TS012	07.2024	700	THAI SON MEDICAL INVESTMENT JOINT STOCK COMPANY



**Laboratory:**  
TÜV SÜD PSB Pte. Ltd.  
15 International Business Park  
TÜV SÜD @ IBP  
Singapore 609937

Phone : +65-6778 7777  
E-mail: info.sg@tuvsud.com  
<https://www.tuvsud.com/sg>  
Co. Reg : 199002667R

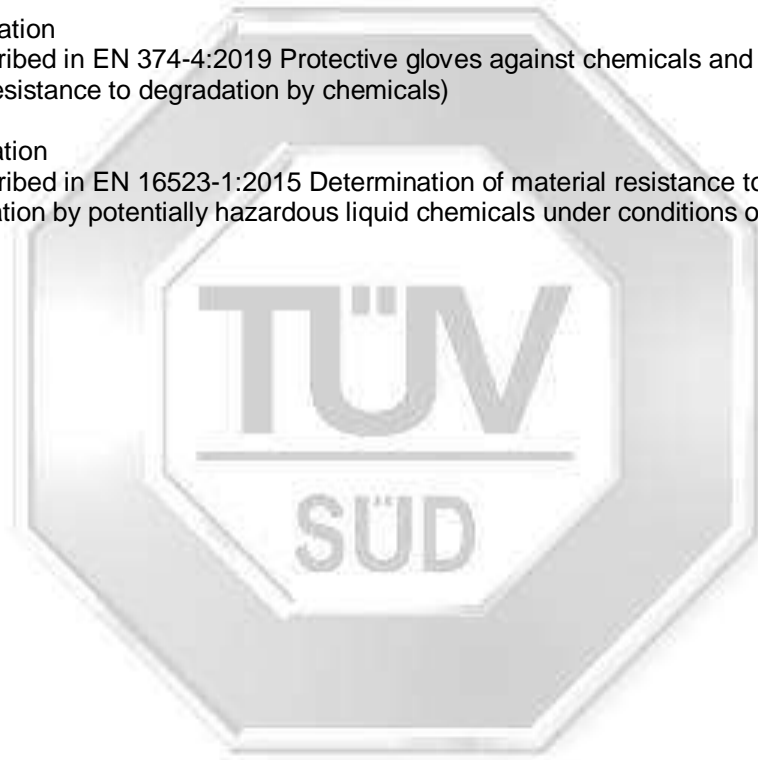
**Regional Head Office:**  
TÜV SÜD Asia Pacific Pte. Ltd.  
15 International Business Park  
TÜV SÜD @ IBP  
Singapore 609937  
TUV

## **METHOD OF TEST**

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

BS EN ISO 374-1:2016+A1:2018 Protective gloves against dangerous chemicals and micro-organisms  
Part 1: Terminology and performance requirements for chemical risks

- Clause 5.1 General requirements  
(Test method described in EN 420:2003+A1:2009 Protective gloves – General requirements and test methods)
- Clause 5.2 Penetration  
(Test method described in EN 374-2:2014 Protective gloves against dangerous chemicals and micro-organisms – Part 2: Determination of resistance to penetration)
- Clause 5.3 Degradation  
(Test method described in EN 374-4:2019 Protective gloves against chemicals and micro-organisms. Determination of resistance to degradation by chemicals)
- Clause 5.4 Permeation  
(Test method described in EN 16523-1:2015 Determination of material resistance to permeation by chemicals. Permeation by potentially hazardous liquid chemicals under conditions of continuous contact)



## RESULTS

Sample: Nitrile Gloves, THAI SON, Blue, Size M

Table 1: Results for tests according to BS EN ISO 374-1:2016+A1:2018 Clauses 5.1-5.4

Clause	Tests	Specification	Results		Inferred Result
5.1	General Requirement	Protective gloves against dangerous chemicals shall comply with the requirements given in EN 420:2009, Clause 4, Clause 5 and Clause 7.	Refer to Table 2 for results of EN 420, Clause 4 and Clause 5 for applicable tests.  The submitted glove and packaging not tested to EN 420 Clause 7 Marking and information as requested by client.		Passed  Not tested
5.2	Penetration	Protective gloves shall not leak when tested according to EN 374-2:2014, 7.2 and 7.3. 7.2 Air leak test 7.3 Water leak test	No leakage for both tests		Passed
5.3	Degradation	The degradation (DR) shall be determined according to EN 374-4 for each chemical claimed in the marking and reported in the user instruction.	Tested Chemicals	Average Degradation Results (%)	NA
			40% Sodium Hydroxide	1.6	
5.4	Permeation	Each combination of protective glove/test chemical shall be classified according to Table A (see remark 5), using the results as given in EN 16523-1:2015, 8.5.1.1 or 8.5.1.3 for the normalized breakthrough time.  For Type C: The permeation performance shall be at least level 1 against minimum of one test chemicals	Tested Chemicals	Permeation performance level	Passed
			40% Sodium Hydroxide	6	

## RESULTS (cont'd)

Sample: Nitrile Gloves, THAI SON, Blue, Size M

Table 2: Results for EN 420:2003+A1:2009

Test	EN 420:2003+A1:2009 Requirements		Results	Inferred Results
I. Determination of pH Value, pH value	> 3.5 and < 9.5		7.6	Passed
II. Sizing, minimum length of glove (mm)	Size	Minimum length of glove (mm)	240	Passed
	M (8)	240		
III. Dexterity, level of performance	Level of performance	Smallest pin diameter fulfilling test conditions (mm)	5	(see Remark 1)
	1	11		
	2	9.5		
	3	8		
	4	6.5		
	5	5		

Table 3: Results for Degradation

S/N	Tested Chemicals	Degradation Results (%)				
		Glove 1	Glove 2	Glove 3	Average	Standard Deviation
1	40% Sodium Hydroxide	-5.1	4.3	5.5	1.6	5.8

Table 4: Results for Permeation

S/N	Tested Chemicals	Normalised Breakthrough Time (mins)				Level
		Glove 1	Glove 2	Glove 3	Average	
1	40% Sodium Hydroxide	>480	>480	>480	>480	6

## REMARKS

1. A glove should allow as much dexterity as possible given its purpose. Four gloves were tested and smallest performance level was reported.
2. For Clause 5.2 Penetration, the test sample will be four gloves per performed test (Air leak test and Water leak test). If one sample fails the penetration test, the test shall be reported as having failed.
3. For Clause 5.3 Degradation, the test specimens for each size will be 3 gloves and 6 specimens will be cut from each glove. For each glove, 3 specimens will be exposed to each of the tested chemical and 3 specimens will be unexposed. After prepare the specimens, and exposed to tested chemical for 1 hour, puncture the specimen and record the peak force required.

Positive values: The material has become weaker after chemical exposure.

Negative values: The material has become harder after chemical exposure.

**REMARKS (cont'd)**

4. For Clause 5.4 Permeation, The palm area of the glove sample was mounted between two halves of a test cell. The test cell consisted of a two-compartment cell with tested chemicals on glove's normal outside surface and Ultrapure Water on the glove's normal inside surface. Testing were carried out at ambient temperature ( $23^{\circ}\text{C} \pm 2^{\circ}\text{C}$ ). The collecting medium were sampled and analysed for tested chemical at 10 min (level 1), 30 min (level 2), 60 min (level 3), 120 min (level 4) , 240 min (level 5) and 480 min (level 6). The extracts were then analysed by the below instruments for different tested chemicals.

40% Sodium Hydroxide --- pH Meter

The results were used to calculate the permeation rate of tested chemicals through the glove material. Based on the result, the minimum rate of sampling was determined.

40% Sodium Hydroxide --- The tests were repeated at 10 min, 30 min, 60 min, 120 min, 240 min and 480 min.

The extracts were then analysed by instruments for chemicals for the Normalised Permeation Rate. A blank test was carried out exactly with the same procedure except Ultrapure Water was used.


Note: Chemical transfer referred to the quantity of chemical which had passed through per  $\text{cm}^2$  of glove sample at the termination of the test. The thickness of the glove is 0.06mm.

5. Table for classification of permeation performance levels according to breakthrough time for Clause 5.4 Permeation.

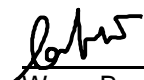
Breakthrough Time (mins) *	Permeation performance level
> 10	1
> 30	2
> 60	3
> 120	4
> 240	5
> 480	6

\* The breakthrough time is deemed to have occurred when the analytical equipment detects a permeation rate of  $1 \mu\text{g}/\text{cm}^2/\text{min}$ .

6. NA: Not applicable



Yeo Poh Kwang  
Associate Engineer



Wong Bee Hui  
Product Manager  
Medical Health Services (NAM)

**APPENDIX**



Photo: Nitrile Gloves, THAI SON, Blue, Size M



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

1. This report applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB in any way "guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific product/equipment.
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 26 January 2021







**Report No.:** 242127567-01 Page 1 of 7

**Client:** THAI SON MEDICAL INVESTMENT JOINT STOCK COMPANY LIMITED

**Contact Information:** No.14D, Lane 30, Phan Dinh Giot Street,  
Phuong Liet Ward, Thanh Xuan District, Vietnam

**Identification /** NITRILE GLOVES

**Model No(s):**

**Sample Receiving date:** 2021-07-30

**Testing Period:** 2021-07-30 to 2021-08-25

**Delivery condition:** *Apparent good, Samples tested as received.*

**Test Specification:**

**Test result:**

Test parameter and specification was selected by client

- |   |                      |
|---|----------------------|
| 1. EN 455-1: 2020: Requirements for freedom from holes      | PASS                 |
| 2. EN 455-2: 2015: Physical properties test;                | PASS                 |
| - Dimension test  | PASS                 |
| - Force at break test                                       | PASS                 |
| 3. EN 455-3: 2015, Annex A : Proteins extraction by aqueous | Refer to result page |

**Other Information:**

Lot No.: TS012

Material type: Nitrile

Manufacture: Thai Son Medical Investment Joint Stock Company Limited

Country of Origin: Vietnam

Country of Destination: Thailand

**For and on behalf of**  
**TÜV Rheinland Thailand Ltd.**



2021-08-25

Wilawan Sriprom / Manager

**Date**

**Name/Position**

*Test result is drawn according to the kind and extent of tests performed. The laboratory applied decision rule for giving verdict, considering measurement of un-certainty at 95% confident level. This test report relates to the above mentioned test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any safety mark on this or similar products*



<b>Test Report No.: 242127567-01</b>	Page 2 of 7
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**Sampling Information:**

Inspection Method: No inspection, submitted sample by client

**Material list:**

Item: NITRILE GLOVES

Material No.	Material	Color	Location
M001	Nitrile glove	Blue	Size M


**Test Report No.: 242127567-01**

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**Freedom from holes**

Test method: With reference to EN 455-1: 2020

Test result:

Gloves Size	Tested samples	No. of samples for Non-compliance	Conclusion
M	200	11	PASS

Remark:

- Information of batch size or sample size is not provided by client.
- All samples were selected and supplied by the client.
- According to test requirement, each lot shall be samples for single sampling plan using general inspection level I and corresponding acceptance/rejection number equivalent to sample size code letter L. The compliance level for freedom from holes shall be an AQL of 0.65 for surgical gloves and 1.5 for examination gloves.
- A minimum sample size equivalent to sample size code letter L ensure that an adequate assessment of the quality of the lot is obtained when the lot size is small or unknown.

Inspection level	Sample size	AQL	Accept	Reject
G-I, code letter L	200	0.65	3	4
G-I, code letter L	200	1.5	7	8

**Test Report No.: 242127567-01**

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**Dimension test**

Test method: With reference to EN 455-2: 2015

Test results:

<b>Test No.:</b>	<b>T001</b>	
<b>Material No.:</b>	<b>M001</b>	
<b>Size:</b>	<b>M</b>	
<b>Tested no.</b>	<b>Length (mm)</b>	<b>Width (mm)</b>
1	245	100
2	239	99
3	240	100
4	248	100
5	236	100
6	245	99
7	243	100
8	246	100
9	240	100
10	242	99
11	244	100
12	242	100
13	247	100
Median result	243	100
Conclusion	Pass	Pass

Abbreviation: mm = Millimeter

Remark: Dimension limit reference to table

Size	Median length (mm)	Median width (mm)
Extra small	≥ 240	≤ 80
Small		80±10
Medium		95±10
Large		110±10
Extra large		≥ 110

**Test Report No.: 242127567-01**

Page 5 of 7

**Force at break**

Test method: With reference to EN 455-2: 2015

Test results:

Test No.	T001	
Material No.	M001	
Tested no.	Before ageing (N)	After ageing (N)
1	5.47	6.01
2	5.77	6.26
3	6.07	6.79
4	6.02	6.62
5	5.44	6.41
6	5.61	5.61
7	6.12	5.96
8	6.15	6.14
9	5.54	5.50
10	5.58	7.46
11	5.60	5.73
12	5.86	7.29
13	5.88	6.92
Median result	5.78	6.36
Conclusion	Pass	Pass

Abbreviation: N = Newton

Remark:

1. Median values of force at break

Force at Break (newton)		
a)	b)	c)
≥ 9.0	≥ 6.0	≥ 3.6

a) Requirements for all surgical gloves

b) Requirements for all examination gloves, except gloves made from thermoplastic materials (e.g. Polyvinylchloride, Polyethylene)

c) Requirements for gloves made from thermoplastic materials (e.g. Polyvinylchloride, Polyethylene)



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**Proteins extraction**

Test method: With reference to EN 455-3: 2015, Annex A.

Test result:

Test No.	Material No.	Test parameter	Unit	LOQ	Test result
T001	M001	Proteins	µg/g	10	<10

Abbreviation: <= Less than

LOQ = Limit of Quantitative

µg/g = Microgram per gram of glove

**Remark:**

According to standard requirements, the lower quantification limit is approximately 10 µg protein per gram of glove (i.e. 2 µg protein per ml of extract) depending on the glove weight and the manufacturers shall strive to minimize the leachable protein level.

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Sample photo:



- END -

## General Terms and Conditions of Business of TÜV Rheinland Thailand Ltd.

1. **Scope**
- 1.1 The following terms and conditions apply to agreed services including consultancy services, information, deliveries and similar services as well as ancillary services and other secondary obligations provided within the scope of contract performance.
- 1.2 The client's General Terms and Conditions of Business, including the client's Terms and Conditions of Purchasing, if any, shall not apply and shall hereby be expressly excluded. No contractual terms and conditions of the client shall form part of the contract even if TÜV Rheinland Thailand Ltd. does not explicitly object to them.
2. **Quotations**
- Unless otherwise agreed, all quotations submitted by TÜV Rheinland Thailand Ltd. shall be subject to change without notice.
3. **Coming into effect and duration of contracts**
- 3.1 The contract shall come into effect for the agreed term upon the quotation letter of TÜV Rheinland Thailand Ltd. or a separate contractual document being signed by both contracting parties, or upon the works requested by the client being carried out by TÜV Rheinland Thailand Ltd.. If the client instructs TÜV Rheinland Thailand Ltd. without receiving a prior quotation from TÜV Rheinland Thailand Ltd. (quotation), TÜV Rheinland Thailand Ltd. is – in its sole discretion – entitled to accept the order by giving written notice of such acceptance (including notice sent via electronic means) or by performing the requested services.
- 3.2 The contract term starts upon the coming into effect of the contract in accordance with article 3.1 and shall continue for the term agreed in the contract.
- 3.3 If the contract provides for an extension of the contract term, the contract term will be extended by the term provided for in the contract unless terminated in writing by either party with a six-week notice to the end of the contractual term.
4. **Scope of services**
- 4.1 The scope of the services shall be decided solely by a unanimous declaration issued by both parties. If no such declaration exists, then the written confirmation of order by TÜV Rheinland Thailand Ltd. shall be decisive.
- 4.2 The agreed services shall be performed in compliance with the regulations in force at the time the contract is entered into.
- 4.3 Furthermore, TÜV Rheinland Thailand Ltd. is entitled to determine (in its sole discretion) the method and nature of the assessment unless otherwise agreed in writing or if mandatory provisions require a specific procedure to be followed.
- 4.4 On execution of the work there shall be no simultaneous assumption of any guarantee of the correctness (proper quality) and working order of either tested or examined parts nor of the installation as a whole and its upstream and/or downstream processes, organisations, use and application in accordance with regulations, nor of the systems on which the installation is based; in particular, no responsibility shall be assumed for the construction, selection of materials and assembly of installations examined, nor for their use and application in accordance with regulations unless these questions are expressly covered by the contract.
- 4.5 In the case of inspection work, TÜV Rheinland Thailand Ltd. shall not be responsible for the accuracy or checking of the safety programmes or safety regulations on which the inspections are based, unless otherwise expressly agreed in writing.
5. **Performance periods/dates**
- 5.1 The contractually agreed periods and dates of performance are based on estimates of the work involved which are prepared in line with the details provided by the client. They shall only be binding if confirmed as binding by TÜV Rheinland Thailand Ltd. in writing.
- 5.2 If binding periods of performance have been agreed, these periods shall not commence until the client has submitted all required documents to TÜV Rheinland Thailand Ltd. This also applies, even without express approval by the client, to all extensions of agreed dates for performance not caused by TÜV Rheinland Thailand Ltd..
6. **The client's obligation to cooperate**
- 6.1 The client shall guarantee that all cooperation required on its part, its agents or third parties will be provided in good time and at no cost to TÜV Rheinland Thailand Ltd..
- 6.2 Design documents, supplies, auxiliary staff, etc. necessary for performance of the services shall be made available free of charge by the client. Moreover, collaborative action of the client must be undertaken in accordance with legal provisions, standards, safety regulations and accident prevention instructions.
- 6.3 The client shall bear any additional cost incurred on account of work having to be redone or being delayed as a result of late, incorrect or incomplete information or lack of proper cooperation. Even where a fixed or maximum price is agreed, TÜV Rheinland Thailand Ltd. shall be entitled to charge extra for such additional expense.
7. **Invoicing of work**
- 7.1 If the scope of performance is not laid down in writing when the order is placed, invoicing shall be based on costs incurred. If no payment is agreed in writing, invoicing shall be in accordance with the TÜV Rheinland Thailand Ltd. price list valid at the time of performance.
- 7.2 Unless otherwise agreed, work shall be invoiced according to the progress of the work.
- 7.3 If the execution of an order extends over more than one month and the value of the contract or the agreed fixed price exceeds €2,500.00, TÜV Rheinland Thailand Ltd. may demand payments on account or in instalments.
8. **Payment terms**
- 8.1 All invoice amounts shall be due for payment without deduction on receipt of the invoice. No discounts shall be granted.
- 8.2 Payments shall be made to the bank account of TÜV Rheinland Thailand Ltd. as indicated on the invoice, stating the invoice and customer numbers.
- 8.3 In cases of default of payment, TÜV Rheinland Thailand Ltd. shall be entitled to claim default interest at a rate of 8% above the base interest rate of German central bank (Deutsche Bundesbank). At the same time, TÜV Rheinland Thailand Ltd. reserves the right to claim further damages.
- 8.4 Should the client default in payment of the invoice despite being granted a reasonable grace period, TÜV Rheinland Thailand Ltd. shall be entitled to cancel the contract, withdraw the certificate, claim damages for non-performance and refuse to continue performance of the contract.
- 8.5 The provisions set forth in article 8.4 shall also apply in cases involving returned cheques, cessation of payment, and commencement of insolvency proceedings against the client's assets or cases in which the commencement of insolvency proceedings has been dismissed due to lack of assets.
- 8.6 Objections to the invoices of TÜV Rheinland Thailand Ltd. shall be submitted in writing within two weeks of receipt of the invoice.
- 8.7 TÜV Rheinland Thailand Ltd. shall be entitled to demand appropriate advance payments.
- 8.8 TÜV Rheinland Thailand Ltd. shall be entitled to raise its fees at the beginning of a month if overheads and/or purchase costs have increased. In this case, TÜV Rheinland Thailand Ltd. shall notify the client in writing of the rise in fees. This notification shall be issued one month prior to the date on which the rise in fees shall come into effect (period of notice of changes in fees). If the rise in fees remains under 5% per contractual year, the client shall not have any special right of termination. If the rise in fees exceeds 5% per contractual year, the client shall be entitled to terminate the contractual relationship by the end of the period of notice of changes in fees. If the contract is not terminated, the changed fees shall be deemed to have been agreed upon expiry of the above period.
- 8.9 Only legally established and undisputed claims may be offset against claims by TÜV Rheinland Thailand Ltd.
9. **Acceptance**
- 9.1 Any part of the work ordered which is complete in itself may be presented by TÜV Rheinland Thailand Ltd. for acceptance as an instalment. The client shall be obliged to accept it immediately.
- 9.2 If the client fails to fulfil its acceptance obligation immediately, acceptance shall be deemed to have taken place 4 calendar weeks after performance of the work if TÜV Rheinland Thailand Ltd. has specifically made the client aware of the aforementioned deadline upon performance of the service.
10. **Confidentiality**
- 10.1 For the purpose of this agreement, "confidential information" means all information, documents, images, drawings, know-how, data, samples and project documentation which one party (the "disclosing party") hands over, transfers or otherwise discloses to the other party (the "receiving party"). Confidential information also includes paper copies and electronic copies of such information.
- 10.2 The disclosing party shall mark all confidential information disclosed in written form as confidential before passing it on to the receiving party. The same applies to confidential information transmitted by e-mail. If confidential information is disclosed orally, the receiving party shall be appropriately informed in advance.
- 10.3 All confidential information which the disclosing party transmits or otherwise discloses to the receiving party in accordance with this agreement:
- may only be used by the receiving party for the purposes of performing the purpose of the contract, unless expressly otherwise agreed in writing with the disclosing party;
  - may not be copied, distributed, published or otherwise disclosed by the receiving party, unless this is necessary for fulfilling the purpose of



- the contract or TÜV Rheinland Thailand Ltd. is required to pass on confidential information, inspection reports or documentation to the authorities or third parties that are involved in the performance of the contract;
- c) must be treated by the receiving party with the same level of confidentiality as the receiving party uses to protect its own confidential information, but never with a lesser level of confidentiality than that which is objectively required.
- 10.4 The receiving party shall disclose any confidential information received from the disclosing party only to those of its employees who need this information to perform the services required for the subject matter of this contract. The receiving party undertakes to oblige these employees to observe the same level of secrecy as set forth in this confidentiality clause.
- 10.5 Information for which the receiving party can furnish proof that:
- it was generally known at the time of disclosure or has become general knowledge without violation of this agreement; or
  - it was disclosed to the receiving party by a third party entitled to disclose this information; or
  - the receiving party already possessed this information prior to disclosure by the disclosing party; or
  - the receiving party developed it itself, irrespective of disclosure by the disclosing party, shall not be deemed to constitute "confidential information" as defined in this agreement.
- 10.6 All confidential information shall remain the property of the disclosing party. The receiving party hereby agrees to immediately (i) return all confidential information, including all copies, to the disclosing party, and/or, on request by the disclosing party, to (ii) destroy all confidential information, including all copies, and confirm the destruction of this confidential information to the disclosing party in writing, at any time if so requested by the disclosing party but at the latest and without special request after termination or expiry of this contract. This does not extend to include reports and certificates prepared for the client solely for the purpose of fulfilling the obligations under this contract, which shall remain with the client. However, TÜV Rheinland Thailand Ltd. is entitled to make file copies of such reports, certificates and confidential information that form the basis for preparing these reports and certificates in order to evidence the correctness of its results and for general documentation purposes.
- 10.7 From the start of this contract and for a period of three years after termination or expiry of this contract, the receiving party shall maintain strict secrecy of all confidential information and shall not disclose this information to any third parties or use it for itself.
- 11. Copyrights**
- 11.1 TÜV Rheinland Thailand Ltd. shall retain all exclusive and joint copyrights in the expert reports, test results, calculations, presentations etc. prepared by TÜV Rheinland Thailand Ltd..
- 11.2 The client may only use expert reports, test results, calculations, presentations etc. prepared within the scope of the contract for the contractually agreed purpose.
- 11.3 The client may use test reports, test results, expert reports, etc. only complete and unshortened. Any publication or duplication for advertising purposes needs the prior written approval of TÜV Rheinland Thailand Ltd..
- 12. Liability of TÜV Rheinland Thailand Ltd.**
- 12.1. Irrespective of the legal basis and in particular in the event of a breach of contractual obligations and tort, the liability of TÜV Rheinland Thailand Ltd. for all damage, loss and reimbursement of expenses caused by legal representatives and/or employees of TÜV Rheinland Thailand Ltd. shall be limited to: (i) in the case of contract with a fixed overall fee, ten times the overall fee for the entire contract; (ii) in the case of contracts for annually recurring services, to the agreed annual fee; (iii) in the case of contracts expressly charged on a time and material basis to a maximum of 20,000 Euro and (iv) in the case of framework agreements that provide for the possibility of placing individual orders, to an amount equal to three times the fee for the individual order under which the damage occurred. The maximum liability of TÜV Rheinland Thailand Ltd. is limited in any event of damage or loss to 2.5 Mio Euro.
- 12.2. The limitation of liability according to article 12.1 above shall not apply to all damage and losses caused by malice, intent or gross negligence on the part of any of the legal representatives of TÜV Rheinland Thailand Ltd. or their vicarious agents. Such limitation shall also not apply to damages arising from a violation of obligations which TÜV Rheinland Thailand Ltd. has guaranteed to perform, damages caused by a person's death, physical injury or illness, or damages for which liability is assumed under the Thai Law.
- 12.3 In cases involving a fundamental breach of contract, TÜV Rheinland Thailand Ltd. will be liable even where minor negligence is involved. For this purpose, a "fundamental breach" is a material contractual obligation, the performance of which permits the due performance of the contract and which the client may rely on being complied with. Any claim for damages for a fundamental breach of contract shall be limited to the amount of damage reasonably foreseen as a possible consequence of such breach of contract at the time of the breach (reasonably foreseeable damage), unless any of the circumstances described in article 12.2 apply.
- 12.4 TÜV Rheinland Thailand Ltd. shall not be liable for personnel made available by the client to support TÜV Rheinland Thailand Ltd. in the performance of its services regulated under this contract, unless personnel made available may be regarded as vicarious agents of TÜV Rheinland Thailand Ltd.. If TÜV Rheinland Thailand Ltd. is not liable for personnel made available by the client under the foregoing provision, the client shall indemnify TÜV Rheinland Thailand Ltd. against any claims made by third parties.
- 12.5 The limitation periods for claims for damages shall be based on statutory provisions.
- 12.6 None of the provisions of this article 12 changes the burden of proof to the disadvantage of the client.
- 13. Partial invalidity, written form, place of jurisdiction**
- 13.1 No ancillary agreements to this contract have been concluded.
- 13.2 All amendments and supplements must be in writing in order to be effective; this also applies to amendments and supplements to the requirement for the written form.
- 13.3 Should one or several of the provisions under this contract be or become ineffective, the contracting parties shall replace the invalid provision with a legally valid provision that comes closest to the content of the invalid provision in legal and commercial terms.
- 13.4 The place of jurisdiction for all disputes arising in connection with this contract shall be Bangkok, Thailand. This contract is governed by the Thailand substantive law.

Status: July 19, 2013



# THANK YOU

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