

**Test Report No. : CRSSA/200946451-CA45818**  
**Company : Siraphan Samoonprai Co., Ltd.**  
**456 Moo 5 Tambol Bangphra,**  
**Amphur Sriracha,**  
**Chonburi 20110**

### TEST REPORT


Sample Description : Examination Glove Nitrile Powder-Free, Non-Sterile  
Brand Name : SIRAPHAN 28  
Style : Size S  
Lot No. : 01062001  
Colour : Blue  
Manufacturer : Siraphan Samoonprai Co., Ltd.  
Production Date : 01/06/2020  
Country of Origin : Thailand  
Country of Destination : USA  
Size : S  
Quantity Tested : 200 pieces  
Test Conducted : Freedom from holes  
Test Method : EN455 Part 1:2000  
Testing Period : 04 September 2020 – 17 September 2020

Based on submitted samples, the following results obtained :-

Acceptable Quality Limit (AQL) : 1.5      Accept : 7      Found : 10

Result : Beyond AQL

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SECTION HEAD  
IKM No. M/3983/6401/12/14

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**TEST REPORT**

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 Brand Name : SIRAPHAN 28  
 Style : Size S  
 Lot No. : 01062001  
 Colour : Blue  
 Manufacturer : Siraphan Samoonprai Co., Ltd.  
 Production Date : 01/06/2020  
 Country of Origin : Thailand  
 Country of Destination : USA  
 Size : S  
 Quantity Tested : 13 pieces  
 Test Conducted : Dimensions  
 Test Method : EN 455 Part 2:2015  
 Testing Period : 04 September 2020 – 17 September 2020

Based on submitted samples, the following results obtained :-

Size	S	S	S	S	S	S	S	S	S	S	S	S	S	Median
Width Median: 80±10mm	82	83	84	83	83	82	83	83	82	83	84	83	82	83
Length Median: ≥ 240mm	251	248	249	244	251	248	251	252	253	252	252	247	247	251

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**TEST REPORT**

Sample Description : Examination Glove Nitrile Powder-Free, Non-Sterile  
 Brand Name : SIRAPHAN 28  
 Style : Size S  
 Lot No. : 01062001  
 Colour : Blue  
 Manufacturer : Siraphan Samoonprai Co., Ltd.  
 Production Date : 01/06/2020  
 Country of Origin : Thailand  
 Country of Destination : USA  
 Size : S  
 Quantity Tested : 13 pieces per each  
 Test Conducted : Force at Break During Shelf Life and After Challenge  
 Test Method : EN 455 Part 2:2015  
 Ageing : 70 ± 2 Deg C for 168 hrs  
 Testing Period : 04 September 2020 – 17 September 2020

SIZE	SAMPLE NO.	Force at Break, N	
		<u>BEFORE AGING</u>	<u>AFTER AGING</u>
S	1	5.6	6.3
	2	5.5	4.3
	3	5.9	5.5
	4	6.3	5.3
	5	5.6	5.7
	6	4.8	4.7
	7	5.6	5.4
	8	5.6	6.6
	9	5.4	5.7
	10	5.6	5.0
	11	5.5	4.4
	12	5.1	5.7
	13	4.7	4.4
Median		5.6	5.4
Requirement		≥ 6.0	≥ 6.0

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**Company : Siraphan Samoonprai Co., Ltd.**  
**456 Moo 5 Tambol Bangphra,**  
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**Chonburi 20110**


### TEST REPORT

Sample Description : Examination Glove Nitrile Powder-Free, Non-Sterile  
Brand Name : SIRAPHAN 28  
Style : Size S  
Lot No. : 01062001  
Colour : Blue  
Manufacturer : Siraphan Samoonprai Co., Ltd.  
Production Date : 01/06/2020  
Country of Origin : Thailand  
Country of Destination : USA  
Size : S  
Quantity Tested : 5 pieces  
Test Conducted : Powder Content  
Test Method : EN455 Part 3:2015  
Testing Period : 04 September 2020 – 17 September 2020

On testing the samples, the following results were obtained:-

<u>SIZE</u>	<u>Average Powder Mass per Glove</u>
S	1.32 mg

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**Company** : Siraphan Samoonprai Co., Ltd.  
 456 Moo 5 Tambol Bangphra,  
 Amphur Sriracha,  
 Chonburi 20110

**TEST REPORT**

Sample Description : Examination Glove Nitrile Powder-Free, Non-Sterile  
 Brand Name : SIRAPHAN 28  
 Style : Size S  
 Lot No. : 01062001  
 Colour : Blue  
 Manufacturer : Siraphan Samoonprai Co., Ltd.  
 Production Date : 01/06/2020  
 Country of Origin : Thailand  
 Country of Destination : USA  
 Size : S  
 Quantity Tested : 8 pieces  
 Test Conducted : Aqueous Extractable Protein Content  
 Test Method : EN455 Part 3:2015  
 Testing Period : 04 September 2020 – 17 September 2020

**EXTRACTABLE PROTEIN CONTENT**

Analysis had been carried out as per your request. We report the following results:

SIZE	AQUEOUS EXTRACTABLE PROTEIN CONTENT, µg/g
S	260

Note: 1) Detection limit = 10 µg/g  
 2) Interference was present in sample

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**Test Report No. : CRSSA/200946452-CA45819**  
**Company : Siraphan Samoonprai Co., Ltd.**  
**456 Moo 5 Tambol Bangphra,**  
**Amphur Sriracha,**  
**Chonburi 20110**

### TEST REPORT


Sample Description : Examination Glove Nitrile Powder-Free, Non-Sterile  
Brand Name : SIRAPHAN 28  
Style : Size XL  
Lot No. : 01062001  
Colour : Blue  
Manufacturer : Siraphan Samoonprai Co., Ltd.  
Production Date : 01/06/2020  
Country of Origin : Thailand  
Country of Destination : USA, Europe, Middle East, Australia  
Size : XL  
Quantity Tested : 200 pieces  
Test Conducted : Freedom from holes  
Test Method : EN455 Part 1:2000  
Testing Period : 04 September 2020 – 17 September 2020

Based on submitted samples, the following results obtained :-

Acceptable Quality Limit (AQL) : 1.5      Accept : 7      Found : 4

Result : Within AQL

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**Chonburi 20110**

**TEST REPORT**

Sample Description : Examination Glove Nitrile Powder-Free, Non-Sterile  
 Brand Name : SIRAPHAN 28  
 Style : Size XL  
 Lot No. : 01062001  
 Colour : Blue  
 Manufacturer : Siraphan Samoonprai Co., Ltd.  
 Production Date : 01/06/2020  
 Country of Origin : Thailand  
 Country of Destination : USA, Europe, Middle East, Australia  
 Size : XL  
 Quantity Tested : 13 pieces  
 Test Conducted : Dimensions  
 Test Method : EN 455 Part 2:2015  
 Testing Period : 04 September 2020 – 17 September 2020

Based on submitted samples, the following results obtained :-

Size	XL	XL	XL	XL	XL	XL	XL	XL	XL	XL	XL	XL	XL	Median
Width Median: ≥ 110mm	119	116	118	115	116	117	116	116	119	116	117	115	115	116
Length Median: ≥ 240mm	245	240	249	245	245	246	241	245	241	243	254	241	245	245

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**Chonburi 20110**

**TEST REPORT**

Sample Description : Examination Glove Nitrile Powder-Free, Non-Sterile  
 Brand Name : SIRAPHAN 28  
 Style : Size XL  
 Lot No. : 01062001  
 Colour : Blue  
 Manufacturer : Siraphan Samoonprai Co., Ltd.  
 Production Date : 01/06/2020  
 Country of Origin : Thailand  
 Country of Destination : USA, Europe, Middle East, Australia  
 Size : XL  
 Quantity Tested : 13 pieces per each  
 Test Conducted : Force at Break During Shelf Life and After Challenge  
 Test Method : EN 455 Part 2:2015  
 Ageing : 70 ± 2 Deg C for 168 hrs  
 Testing Period : 04 September 2020 – 17 September 2020

SIZE	SAMPLE NO.	Force at Break, N	
		<u>BEFORE AGING</u>	<u>AFTER AGING</u>
XL	1	7.6	7.5
	2	7.3	6.6
	3	6.5	7.1
	4	8.0	8.0
	5	7.2	6.9
	6	6.9	6.4
	7	7.2	6.1
	8	6.9	5.8
	9	7.6	7.0
	10	6.5	7.5
	11	6.4	5.5
	12	7.3	5.9
	13	6.9	6.0
Median		7.2	6.6
Requirement		≥ 6.0	≥ 6.0

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**Chonburi 20110**


### TEST REPORT

Sample Description : Examination Glove Nitrile Powder-Free, Non-Sterile  
Brand Name : SIRAPHAN 28  
Style : Size XL  
Lot No. : 01062001  
Colour : Blue  
Manufacturer : Siraphan Samoonprai Co., Ltd.  
Production Date : 01/06/2020  
Country of Origin : Thailand  
Country of Destination : USA, Europe, Middle East, Australia  
Size : XL  
Quantity Tested : 5 pieces  
Test Conducted : Powder Content  
Test Method : EN455 Part 3:2015  
Testing Period : 04 September 2020 – 17 September 2020

On testing the samples, the following results were obtained:-

<u>SIZE</u>	<u>Average Powder Mass per Glove</u>
XL	1.34 mg

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**Company** : Siraphan Samoonprai Co., Ltd.  
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 Amphur Sriracha,  
 Chonburi 20110

**TEST REPORT**

Sample Description : Examination Glove Nitrile Powder-Free, Non-Sterile  
 Brand Name : SIRAPHAN 28  
 Style : Size XL  
 Lot No. : 01062001  
 Colour : Blue  
 Manufacturer : Siraphan Samoonprai Co., Ltd.  
 Production Date : 01/06/2020  
 Country of Origin : Thailand  
 Country of Destination : USA, Europe, Middle East, Australia  
 Size : XL  
 Quantity Tested : 8 pieces  
 Test Conducted : Aqueous Extractable Protein Content  
 Test Method : EN455 Part 3:2015  
 Testing Period : 04 September 2020 – 17 September 2020

**EXTRACTABLE PROTEIN CONTENT**

Analysis had been carried out as per your request. We report the following results:

SIZE	AQUEOUS EXTRACTABLE PROTEIN CONTENT, µg/g
XL	66

Note: Detection limit = 10 µg/g

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สำนักงานคณะกรรมการอาหารและยา

Food and Drug Administration

CERTIFICATE OF ORIGIN

Ref.No. 1-1-08-02-20-01020

September 25, 2020

It is hereby certified that the following information concerning the product(s) to be exported listed below are the manufacturer which produces pursuant to the Medical Device Act 2008. The following product(s) is exported without restriction.

**Name of Manufacturer, Address**

Siraphan samoonprai Co., Ltd.

465 Moo 5 Bangphra, Si Racha Chonburi, 20110 Thailand.

**Name of Product(s)**

Siraphan 28 Examination Glove  
Size XS,S,M,L,XL

This certificate is only destined to the request of Siraphan samoonprai Co., Ltd..

Valid until 24 September 2022

Sittaya Sumananont

(Mrs. Sittaya Sumananont)  
Pharmacist, Senior Professional Level  
Person designated by the Secretary-General  
of the Food and Drug Administration

Division of Medical Device Control, Food and Drug Administration  
88/24 Tivanon Road, Nonthaburi 11000, Thailand  
Tel. (662) 590-7148, Fax. (662) 591-8445



สำนักงานคณะกรรมการอาหารและยา  
Food and Drug Administration

CERTIFICATE FOR EXPORTATION

Ref.No. 1-1-07-02-20-01039

September 25, 2020

It is hereby certified that the following information concerning the product(s) to be exported listed below are the manufacturer which produces is pursuant to the Medical Device Act 2008. The following product(s) is exported without restriction.

**Name of Manufacturer, Address**

Siraphan samoonprai Co., Ltd.  
465 Moo 5 Bangphra, Si Racha Chonburi, 20110 Thailand.

**Name of Product(s)**

Siraphan 28 Examination Glove  
Size XS,S,M,L,XL

This certificate is only destined to the request of Siraphan samoonprai Co., Ltd..

Valid until 24 September 2022

(Mrs. Sittaya Sumananont)

Pharmacist, Senior Professional Level  
Person designated by the Secretary-General  
of the Food and Drug Administration

Division of Medical Device Control, Food and Drug Administration  
88/24 Tivanon Road, Nonthaburi 11000, Thailand  
Tel. (662) 590-7148, Fax. (662) 591-8445









## CERTIFICATE OF REGISTRATION

*This certifies that:*

**SIRAPHAN SAMOONPRAI CO., LTD.**  
**456 Moo5, Tambon Bang Phra**  
**Sriracha Chon Buri, TH 20110**

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 Owner/Operator Number:  
Device Classification Name:

**10077301**  
**POLYMER PATIENT EXAMINATION**  
**GLOVE**  
**LZA**

Product Code:  
Regulation Number:  
Official Correspondent  
and U.S. Agent:

**880.6250**  
**Registrar Corp**  
144 Research Drive, Hampton, Virginia,  
23666, USA  
Telephone: +1-757-224-0177 • Fax: +1-757-  
224-0179

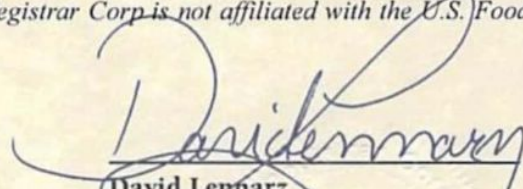
*Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does 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.*

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**Registrar Corp**

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info@registrarcorp.com • www.registrarcorp.com

  
David Lennarz  
Executive Director  
Registrar Corp  
Dated: August 24, 2020





ISO 13485:2016

**GSCS International Ltd.**

## Certificate of Registration

*This is to certify that*

**Medical Devices Quality Management System**

*Of*

**SIRAPHAN SAMOONPRAI CO., LTD.**

456 Moo 5, T.Bangphra, A.Siracha, Chonburi 20110 Thailand

*for*

**Manufacture of Latex Powdered Examination Gloves, Latex Powder Free Examination Gloves, Nitrile Examination Gloves**

*has been assessed and registered against the provision of*

**ISO 13485:2016**

*International Standard With*

Registration Number : 20011063  
Certification Date : 31 July, 2020  
First Surveillance Due date : 30 July, 2021  
Second Surveillance Due Date : 30 July, 2022  
Expiry date : 30 July, 2023

Project : GSCS-103-1004-M  
Code : C.32.99  
Exclusions : 7.3, 7.5.3, 7.5.4, 7.5.5, 7.5.7, 7.5.9.2  
Issue No : 01

Certification Approved By:

Managing Director



Registration is subject to the management system being continually maintained to the above standard under regular surveillance. Should surveillance not take place when required, registration shall be removed.

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GMP

**GSCS International Ltd.**

## Certificate of Registration

*This is to certify that*

**Good Manufacturing Practices**

*Of*

**SIRAPHAN SAMOONPRAI CO., LTD.**

456 Moo 5, T.Bangphra, A.Siracha, Chonburi 20110 Thailand

*for*

**Manufacture of Latex Powdered Examination Gloves, Latex Powder Free Examination Gloves, Nitrile Examination Gloves**

*has been assessed and registered against the provision of*

**GMP**

*International Standard With*

Registration Number : 20011064  
Certification Date : 31 July, 2020  
First Surveillance Due date : 30 July, 2021  
Second Surveillance Due Date : 30 July, 2022  
Expiry date : 30 July, 2023

Project : GSCS-103-1004-G  
Code : C.32.99  
Exclusions : N/A  
Issue No : 01

Certification Approved By:

Managing Director



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ISO 9001:2015



**GSCS International Ltd.**

## Certificate of Registration

*This is to certify that*

**Quality Management System**

*Of*

**SIRAPHAN SAMOONPRAI CO., LTD.**

456 Moo 5, T.Bangphra, A.Siracha, Chonburi 20110 Thailand

*for*

**Manufacture of Latex Powdered Examination Gloves, Latex Powder Free Examination Gloves, Nitrile Examination Gloves**

*has been assessed and registered against the provision of*

**ISO 9001:2015**

*International Standard With*

Registration Number : **20011062**  
Certification Date : **31 July, 2020**  
First Surveillance Due date : **30 July, 2021**  
Second Surveillance Due Date : **30 July, 2022**  
Expiry date : **30 July, 2023**

Project : **GSCS-103-1026-Q**  
Code : **C.32.99**  
Exclusions : **8.3**  
Issue No : **01**

Certification Approved By:

Managing Director



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ISO 13485:2016



**GSCS International Ltd.**

## Certificate of Registration

*This is to certify that*

**Medical Devices Quality Management System**

*Of*

**SIRAPHAN SAMOONPRAI CO., LTD.**

456 Moo 5, T.Bangphra, A.Siracha, Chonburi 20110 Thailand

*for*

**Manufacture of Latex Powdered Examination Gloves, Latex Powder Free Examination Gloves, Nitrile Examination Gloves**

*has been assessed and registered against the provision of*

**ISO 13485:2016 & EN ISO 13485:2016**

*International Standard With*

Registration Number : **20011063**  
Certification Date : **31 July, 2020**  
First Surveillance Due date : **30 July, 2021**  
Second Surveillance Due Date : **30 July, 2022**  
Expiry date : **30 July, 2023**

Project : **GSCS-103-1004-M**  
Code : **C.32.99**  
Exclusions : **7.3, 7.5.3, 7.5.4, 7.5.5, 7.5.7, 7.5.9.2**  
Issue No : **01**

Certification Approved By:

Managing Director



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**GSCS International Ltd.**

## Certificate of Registration

*This is to certify that*

**Food Safety Management System**

*Of*

**SIRAPHAN SAMOONPRAI CO., LTD.**

456 Moo 5, T.Bangphra, A.Siracha, Chonburi, 20110, THAILAND

*for*

**Manufacture of Latex Powdered Examination Gloves, Latex Powder Free Examination Gloves, Nitrile Examination Gloves**

*has been assessed and registered against the provision of*

**ISO 22000:2018**

*International Standard With*

Registration Number : **20011075**  
Certification Date : **28 August, 2020**  
First Surveillance Due date : **27 August, 2021**  
Second Surveillance Due Date : **27 August, 2022**  
Expiry date : **27 August, 2023**

Project : **GSCS-103-1001-F**  
Code : **C.32.99**  
Exclusions : **N/A**  
Issue No : **01**

Certification Approved By:

Managing Director



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**Test Report No. : CRSSA/200844465-CA43470**  
**Company : Siraphan Samoonprai Co., Ltd.**  
**456 Moo 5 Tambol Bangphra,**  
**Amphur Sriracha,**  
**Chonburi 20110**

### TEST REPORT

Sample Description : Examination Glove Nitrile Powder-Free, Non-Sterile  
Brand Name : SIRAPHAN 28  
Style : Size L  
Lot No. : 01062001  
Colour : Blue  
Manufacturer : Siraphan Samoonprai Co., Ltd.  
Production Date : 01/06/2020  
Country of Origin : Thailand  
Country of Destination : USA  
Size : L  
Quantity Tested : 200 pieces  
Test Conducted : Freedom from holes  
Test Method : EN455 Part 1:2000  
Testing Period : 05 August 2020 – 18 August 2020

Based on submitted samples, the following results obtained :-

Acceptable Quality Limit (AQL) : 1.5      Accept : 7      Found : 4

Result : Within AQL

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SECTION HEAD  
IKM No. M/3983/6401/12/14

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**Test Report No. : CRSSA/200844465-CA43470**  
**Company : Siraphan Samoonprai Co., Ltd.**  
**456 Moo 5 Tambol Bangphra,**  
**Amphur Sriracha,**  
**Chonburi 20110**

**TEST REPORT**

Sample Description : Examination Glove Nitrile Powder-Free, Non-Sterile  
 Brand Name : SIRAPHAN 28  
 Style : Size L  
 Lot No. : 01062001  
 Colour : Blue  
 Manufacturer : Siraphan Samoonprai Co., Ltd.  
 Production Date : 01/06/2020  
 Country of Origin : Thailand  
 Country of Destination : USA  
 Size : L  
 Quantity Tested : 13 pieces  
 Test Conducted : Dimensions  
 Test Method : EN 455 Part 2:2015  
 Testing Period : 05 August 2020 – 18 August 2020

Based on submitted samples, the following results obtained :-

Size	L	L	L	L	L	L	L	L	L	L	L	L	L	Median
Width Median: 110±10mm	100	99	100	99	99	100	100	99	99	100	100	102	100	100
Length Median: ≥ 240mm	244	243	240	245	245	248	250	241	246	245	245	250	246	245

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**Test Report No. : CRSSA/200844465-CA43470**  
**Company : Siraphan Samoonprai Co., Ltd.**  
**456 Moo 5 Tambol Bangphra,**  
**Amphur Sriracha,**  
**Chonburi 20110**

**TEST REPORT**

Sample Description : Examination Glove Nitrile Powder-Free, Non-Sterile  
 Brand Name : SIRAPHAN 28  
 Style : Size L  
 Lot No. : 01062001  
 Colour : Blue  
 Manufacturer : Siraphan Samoonprai Co., Ltd.  
 Production Date : 01/06/2020  
 Country of Origin : Thailand  
 Country of Destination : USA  
 Size : L  
 Quantity Tested : 13 pieces per each  
 Test Conducted : Force at Break During Shelf Life and After Challenge  
 Test Method : EN 455 Part 2:2015  
 Ageing : 70 ± 2 Deg C for 168 hrs  
 Testing Period : 05 August 2020 – 18 August 2020

SIZE	SAMPLE NO.	Force at Break, N	
		BEFORE AGING	AFTER AGING
L	1	9.3	7.9
	2	8.1	9.5
	3	9.5	9.4
	4	9.4	6.3
	5	8.4	8.9
	6	7.6	8.1
	7	9.5	7.8
	8	8.3	8.7
	9	8.7	9.3
	10	9.3	8.9
	11	8.4	9.0
	12	9.0	8.5
	13	10.0	9.0
Median		9.0	8.9
Requirement		≥ 6.0	≥ 6.0

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**Test Report No. : CRSSA/200844465-CA43470**  
**Company : Siraphan Samoonprai Co., Ltd.**  
**456 Moo 5 Tambol Bangphra,**  
**Amphur Sriracha,**  
**Chonburi 20110**

### TEST REPORT

Sample Description : Examination Glove Nitrile Powder-Free, Non-Sterile  
Brand Name : SIRAPHAN 28  
Style : Size L  
Lot No. : 01062001  
Colour : Blue  
Manufacturer : Siraphan Samoonprai Co., Ltd.  
Production Date : 01/06/2020  
Country of Origin : Thailand  
Country of Destination : USA  
Size : L  
Quantity Tested : 5 pieces  
Test Conducted : Powder Content  
Test Method : EN455 Part 3:2015  
Testing Period : 05 August 2020 – 18 August 2020

On testing the samples, the following results were obtained:-

<u>SIZE</u>	<u>Average Powder Mass per Glove</u>
L	0.82 mg

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**Test Report No. : CRSSA/200844465-CA43470**  
**Company : Siraphan Samoonprai Co., Ltd.**  
**456 Moo 5 Tambol Bangphra,**  
**Amphur Sriracha,**  
**Chonburi 20110**

**TEST REPORT**

Sample Description : Examination Glove Nitrile Powder-Free, Non-Sterile  
 Brand Name : SIRAPHAN 28  
 Style : Size L  
 Lot No. : 01062001  
 Colour : Blue  
 Manufacturer : Siraphan Samoonprai Co., Ltd.  
 Production Date : 01/06/2020  
 Country of Origin : Thailand  
 Country of Destination : USA  
 Size : L  
 Quantity Tested : 8 pieces  
 Test Conducted : Aqueous Extractable Protein Content  
 Test Method : EN455 Part 3:2015  
 Testing Period : 05 August 2020 – 18 August 2020

**EXTRACTABLE PROTEIN CONTENT**

Analysis had been carried out as per your request. We report the following results:

SIZE	AQUEOUS EXTRACTABLE PROTEIN CONTENT, µg/g
L	27

Note: Detection limit = 10 µg/g

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**Test Report No. : CRSSA/200844466-CA43471**  
**Company : Siraphan Samoonprai Co., Ltd.**  
**456 Moo 5 Tambol Bangphra,**  
**Amphur Sriracha,**  
**Chonburi 20110**

### TEST REPORT

Sample Description : Examination Glove Nitrile Powder-Free, Non-Sterile  
Brand Name : SIRAPHAN 28  
Style : Size M  
Lot No. : 01062001  
Colour : Blue  
Manufacturer : Siraphan Samoonprai Co., Ltd.  
Production Date : 01/06/2020  
Country of Origin : Thailand  
Country of Destination : USA, Europe, Middle East, Australia  
Size : M  
Quantity Tested : 200 pieces  
Test Conducted : Freedom from holes  
Test Method : EN455 Part 1:2000  
Testing Period : 05 August 2020 – 18 August 2020

Based on submitted samples, the following results obtained :-

Acceptable Quality Limit (AQL) : 1.5      Accept : 7      Found : 2

Result : Within AQL

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**Test Report No. : CRSSA/200844466-CA43471**  
**Company : Siraphan Samoonprai Co., Ltd.**  
**456 Moo 5 Tambol Bangphra,**  
**Amphur Sriracha,**  
**Chonburi 20110**

**TEST REPORT**

Sample Description : Examination Glove Nitrile Powder-Free, Non-Sterile  
 Brand Name : SIRAPHAN 28  
 Style : Size M  
 Lot No. : 01062001  
 Colour : Blue  
 Manufacturer : Siraphan Samoonprai Co., Ltd.  
 Production Date : 01/06/2020  
 Country of Origin : Thailand  
 Country of Destination : USA, Europe, Middle East, Australia  
 Size : M  
 Quantity Tested : 13 pieces  
 Test Conducted : Dimensions  
 Test Method : EN 455 Part 2:2015  
 Testing Period : 05 August 2020 – 18 August 2020

Based on submitted samples, the following results obtained :-

Size	M	M	M	M	M	M	M	M	M	M	M	M	M	Median
Width Median: 95±10mm	90	92	90	90	92	91	90	91	92	90	91	90	90	90
Length Median: ≥ 240mm	235	239	241	240	242	241	240	240	240	237	240	241	240	240

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**Test Report No. : CRSSA/200844466-CA43471**  
**Company : Siraphan Samoonprai Co., Ltd.**  
**456 Moo 5 Tambol Bangphra,**  
**Amphur Sriracha,**  
**Chonburi 20110**

**TEST REPORT**

Sample Description : Examination Glove Nitrile Powder-Free, Non-Sterile  
 Brand Name : SIRAPHAN 28  
 Style : Size M  
 Lot No. : 01062001  
 Colour : Blue  
 Manufacturer : Siraphan Samoonprai Co., Ltd.  
 Production Date : 01/06/2020  
 Country of Origin : Thailand  
 Country of Destination : USA, Europe, Middle East, Australia  
 Size : M  
 Quantity Tested : 13 pieces per each  
 Test Conducted : Force at Break During Shelf Life and After Challenge  
 Test Method : EN 455 Part 2:2015  
 Ageing : 70 ± 2 Deg C for 168 hrs  
 Testing Period : 05 August 2020 – 18 August 2020

SIZE	SAMPLE NO.	Force at Break, N	
		BEFORE AGING	AFTER AGING
M	1	10.6	7.7
	2	7.5	10.6
	3	8.5	10.2
	4	10.4	9.9
	5	9.8	10.9
	6	9.2	10.7
	7	9.2	9.6
	8	10.4	10.6
	9	10.0	9.4
	10	9.4	6.2
	11	9.9	9.9
	12	10.4	9.4
	13	9.7	9.9
Median		9.8	9.9
Requirement		≥ 6.0	≥ 6.0

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**Test Report No. : CRSSA/200844466-CA43471**  
**Company : Siraphan Samoonprai Co., Ltd.**  
**456 Moo 5 Tambol Bangphra,**  
**Amphur Sriracha,**  
**Chonburi 20110**

### TEST REPORT

Sample Description : Examination Glove Nitrile Powder-Free, Non-Sterile  
Brand Name : SIRAPHAN 28  
Style : Size M  
Lot No. : 01062001  
Colour : Blue  
Manufacturer : Siraphan Samoonprai Co., Ltd.  
Production Date : 01/06/2020  
Country of Origin : Thailand  
Country of Destination : USA, Europe, Middle East, Australia  
Size : M  
Quantity Tested : 5 pieces  
Test Conducted : Powder Content  
Test Method : EN455 Part 3:2015  
Testing Period : 05 August 2020 – 18 August 2020

On testing the samples, the following results were obtained:-

<u>SIZE</u>	<u>Average Powder Mass per Glove</u>
M	0.88 mg

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**Test Report No. : CRSSA/200844466-CA43471**  
**Company : Siraphan Samoonprai Co., Ltd.**  
**456 Moo 5 Tambol Bangphra,**  
**Amphur Sriracha,**  
**Chonburi 20110**

**TEST REPORT**

Sample Description : Examination Glove Nitrile Powder-Free, Non-Sterile  
 Brand Name : SIRAPHAN 28  
 Style : Size M  
 Lot No. : 01062001  
 Colour : Blue  
 Manufacturer : Siraphan Samoonprai Co., Ltd.  
 Production Date : 01/06/2020  
 Country of Origin : Thailand  
 Country of Destination : USA, Europe, Middle East, Australia  
 Size : M  
 Quantity Tested : 8 pieces  
 Test Conducted : Aqueous Extractable Protein Content  
 Test Method : EN455 Part 3:2015  
 Testing Period : 05 August 2020 – 18 August 2020

**EXTRACTABLE PROTEIN CONTENT**

Analysis had been carried out as per your request. We report the following results:

SIZE	AQUEOUS EXTRACTABLE PROTEIN CONTENT, µg/g
M	29

Note: Detection limit = 10 µg/g

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**Report No.:** 60393369-001a Page 1 of 6

**Client:** SIRAPHAN SAMOONPRAI COMPANY LIMITED

**Contact Information:** 456 Moo 5, T. Bangpra, Sriracha Chonburi 20110 Thailand

**Identification / Model No(s):** Nitrile Glove

**Sample Receiving date:** 2020-07-10

**Testing Period:** 2020-07-10 to 2020-07-31

**Reference Order No.:** 00000633

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

**Test Specification:**

- | <b>Test Specification:</b>   | <b>Test result:</b>  |
|--|----------------------|
| 1. EN 455-1: 2000: Requirements for freedom from holes                               | PASS                 |
| 2. EN 455-2: 2015: Physical properties test;   |                      |
| - Dimension test   | PASS                 |
| - Force at break test  | PASS                 |
| 3. EN 455-3: 2015 (E), Annex A : Proteins extraction by aqueous                      | Refer to result page |
| 4. US FDA 21 CFR 177.2600 (Rubber Articles) - Determination of Amount of Extractives | PASS                 |

**Other Information:**

Grade: MEDICAL GRADE  
 Manufacture: Siraphan Samoonprai Co., Ltd.  
 Country of Origin: THAILAND

The report 60393369-001a supersede report 60393369-001 (Change the company name)

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




2020-09-24

Wilawan Sriprom / Manager

**Date****Name/Position**

*Test result is drawn according to the kind and extent of tests performed.*

*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.*

TÜV Rheinland Thailand Ltd. · Global Technology Assessment Center Bangkok (GTAC BKK) Ladkrabang Industrial Estate 123/1,  
 Soi Chalongsung 31, Lamplatew, Ladkrabang, Bangkok 10520 Thailand  
 Tel.: +66 (0) 2326-1333 Fax.: +66 (0) 2326-1334-5 Email: [info@tha.tuv.com](mailto:info@tha.tuv.com) · Web: [www.tuv.com](http://www.tuv.com)



**Test Report No.:** 60393369-001a

Page 2 of 6

**Sampling Information:**

Inspection Method: No inspection, submitted sample by client  
 Inspection level: N/A  
 AQL: N/A  
 Sample size: N/A

**Material list:**

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

**Freedom from holes**

Test method: With reference to EN 455-1: 2000

Test result:

Gloves Size	Tested samples	No. of samples for Non-compliance	Conclusion
M	200 pcs.	1	Pass

**Remark:**

- All samples were selected and supplied by the client.
- The batch size of the gloves supplied was not stated by the client. In accordance with BS EN 455-1, a batch size between 35,001 to 150,000 was chosen, and therefore 50 gloves per stage were tested for perforations using General Inspection Level I at an AQL of 1.5% with reference to table;

Stage No.	Cumulative no. tested	Accept	Reject
First	50	0	4
Second	100	1	6
Third	150	3	8
Fourth	200	5	9
Fifth	250	9	19

**Test Report No.: 60393369-001a**

Page 3 of 6

**Dimension test**

Test method: EN 455-2: 2015

**Test results:**

Test No.:	T001	
Material No.:	M001	
Tested no.	Length (mm)	Width (mm)
1	247	92
2	244	91
3	245	93
4	245	92
5	246	92
6	245	92
7	245	91
8	244	92
9	244	93
10	245	93
11	243	93
12	245	92
13	246	92
Median result	245	92
Conclusion	Pass	Pass

Abbreviation: mm denotes 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.:** 60393369-001a

Page 4 of 6

**Force at break**

Test method: EN 455-2: 2015

**Test results:**

Test No.	T001	
Material No.	M001	
Tested no.	Force at break Before ageing (N)	Force at break After ageing (N)
1	8.25	7.29
2	7.49	7.51
3	7.68	8.43
4	6.81	7.87
5	7.72	8.45
6	7.62	8.21
7	8.87	6.92
8	7.57	6.19
9	8.90	7.89
10	8.27	8.24
11	7.06	7.31
12	7.63	6.94
13	7.56	7.19
Median result	7.80	7.57
Conclusion	Pass	Pass

Abbreviation: N denotes Newton

**Remark:**

1. Median values of force at break

Force at Break (newton)		
a)	b)	c)
≥ 9.0	≥ 6.0	≥ 3.0

- 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)

**Test Report No.: 60393369-001a**

Page 5 of 6

**Proteins extraction**

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

Test result:

Test No.	Material No.	Test parameter	Unit	MDL	Test result
T001	M001	Proteins	µg/g	3	n.d.

Abbreviation: n.d. denotes Not Detected (&lt;MDL)

MDL denotes Method Detection Limit

µg/g denotes Microgram per gram

Remark: The leachable protein level shall be "As Low As Reasonable Practicable" (ALARP)

**US FDA 21 CFR 177.2600 (Rubber Articles) – Determination of Amount of Extractives**

Test Method: With reference to US FDA 21 CFR 177.2600.

For use in contact with aqueous foods:

Extractants	Test Condition	MDL (mg/inch <sup>2</sup> )	Result (mg/inch <sup>2</sup> )	Permissible Limit (mg/inch <sup>2</sup> )
			M001	
Distilled Water	Reflux temperature for 7 hours	0.1	0.7	20
	Succeeding 2 hours of extraction	0.1	0.2	1
<b>Comment</b>	--	--	Pass	--

For use in contact with fatty foods:

Extractants	Test Condition	MDL (mg/inch <sup>2</sup> )	Result (mg/inch <sup>2</sup> )	Permissible Limit (mg/inch <sup>2</sup> )
			M001	
n-Hexane	Reflux temperature for 7 hours	0.1	0.4	175
	Succeeding 2 hours of extraction	0.1	0.1	4
<b>Comment</b>	--	--	Pass	--

Abbreviation: n.d. denotes Not Detected (&lt;MDL)

MDL denotes Method Detection Limit

 mg/inch<sup>2</sup> denotes Milligram per square inch

Test Report No.: 60393369-001a

Page 6 of 6

Sample photo

**60393369-001a**



M001 - Size M

- END -

**Test Report No. : CRSSA/200945694-CA44682**  
**Company : Siraphan Samoonprai Co., Ltd.**  
**456 Moo 5 Tambol Bangphra,**  
**Amphur Sriracha,**  
**Chonburi 20110**

### TEST REPORT

Sample Description : Examination Glove Nitrile Powder-Free, Non-Sterile  
Brand Name : SIRAPHAN 28  
Style : Size L  
Lot No. : 01062001  
Colour : Blue  
Manufacturer : Siraphan Samoonprai Co., Ltd.  
Production Date : 01/06/2020  
Country of Origin : Thailand  
Country of Destination : USA, Europe, Middle East, Australia  
Size : L  
Quantity Tested : 200 pieces  
Test Conducted : Freedom from holes  
Test Method : ASTM D6319-10 (Reapproved 2015)  
Testing Period : 21 August 2020 – 04 September 2020

Based on submitted samples, the following results obtained :-

Acceptable Quality Limit (AQL) : 2.5      Accept : 10      Found : 2  
Result : Within AQL

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**Test Report No. : CRSSA/200945694-CA44682**  
**Company : Siraphan Samoonprai Co., Ltd.**  
**456 Moo 5 Tambol Bangphra,**  
**Amphur Sriracha,**  
**Chonburi 20110**

**TEST REPORT**

Sample Description : Examination Glove Nitrile Powder-Free, Non-Sterile  
 Brand Name : SIRAPHAN 28  
 Style : Size L  
 Lot No. : 01062001  
 Colour : Blue  
 Manufacturer : Siraphan Samoonprai Co., Ltd.  
 Production Date : 01/06/2020  
 Country of Origin : Thailand  
 Country of Destination : USA, Europe, Middle East, Australia  
 Size : L  
 Quantity Tested : 13 pieces  
 Test Conducted : Dimensions  
 Test Method : ASTM D6319-10 (Reapproved 2015)  
 Testing Period : 21 August 2020 – 04 September 2020

Based on submitted samples, the following results obtained :-

Size	L	L	L	L	L	L	L	L	L	L	L	L	L
Width 110 ± 10mm	90	92	91	92	91	92	90	90	90	89	91	89	90
Length Min. 230mm	250	246	248	244	243	245	248	244	245	244	243	243	244
Thickness at palm Min. 0.05mm	0.07	0.08	0.08	0.08	0.08	0.08	0.08	0.08	0.08	0.08	0.08	0.08	0.08
Thickness at finger Min. 0.05mm	0.10	0.10	0.09	0.10	0.10	0.10	0.11	0.10	0.10	0.10	0.10	0.10	0.10

Acceptable Quality Limit (AQL) : 4.0      Accept : 1      Found : 0

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**Test Report No. : CRSSA/200945694-CA44682**  
**Company : Siraphan Samoonprai Co., Ltd.**  
**456 Moo 5 Tambol Bangphra,**  
**Amphur Sriracha,**  
**Chonburi 20110**

**TEST REPORT**

Sample Description : Examination Glove Nitrile Powder-Free, Non-Sterile  
 Brand Name : SIRAPHAN 28  
 Style : Size L  
 Lot No. : 01062001  
 Colour : Blue  
 Manufacturer : Siraphan Samoonprai Co., Ltd.  
 Production Date : 01/06/2020  
 Country of Origin : Thailand  
 Country of Destination : USA, Europe, Middle East, Australia  
 Size : L  
 Sample Quantity : 13 pieces per each  
 Test Conducted : Tensile Strength & Elongation (Before Ageing & After Ageing)  
 Test Method : ASTM D6319-10 (Reapproved 2015)  
 Ageing : 70 ± 2 Deg C for 168 hrs  
 Testing Period : 21 August 2020 – 04 September 2020

Size	Sample No.	<u>BEFORE AGEING</u>		<u>AFTER AGEING</u>	
		Tensile Strength (MPa)	Ultimate Elongation (%)	Tensile Strength (MPa)	Ultimate Elongation (%)
L	1	33.9	560	42.6	620
	2	33.5	580	37.4	600
	3	33.0	580	39.7	600
	4	30.8	560	32.7	580
	5	43.0	620	31.0	560
	6	28.6	560	42.7	620
	7	36.6	580	33.2	580
	8	36.3	580	40.2	600
	9	29.1	560	45.1	620
	10	30.1	560	33.6	580
	11	33.4	580	36.2	580
	12	34.5	600	42.0	600
	13	36.8	620	36.0	580

Requirements: 14 min 500 min 14 min 400 min  
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**Test Report No. : CRSSA/200945694-CA44682**  
**Company : Siraphan Samoonprai Co., Ltd.**  
**456 Moo 5 Tambol Bangphra,**  
**Amphur Sriracha,**  
**Chonburi 20110**

**TEST REPORT**

Sample Description : Examination Glove Nitrile Powder-Free, Non-Sterile  
Brand Name : SIRAPHAN 28  
Style : Size L  
Lot No. : 01062001  
Colour : Blue  
Manufacturer : Siraphan Samoonprai Co., Ltd.  
Production Date : 01/06/2020  
Country of Origin : Thailand  
Country of Destination : USA, Europe, Middle East, Australia  
Size : L  
Quantity Tested : 5 pieces  
Test Conducted : Powder Content  
Test Method : ASTM D6124-06 (Reapproved 2017)  
Testing Period : 21 August 2020 – 04 September 2020

On testing the samples, the following results were obtained:-

**SIZE**

**Average Powder Mass per Glove**

L

0.90 mg

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**Test Report No. : CRSSA/200945694-CA44682**  
**Company : Siraphan Samoonprai Co., Ltd.**  
**456 Moo 5 Tambol Bangphra,**  
**Amphur Sriracha,**  
**Chonburi 20110**

**TEST REPORT**

Sample Description : Examination Glove Nitrile Powder-Free, Non-Sterile  
 Brand Name : SIRAPHAN 28  
 Style : Size L  
 Lot No. : 01062001  
 Colour : Blue  
 Manufacturer : Siraphan Samoonprai Co., Ltd.  
 Production Date : 01/06/2020  
 Country of Origin : Thailand  
 Country of Destination : USA, Europe, Middle East, Australia  
 Size : L  
 Quantity Tested : 3 pieces  
 Test Conducted : Aqueous Extractable Protein Content  
 Test Method : ASTM D5712-15  
 Testing Period : 21 August 2020 – 04 September 2020

On testing the samples, the following results were obtained:-

SIZE	AQUEOUS EXTRACTABLE PROTEIN CONTENT, µg/dm <sup>2</sup>
L	29

Note: Detection limit = 20 µg/dm<sup>2</sup>

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**Test Report No. 7191243668-EEC20/02-WBH**  
dated 22 Sep 2020



PSB Singapore

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**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 Examination Gloves submitted by Siraphan Samoonprai Co., Ltd.  
on 07 Sep 2020.

**TESTED FOR:**

Siraphan Samoonprai Co., Ltd.  
456 Moo 5, Bangphra, Si Racha,  
Chonburi 20110, Thailand

**TEST DATE:**

09 Sep 2020

**DESCRIPTION OF SAMPLES:**

S/N	Product Description	Brand/ Model	Size	Colour	Lot No.	Expiry date	Sample received (pieces)	Manufacturer
1	Examination Gloves Nitrile Powder Free	Siraphan 28	M	Blue	01062001	01-06-2023	494	Siraphan Samoonprai 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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TÜV SÜD PSB Pte. Ltd.  
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Regional Head Office:  
TÜV SÜD Asia Pacific Pte. Ltd.  
1 Science Park Drive, #02-01  
Singapore 118221  
**TUV**<sup>®</sup>

**RESULTS:**

Sample: Examination Gloves Nitrile Powder Free, Siraphan 28, Blue, Size M

Test	BS EN ISO 21420:2020 Requirements		Results	Inferred Results
I. Determination of pH Value, pH value	> 3.5 and < 9.5		8.6	Passed
II. Sizing, minimum length of glove (mm)	-		240	(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. Four gloves were tested and smallest performance level was reported.

  
\_\_\_\_\_  
Lee Dan Yi  
Engineer

  
\_\_\_\_\_  
Wong Bee Hui  
Product Manager  
Medical Health Services (NAM)

**APPENDIX:**



Photo: Examination Gloves Nitrile Powder Free, Siraphan 28, 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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5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, No.1 Science Park Drive Singapore 118221.
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



**Test Report No. 7191243668-EEC20/01B-WBH**  
dated 22 Sep 2020



PSB Singapore

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**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 Examination Gloves submitted by Siraphan Samoonprai Co., Ltd.  
on 07 Sep 2020.

**TESTED FOR:**

Siraphan Samoonprai Co., Ltd.  
456 Moo 5, Bangphra, Si Racha,  
Chonburi 20110, Thailand

**TEST DATE:**

11 Sep 2020 to 22 Sep 2020

**DESCRIPTION OF SAMPLES:**

S/N	Product Description	Brand/ Model	Size	Colour	Lot No.	Expiry date	Sample received (pieces)	Manufacturer
1	Examination Gloves Nitrile Powder Free	Siraphan 28	M	Blue	01062001	01-06-2023	494	Siraphan Samoonprai Co., Ltd.



Laboratory:  
TÜV SÜD PSB Pte. Ltd.  
No.1 Science Park Drive  
Singapore 118221

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<https://www.tuvsud.com/en-sg>  
Co. Reg : 199002667R

Regional Head Office:  
TÜV SÜD Asia Pacific Pte. Ltd.  
1 Science Park Drive, #02-01  
Singapore 118221  
**TUV**<sup>®</sup>

**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 5.4 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: Examination Gloves Nitrile Powder Free, Siraphan 28, Blue, Size M

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

Clause	Tests	Specification	Results	Inferred Result	
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.  Tested Chemical: Methanol  For Type C: The permeation performance shall be at least level 1 against minimum of one test chemical	Breakthrough Time (mins)	Failed	
			Glove 1		<1
			Glove 2		<1
			Glove 3		<1
			Mean Value		<1
			Lowest Value		<1
			The breakthrough time occurred before 10 mins, the tested glove is classified as <b>Level 0</b>  Slight change was observed on the glove test specimen after the test.		

**REMARKS:**


1. 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 Methanol 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 Methanol 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 Gas Chromatography. The results were used to calculate the permeation rate of Methanol through the glove material. Based on the result, the minimum rate of sampling was determined. The tests repeated at sampling interval of 75 secs and collected until 10 mins. The extracts were then analysed by Methanol 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 0.06 mm.

2. 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  $1 \mu\text{g}/\text{cm}^2/\text{min}$ .



Lee Dai Yi  
Engineer



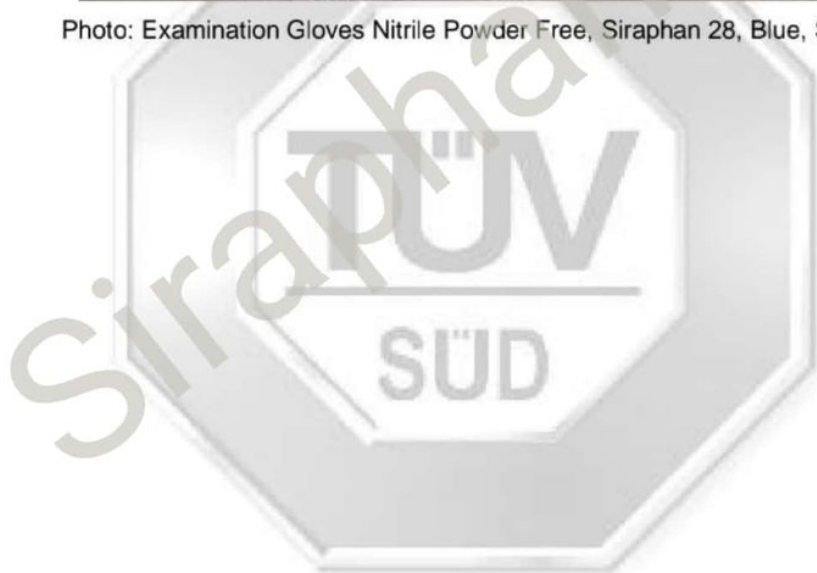
Wong Bee Hui  
Product Manager  
Medical Health Services (NAM)



**APPENDIX:**



Photo: Examination Gloves Nitrile Powder Free, Siraphan 28, 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 01 September 2020



**Test Report No. 7191243668-EEC20/01A-WBH**  
dated 22 Sep 2020



PSB Singapore

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**SUBJECT:**

Testing of Examination Gloves submitted by Siraphan Samoonprai Co., Ltd.  
on 07 Sep 2020.

**TESTED FOR:**

Siraphan Samoonprai Co., Ltd.  
456 Moo 5, Bangphra, Si Racha,  
Chonburi 20110, Thailand

**TEST DATE:**

11 Sep 2020 to 22 Sep 2020

**DESCRIPTION OF SAMPLES:**

S/N	Product Description	Brand/ Model	Size	Colour	Lot No.	Expiry date	Sample received (pieces)	Manufacturer
1	Examination Gloves Nitrile Powder Free	Siraphan 28	M	Blue	01062001	01-06-2023	494	Siraphan Samoonprai Co., Ltd.



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<https://www.tuvsud.com/en-sg>  
Co. Reg : 199002667R

Regional Head Office:  
TÜV SÜD Asia Pacific Pte. Ltd.  
1 Science Park Drive, #02-01  
Singapore 118221  
**TUV**<sup>®</sup>

**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)



**RESULTS:**

Sample: Examination Gloves Nitrile Powder Free, Siraphan 28, Blue, Size M

Table 1: Results for tests according to BS EN ISO 374-1:2016+A1:2018 Clause 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 Chemical: Methanol	Degradation Results (%)		NA
			Glove 1	74.5	
			Glove 2	78.4	
			Glove 3	72.6	
			Average	75.2	
Standard Deviation	3.0				

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		8.6	Passed
II. Sizing, minimum length of glove (mm)	Size	Minimum length of glove (mm)	240	Passed
	M (7)	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			

**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 of each size, with an overall minimum of 4 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.

4. NA: Not applicable



Lee Dai Yi  
Engineer



Wong Bee Hui  
Product Manager  
Medical Health Services (NAM)

**APPENDIX:**



Photo: Examination Gloves Nitrile Powder Free, Siraphan 28, Blue, Size M

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Effective 01 September 2020



TESTING & CERTIFICATION EXPERT LTD  
Company number: 13031620 Phone: +1-619-869-0249  
UK 20-22 Wenlock Road, London N1 7GUTD  
contact@fda4you.com



# Certificate of Compliance

Certificate Number : TECRO202012616059

This is to certify that, in accordance with the Medical Device Directive 98/79/EC, Awintoo Romania agrees to perform all duties and responsibilities as the Authorized Representative for:

Certificate Holder **SIRAPHAN SAMOONPRAI CO.,LTD.**

Manufacturer SIRAPHAN SAMOONPRAI CO.,LTD. 456 Moo 5 , Bangphra Sub-District, Sriracha District, Chonburi, 20110 THAILAND

Trade Mark : SIRAPHAN 28+

Product NITRILE POWDER FREE EXAMINATION GLOVES

Test Standard ISO 10993-10 biological evaluation of medical devices Test for irritation  
Glove dimension testing  
Physical property testing  
1000 ml water tight testing  
EN 455 :2003

The manufacturer has provided the appropriate Declaration (s) of conformity confirming that produced medical devices meet the applicable requirements of Directive 98/79 / EC. Under European law, a safety officer has been appointed for EU .

Valid 1 year from: 09.12.2020

Medical Device Safety department

Director Mathias Krisp



The certificate of conformance is based on single evaluation of the submitted sample[s] and test report . CHECK THE VALIDITY OF YOUR CERTIFICATE

+40744709992

certificate@fda4you.com

www.CE4you.eu



# Certificate of GTIN Assignment

## Proof of Ownership from Brand Owner

The Brand Owner, AAA Adventures, Inc, of GS1 Prefix (616430) has contracted with Bar Codes Talk, LLC to assign and transfer the Global Trade Item Number (GTIN) range listed below to:

**SIRAPHAN SAMOONPRAI CO.,LTD.**

Global Trade Item Number(s) (GTINs)

Quantity (5): **616430509435** to **616430509473**

GTINs assigned for use in creating  
GS1 Identification Numbers

- Universal Product Code (UPC / GTIN-12)
- European Article Number (EAN / GTIN-13)
- Shipping Container Code (SCC / GTIN-14)
- Global Location Number (GLN)

Account Number: **294144**

GTIN Coordinator: **Miss Phatranit Piyasammawat**

Order Number: **357216**

Issued Date: **December 11, 2020**



Scan to Verify  
this Certificate



Bar Codes Talk, LLC  
924 Hale Avenue  
Brooksville, FL 34601

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**TECHNICAL SHEET  
FOR  
NITRILE EXAMINATION GLOVES  
(Powdered or powder free)  
(SIRAPHAN-AW /002)**

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8.0	List of applicable standards	001
9.0	EC Declaration of Conformity	001





## Requirements

- e) Category I: Use for minimal risks condition (Laboratory, gardening, general cleaning at temperature of 10 – 50 °C).
- f) The obsolescence deadline is 3 years from date of manufacture.
- g) For transportation, the gloves are packed in Paper Dispenser Boxes / Plastic bag. A paper carton then encloses these Dispenser packages.
- h) The “Low Chemical Risk and Waterproof” pictograms are placed on the Dispenser Packages (refer section 7) to signify that the gloves were not tested against chemicals.
- i) The gloves comply with “Council Directive of 21 December 1989 relating to Personal Protective Equipment, 89/686/EEC.
- j) A Notified Body is not required to assess and verify the minimal risks PPE.

### **2.2 Additional Requirements for PPE Glove.**

- 2.2.1 A bead is provided on the glove cuff to aid in donning of the hand.
- 2.2.2 The date of obsolescence, 3 years after manufacture is affixed on the dispenser boxes as the glove deteriorate slightly on aging. The useful life of the gloves can be prolong with careful storage (refer clause 1.4 above).
- 2.2.3 The glove can be torn by a sufficiently large force, thereby preventing it being caught-up by a moving object.
- 2.2.4 The gloves are ambidextrous in design, so it is easily don on the left or right hands. This also minimizes the time to don the gloves.
- 2.2.5 The Pictograms “Low Chemical Risk and Water proof” is placed on the dispenser packages to indicate the risk that the user is protected against.

### **2.3 Additional Requirements Specific To Particular Risks.**

- 2.3.1 Protection against infective agents.
  - a) The glove when worn is capable of protecting the user hands against infective agent (micro-organism) as encountered in general use.
  - b) The Leak-tightness of the glove does not change on prolong usage, except when it is cut, puncture or torn. The gloves should then be immediately changed.
  - c) The product may cause allergic reactions, this mention is mandatory and is on the packaging

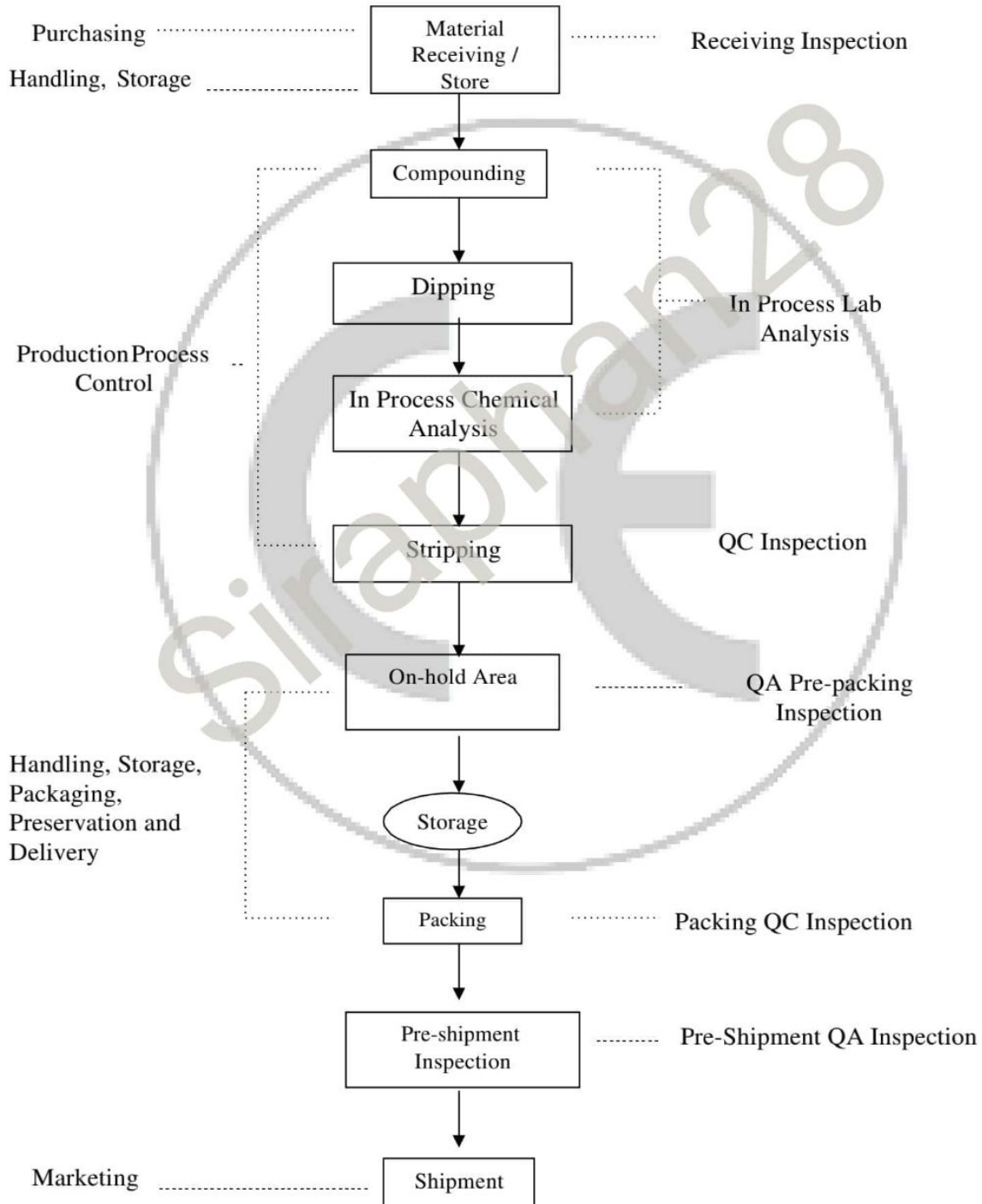
The data sheet was made in collaboration with Awintoo consulting for use with the CE or FDA certificate.

**SECTION 3.0 MANUFACTURING PROCESS**

**3.1 Manufacturing Flow Chart of Powder-Free Disposable Nitrile Gloves**

**Process – Procedure**

**Inspection & Testing Procedure**



The data sheet was made in collaboration with Awintoo consulting for use with the CE or FDA certificate.

## **SECTION 4.0 QUALITY CONTROL SYSTEM**

### **4.1 Incoming Material Inspection**

- 4.1.1 All Incoming raw materials (that will affect the product's quality) that are subjected to inspection are placed under "Quarantine" area in the store.
- 4.1.2 Incoming materials are selected randomly as per ISO 2859 sampling plan and inspected by Incoming Material Inspector.
- 4.1.3 Incoming materials that meet In-house specifications are attached with "Passed" Sticker.
- 4.1.4 Incoming materials that do not meet In-house specifications are quarantined pending management disposition decision.
  - The Incoming materials are needed to be screened are attached with "Rejected" Sticker and with "SCREEN" stamp on it.
  - The Incoming materials that can be "Used as it" is (substandard material but without functional implication and actual affect on quality) are attached with "Rejected" Sticker and with "UAI" stamp on it.
  - Incoming materials that cannot be used and needed to be returned back to supplier are attached with "Reject" sticker.
- 4.1.5 All Reject Materials are return immediately to Supplier or stored in "Reject Area" pending return to supplier.

### **4.2 Milling and Compounding of Raw Material**

- 4.2.1 Only the materials that with "Passed" Sticker can be used for milling process.
- 4.2.2 The milled chemical is analyzed by laboratory personnel.
- 4.2.3 Only the milled chemical that has passed laboratory analysis will be released to be used in Compounding Process.
- 4.2.4 The milled chemical that has failed laboratory analysis shall be re-milled and quarantined to be used until it passes laboratory analysis.
- 4.2.5 Only the approved milled chemicals and chemicals with "Passed" sticker are used for compounding process.
- 4.2.6 The nitrile compounds are analyzed by laboratory personnel.
- 4.2.7 The nitrile compounds that pass all the In-house specification will be released to be use in production.
- 4.2.8 The nitrile compounds that fail the In-house specification will be quarantined to be used and shall wait for management disposition decision.
- 4.2.9 All adjustments made on the nitrile compounds will be documented in a work sheet and shall be analyzed by laboratory personnel again.

### **4.3 Production On-line Goods**

- 4.3.1 Each bin of gloves is issued with a Travel Card and is controlled to 8 kgs.
- 4.3.2 Samples are taken and inspected as per ISO 2859 table I and II-A.
- 4.3.3 Every 6 bins, grouped as one Lot shall be tested as follow;

---

The data sheet was made in collaboration with Awintoo consulting for use with the CE or FDA certificate.



<u>Inspect On</u>	<u>Inspection Level</u>	<u>AQL</u>
i) <i>Pin-hole</i>	<i>80 pcs</i>	<i>4.0</i>
ii) <i>Dimension</i>	<i>S2</i>	<i>1.5</i>
iii) <i>Visual Major</i>	<i>80 pcs</i>	<i>4.0</i>
iv) <i>Visual Minor</i>	<i>80 pcs</i>	<i>6.5</i>

4.3.4 The bins that have passed the above inspection will be marked as grade AQL 4.0 on the Travel card.

4.3.5 The bins that had failed the above inspection will be segregated and quarantined and stored in a specified area in store.

4.3.6 The passed bins will proceed to WIP Store or Packing Department.

#### 4.4 Packing QC Inspection

4.4.1 At packing, Packing QC conduct line clearance inspection before commence packing and at every hourly.

#### 4.5 Finished Goods

4.5.1 The pallets of finish packed gloves are inspected by pre-shipment QA.

4.5.2 The samples are randomly picked and inspected as per ISO 2859 table I and II-A for;

<u>Inspect On</u>	<u>Inspection Level</u>	<u>AQL</u>
i) <i>Pin-hole (Watertight)</i>	<i>S4</i>	<i>4.0</i>
ii) <i>Dimension</i>	<i>S2</i>	<i>4.0</i>
iii) <i>Visual Major</i>	<i>S4</i>	<i>4.0</i>
iv) <i>Visual Minor</i>	<i>S4</i>	<i>6.5</i>
v) <i>pH of Glove</i>	<i>N = 3</i>	<i>-</i>

4.5.3 The pallets of packed gloves that have passed Pre-shipment QA Inspection are ready to deliver and store in outgoing store.

4.5.4 The pallets of packed gloves that have failed Pre-shipment QA Inspections shall be reworked by Packing Department.

4.5.5 The sorted gloves will be quarantined and stored in specified area and wait for management disposition decision.

## **SECTION 5.0 CONTROL AND TEST FACILITIES**

### **5.1 Description of the Control and Test Facilities.**

<u>Area</u>	<u>Control and Test Facilities</u>
a) Laboratory	1) Chemical concentration testing apparatus.
b) Quality Control (QC) Section	1) Water-tight Test Equipment. 2) Stainless Steel Ruler. 3) Thickness Gauge.
c) Pre-Packing QA Section	1) Water-tight Test Equipment. 2) Stainless Steel Ruler.
d) Pre-shipment QA Section	1) Water-tight Test Equipment. 2) Stainless Steel Ruler. 3) Thickness Gauge.

---

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## **SECTION 6.0 PRODUCT TESTING**

Tests were conducted to assure that the safe and correct operation of the product maintained as well as achieving the performance and compatibilities as required by the Directive. The test results include as attached:

- Skin Irritation Test
- Dermal Sensitization Test
- Chemical Residue Test
- Product Test Report
- Biocompatibility test

---

The data sheet was made in collaboration with Awintoo consulting for use with the CE or FDA certificate.

Section 7.0: List of Pictogram


**SECTION 7.0 LIST OF PICTOGRAMS (FOR LABELLING)**

7.1 The Pictograms listed below can be replaced by suitable wordings, if necessary:



- 1) Keep away from moisture
- 2) Open packages  
Keep away from heat (sunlight or fluorescence light).
- 3) Store at 10 to 40 °C



Lot No. of the PPE, e.g.  123456



Date of obsolescence, e.g.  2010-05



Low Chemical Resistance and Water proof



Mark of conformity.  
(minimum height 5mm)

7.2 Refer attachment for a sample of dispenser labeling.

## **SECTION 8.0 LIST OF STANDARDS APPLIED OR TO BE APPLIED**

### **8.1 The referenced harmonized standards applied**

- EN 374-1:2003, Protective gloves against chemicals and micro-organism - Part 1: Terminology and performance requirements.
- EN 374-2:2003, Protective gloves against chemicals and micro-organism - Part 2: Determination of resistance to penetration.
- EN 420: 2003 + A1: 2009, Protective gloves – General requirements and test methods.
- EN 455-2: 2009 Medical gloves for single use - Part 2: Requirements and testing for physical properties.
- EN 455-3:2006, Medical gloves for single use - Part 3: Requirements and testing for biological evaluation.
- EN ISO 3071: 2006 Textiles – Determination of pH of aqueous extract.
- ISO 2859-1:1999, Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection.
- ISO 9001:2008, Quality management systems - Requirements.  
(Certificate to be attached)
- ISO 10993-1: 2003, Biological evaluation of medical devices – Part:1 Evaluation and Testing.
- ISO 10993-10: 2002, Biological evaluation of medical devices – Part:10 Tests for irritation and sensitization.

***Please note that the red marked will be required after the marketing of the product as PPE***



2021

## CERTIFICATE OF REGISTRATION

*This certifies that:*

**SIRAPHAN SAMOONPRAI CO., LTD.**  
**456 Moo5, Tambon Bang Phra**  
**Sriracha Chon Buri, TH 20110**

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 Registration:	<b>3017399134</b>
Device Classification Name:	<b>POLYMER PATIENT EXAMINATION GLOVE</b>
Product Code:	<b>LZA</b>
Regulation Number:	<b>880.6250</b>
Official Correspondent and U.S. Agent:	<b>Registrar Corp</b> 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224- 0179

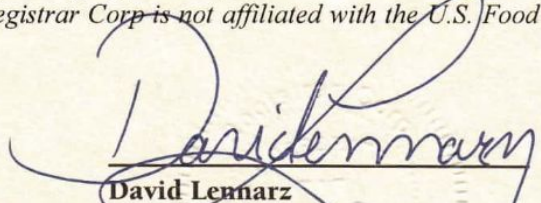
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David Lennarz  
Executive Director  
Registrar Corp  
Dated: November 23, 2020