



## DR. BOO Co., Ltd.

33/48 Wall Street Tower 11Th Room 1102

Surawong Rd., Suriyawong, Bangrak, Bangkok THAILAND 10500

Tel: (66-2) 267-0685 to 88 Fax: (66-2) 266-7972 E-mail: drboo@drboo.co.th

### LETTER OF AUTHORIZATION

July 6<sup>th</sup>, 2020

To: Ministry of Health (Department of Medical Equipment and Construction) - Department of Health

We, DR. BOO COMPANY LIMITED, Address : 662/1-4 Moo 3, Panomsara-Sataheb Road Tumbol Khaokhansong, Amphur Siracha Chonburi 20110, Thailand as the owner of medical equipment, do hereby authorize:

Company Name: Clover Glove Co., Ltd.

Address: 222/36 NAWAMIN 42, YEAK 2 KLONG KUM, BUNGKUM, BANGKOK 10240, THAILAND

To sell in USA market the following medical equipment:

NON-STERILE NITRILE GLOVES, POWDER FREE

We hereby undertake to provide and assist the fulfillment of requirements related to the information and quality and ensure the requirements pertaining to warranty and maintenance and supply of materials and substitutes for such medical equipment. This LETTER OF AUTHORIZATION is effect until: 31<sup>st</sup> December, 2020.

DR. BOO COMPANY LIMITED

  
(DARUNEE VARABUNTOONVIT)  
DIRECTOR

**Products**



**TÜVRheinland®**  
Precisely Right

**Report No.:**

**242121053-01**

Page 1 of 5

**Client:**

**DR. BOO COMPANY LIMITED**

**Contact Information:**

**33/48 WALLSTREET TOWER, ROOM NO. 1102, 11TH FL. SURAWONG RD.,  
SURIYAWONG, BANGRAK, BANGKOK 10500 THAILAND**

**Identification/**

**NITRILE GLOVES**

**Model No(s):**

**Sample Receiving date:**

**2020-05-28**

**Testing Period:**

**2020-05-28 to 2020-06-08**

**Delivery condition:**

**Apparent good, Samples tested as received**

**Test Specification:**

1. EN 455-1: 2000. Requirements for freedom from holes
2. EN 455-2: 2000. Physical properties test;
  - Dimension test
  - Force at break test

**Test result:**

**PASS**

**PASS**

**PASS**

**Other Information provided by client:**

**Material type: NBR LATEX RUBBER**

**Grade: MEDICAL GRADE / FOOD GRADE**

**Manufacture: DR. BOO COMPANY LIMITED**

**Batch No.: FN1517**

**Country of Origin: THAILAND**

**For and on behalf of**

**TÜV Rheinland Thailand Ltd.**



**Wilawan Sriprom / Manager**

**2020-06-16**

**Date**

**Name/Position**

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

*This test report relates to the a. M. 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 Chalangkung 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.co.th](http://www.tuv.co.th)




**Test Report No.: 242121053-01**

Page 2 of 5

**Sampling Information:**

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

**Material list:**

Material No.	Material	Color	Location
M001	Nitrile gloves	Blue	Size S

**1. Freedom from holes**

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

**Test result:**

Test parameter	Tested samples	No. of samples for Non-compliance	Conclusion
Freedom from holes	200	0	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, the result can be judged as above AQL 0.65.

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.: 242121053-01**

Page 3 of 5

**2. Dimension test**

Test method: EN 455-2: 2015

**Test results:**

<b>Test No.:</b>	<b>T001</b>	
<b>Material No.:</b>	<b>M001</b>	
<b>Tested no.</b>	<b>Length (mm)</b>	<b>Width (mm)</b>
1	245	83
2	247	83
3	246	84
4	245	83
5	245	84
6	245	85
7	245	83
8	245	83
9	245	83
10	245	83
11	245	82
12	245	83
13	245	83
Median result	245	83
Conclusion	Pass	Pass

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.: 232121053-01**

Page 4 of 5

**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	8.956	8.766
2	10.450	10.410
3	10.484	10.257
4	9.163	8.819
5	9.290	9.083
6	6.570	10.556
7	9.428	9.245
8	10.155	9.219
9	8.939	9.902
10	9.879	9.003
11	9.584	9.084
12	9.506	8.178
13	9.124	9.129
Median result	9.510	9.358
Conclusion	Pass	Pass

**Remark:**

1. Median values of force at break

Force at Break (newton)		
a)	b)	c)
≥9.0	≥6.0	≥5.6

- 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)

Products



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**Test Report No.: 242121053-01**

Page 5 of 5

Sample photo:



-END-





Certificate TH18/11436

The management system of

## Dr. Boo Co., Ltd.

662/14 Moo 3, Panomsara-Satahob Road, Tambol Khaokhansong,  
Amphur Siracha, Chonburi 20110, Thailand

has been assessed and certified as meeting the requirements of

## ISO 13485:2016 EN ISO 13485:2016

For the following activities

**Manufacture Non-Sterile Powdered Natural Rubber Latex  
Examination Gloves**

**Manufacture Non-Sterile Powder Free Natural Rubber Latex  
Examination Gloves**

This certificate is valid from 13 October 2018 until 13 October 2021 and  
remains valid subject to satisfactory surveillance audits.

Re certification audit due before 27 June 2021

Issue 1. Certified since 13 October 2018

Authorised by

SGS United Kingdom Ltd  
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK  
t +44 (0)151 350-6666 f +44 (0)151 350-6600 [www.sgs.com](http://www.sgs.com)

HC SGS 13485 2016 0118

Page 1 of 1



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Test Report No. 4448445

Date : 13-Dec-2019

Page 1 of 3

Client : DR. BOO CO., LTD.

ROOM NO:1102-11 FLOOR WALL STREET TOWER BLDG 33/48 SURTWONG RD BANGKOK  
10500 Thailand

The following sample(s) was/were submitted and identified by client as:

Sample Name : NITRILE GLOVES  
Sample Description : FOOD GRADE NITRILE GLOVES  
Batch/Lot No. : 10005077787  
Color : Blue  
Manufacturer/Vendor : DR. BOO CO., LTD  
Country of Origin : THAILAND

The following sample(s) was/were identified by SGS as:

SGS Sample No. : 4593693  
Sample Condition : Sample is contained in a plastic bag.  
Quantity Submitted : 15 pcs

Sample Receiving Date : 20-Nov-2019

Testing Period : 20-Nov-2019 to 13-Dec-2019

Test Method & Results : Please refer to next page(s).

#### Test Requested & Result Summary

Test Requested : Please refer to the result summary (Test parameter(s) was/were selected by client).

#### Result Summary:

Test Requested  
US FDA 21 CFR 177.2600 (Rubber Articles)-  
Determination of Amount of Extractives  
- Distilled Water Extractants  
- n-Hexane Extractants

#### Conclusion

--

PASS  
PASS

Remark: Test results in this report are applicable for the item tested and reflects the tested sample as received.

Signed for and on behalf of  
SGS (Thailand) Limited

Rutuchorn Mungsorn  
Laboratory manager - Toy and Hardgood

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## TEST RESULTS

### US FDA 21 CFR 177.2600 (Rubber Articles)-Determination of Amount of Extractives

Method : With reference to US FDA 21 CFR 177.2600.

For use in contact with aqueous foods :

Extractants	Test Condition	Result (1) (mg/inch <sup>2</sup> )	Reporting Limit (mg/inch <sup>2</sup> )	Permissible Limit (mg/inch <sup>2</sup> )
Distilled Water	Reflux temperature for 7 hours	1.4	0.3	20
Distilled Water	Succeeding 2 hours of extraction	ND	0.3	1
Comment	--	PASS	--	--

For use in contact with fatty foods :

Extractants	Test Condition	Result (1) (mg/inch <sup>2</sup> )	Reporting Limit (mg/inch <sup>2</sup> )	Permissible Limit (mg/inch <sup>2</sup> )
n-Hexane	Reflux temperature for 7 hours	0.5	0.3	175
n-Hexane	Succeeding 2 hours of extraction	ND	0.3	4
Comment	--	PASS	--	--

Sample Description :

1. Blue rubber glove

Note : 1. mg/inch<sup>2</sup> = milligram per square inch

2. ND = Not Detected

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**Test Report No.** 4448445

Date : 13-Dec-2019

Page 3 of 3

**SAMPLE/ATTACHMENT PICTURE**



End of Report

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