



Since 1988

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) 265-7972 E-mail: drboo@drboo.co.th

LETTER OF AUTHORIZATION

July 6th, 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: 31st
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: 2013. 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.

2020-06-16

Date

Wilawan Sriprom / Manager

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 Web: www.tuv.co.th

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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 |

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2. Dimension test

Test method: EN 455-2: 2015

Test results:

| | | |
|---------------|-------------|------------|
| Test No.: | T001 | |
| Material No.: | M001 | |
| Tested no. | Length (mm) | Width (mm) |
| 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 |

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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 | 9.200 | 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 | ≥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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Sample photo:



-END-

Certificate TH18/11436

The management system of

Dr. Boo Co., Ltd.

662/1 4 Moo 3, Panomsara-Sataheh 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
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HC SGS 13485 2016 0118

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Test Report No. 4448445

Date : 13-Dec-2019

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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. : 10005077737
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

Rutchuporn Mungsorn
Laboratory manager - Toy and Hardgood

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Test Report No. 4448445

Date : 13-Dec-2019

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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 ²) | Reporting Limit (mg/inch ²) | Permissible Limit (mg/inch ²) |
|-----------------|-------------------------------------|---------------------------------------|--|--|
| 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 ²) | Reporting Limit (mg/inch ²) | Permissible Limit (mg/inch ²) |
|-------------|-------------------------------------|---------------------------------------|--|--|
| 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 gloveNote : 1. mg/inch² = milligram per square inch
2. ND = Not Detected

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Test Report No. 4448445

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SAMPLE/ATTACHMENT PICTURE



End of Report

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