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
Since 1988

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

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/ Model No(s): NITRILE GLOVES

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:	*Test result:*
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

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 Wilawan Sriphrom / Manager

Date *Name/Position*

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

Test Report No.: 242121053-01

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:

1. All samples were selected and supplied by the client.
2. 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

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	83
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

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	8.670	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)

Sample photo:

-END-

Certificate TH18/11436

The management system of

Dr. Boo Co., Ltd.

662/1-4 Moo 3, Panomsara-Sataheb Road, Tumbol 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

HC SGS 13485 2016 0118

Test Report No. 4448445 **Date** : 13-Dec-2019

Client : DR. BOO CO., LTD.
ROOM NO:1102-11 FLOOR WALL STREET TOWER BLDG 33/48 SURIWONG 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	Conclusion
US FDA 21 CFR 177.2600 (Rubber Articles)- Determination of Amount of Extractives	--
- Distilled Water Extractants	PASS
- n-Hexane Extractants	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 Moungsorn
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/inch2)	Reporting Limit (mg/inch2)	Permissible Limit (mg/inch2)
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/inch2)	Reporting Limit (mg/inch2)	Permissible Limit (mg/inch2)
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/inch2 = milligram per square inch
2. ND = Not Detected

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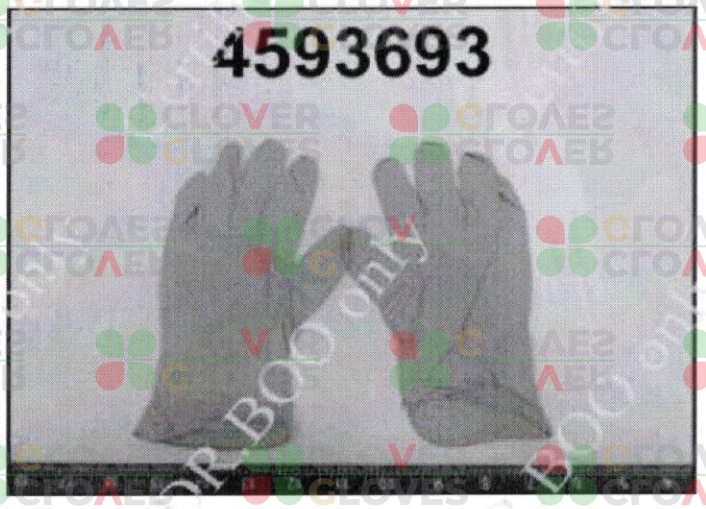
SAMPLE/ATTACHMENT PICTURE



********** End of Report **********

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