





**Date: 6<sup>th</sup> June 2020**

To Whom It May Concern

**EU DECLARATION OF CONFORMITY**

We, **MAXTER GLOVE MANUFACTURING SDN. BHD.** located at **Lot 6070, Jalan Haji Abdul Manan, 6<sup>th</sup> Miles off Jalan Meru, 41050 Klang**, declares that the medical devices described hereafter as:-

- **“MAXTER” Label**, Non Sterile Cobalt Blue Powder Free Nitrile Examination Gloves
- Are in conformity with the general safety and performance requirements of Annex I Medical Device Regulation (EU) 2017/745 for Class I medical devices.
- Classification: Class I based on Rule 5 transient use, Annex VIII of Medical Device Regulation (EU) 2017/745.
- Are in conformity with the national standard transposing harmonized standard EN 455-1, EN 455-2, EN 455-3 and EN455-4.
- The gloves are manufactured according to ISO 9001:2015 and EN ISO 13485:2016 Quality Management Systems and certified by Notified Body, SGS UK Ltd System & Services Certification, Rossmore Business Park Ellesmere Port Cheshire CH653EN, United Kingdom.
- Our Authorized Representative is Supermax Healthcare (Europe) Limited, 38 Main Street, Swords Co. Dublin, Ireland K67 E0A2.

Klang, Selangor  
Malaysia

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Yap Peak Geeh  
QA & Regulatory Affairs Manager




**CERTIFICATE OF QUALITY**

LABEL : MAXTER  
 OUR REF NO. : G/92179  
 TYPE OF GLOVE : Non Sterile Cobalt Blue Powder Free Nitrile Examination Glove  
 ANALYSIS DATE : 20/04/2020  
 REFERENCE STANDARD : EN 455 -1, 2 and 3

Size	Quantity (Cartons)	Quantity (Pieces)	Lot No.
S	400	400,000	B0161 27196 - B0161 27199
M	1,800	1,800,000	B0162 27200 - B0162 27217
L	1,800	1,800,000	B0163 27218 - B0163 27235
XL	800	800,000	B0164 27236 - B0164 27243
Total	4,800	4,800,000	

1. **WATERTIGHT TEST**  
 Inspection level: G1  
 AQL: 1.5

Size	Sample size (pcs)	Acceptance (pcs)	Defects(pcs)	Result
S	315	10	4	Pass
M	500	14	7	Pass
L	500	14	8	Pass
XL	500	14	6	Pass

2. **DIMENSIONS**

Sample Size: 13 Pieces/ Size

Acceptance: Median value obtained shall meet the EN 455-2 requirements

Defects found: 0  
 Result: Pass

**EN 455-2**

**Requirements:**

Length:  
 Min 240mm (All Sizes)

Width:  
 XS: 70-79 mm  
 S: 80-89 mm  
 M: 90-99 mm  
 L: 100-109 mm  
 XL: 110-119 mm

Median Value				
Size	Length (mm)	Width (mm)	Thickness (single wall) (mm)	
			Fingertip	Palm
S	245	86	0.10	0.05
M	244	95	0.10	0.05
L	247	105	0.10	0.05
XL	244	114	0.10	0.05


**CERTIFICATE OF QUALITY**

3. **FORCE AT BREAK BEFORE ACCELERATED AGEING AND AFTER ACCELERATED AGEING**  
 Sample size: 13 pieces/size  
 Defects found: 0  
 Result: Pass

Size	Median Value	
	Before Accelerated Aging	After Aging
	Force at break(N) (Min 6 N)	Force at break(N) (Min 6 N)
S	6.5	6.2
M	6.4	6.1
L	6.4	6.0
XL	6.5	6.1

Median Value				
Size	Length (mm)	Width (mm)	Thickness (single wall) (mm)	
			Fingertip	Palm
S	245	86	0.10	0.05
M	244	95	0.10	0.05
L	247	105	0.10	0.05
XL	244	114	0.10	0.05



**MAXTER**  
GLOVE MANUFACTURING SDN BHD  
(229862-H)

**LOT 6070**  
Jalan Haji Abdul Manan, 6th Miles Off Jalan Meru  
41050 Klang, Selangor, Malaysia  
Tel: 603-33929888 (8 lines) Fax: 603-33923328  
E-MAIL: info@maxter.com.my

**CERTIFICATE OF QUALITY**

**3. FORCE AT BREAK BEFORE ACCELERATED AGEING AND AFTER ACCELERATED AGEING**

Sample size: 13 pieces/size  
Defects found: 0  
Result: Pass

Size	Median Value	
	Before Accelerated Aging	After Aging
	Force at break(N) (Min 6 N)	Force at break(N) (Min 6 N)
S	6.5	6.2
M	6.4	6.1
L	6.4	6.0
XL	6.5	6.1

**4. PROTEIN CONTENT TEST**

Size	Protein Content (Max 50µg/g)	Result
S	N/A	N/A
M	N/A	N/A
L	N/A	N/A
XL	N/A	N/A

**5. POWDER RESIDUE**

Size	Powder Content (Max 2mg/glove)	Result
S	0.12	Pass
M	0.10	Pass
L	0.16	Pass
XL	0.18	Pass

**CONCLUSION:** The lots tested are complied with EN 455 -1, 2 and 3 standards as referring to the above findings of randomly selected samples

PREPARED BY:

*Tracy*  
Tracy Chia  
QA Chemist



SGS

Certificate MY00/51619

The management system of

# Maxter Glove Manufacturing Sdn. Bhd.

Lot 6070, Jalan Haji Abdul Manan  
6th Miles Off Jalan Meru, 41050 Klang, Selangor Darul Ehsan  
MALAYSIA

has been assessed and certified as meeting the requirements of

## ISO 9001:2015

For the following activities

**Manufacture of Natural Latex and Nitrile Rubber Gloves**

This certificate is valid from 25 June 2018 until 04 May 2021 and remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 04 March 2021  
Issue 10. Certified since 04 May 2000

The audit leading to this certificate commenced on 01 March 2018  
Previous issue certificate validity date was until 04 May 2018

Authorised by

SGS United Kingdom Ltd  
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK  
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Lot 6070, Jalan Haji Abdul Manan  
6th Miles Off Jalan Meru, 41050 Klang, Selangor Darul Ehsan  
MALAYSIA

has been assessed and certified as meeting the requirements of

## ISO 13485:2016 EN ISO 13485:2016

For the following activities

**Manufacture of non sterile Natural Latex and Nitrile Rubber Examination Gloves**

This certificate is valid from 04 May 2018 until 04 May 2021  
and remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 04 March 2021  
Issue 13. Certified since 04 May 2000

Authorised by

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