



M A X T E R
GLOVE MANUFACTURING SDN BHD
(229862-H)

LOT 6070

Jalan Haji Abdul Manan, 6th Miles Off Jalan Meru
41050 Klang, Selangor, Malaysia
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Date: 31st May 2021

To Whom It May Concern

EU DECLARATION OF CONFORMITY

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

- **Non Sterile Powder Free Latex Examination Gloves, Basic UDI-DI: 955 500211 6378**
 - **Non Sterile Powdered Latex Examination Gloves, Basic UDI-DI: 955 500211 6361**
 - **Non Sterile Powder Free Nitrile Examination Gloves, Basic UDI-DI: 955 500211 6385**
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- 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.
 - The gloves are manufactured according to ISO 9001:2015 and EN ISO 13485:2016 Quality Management Systems and certified by Notified Body, SGS United Kingdom Ltd Systems & Services Certification.
 - Our Authorized Representative is Supermax Healthcare (Europe) Limited, 38 Main Street, Swords Co. Dublin, Ireland K67 E0A2.

Klang, Selangor
Malaysia



Yap Peak Geeh
QA & Regulatory Affairs Manager

**MAXTER GLOVE MANUFACTURING SDN BHD
 GLOVE SPECIFICATION**

1. Product : **5.0 Mil (5.5g) Black Powder Free Nitrile Examination Gloves**
2. Material : **Nitrile**
3. Type : **Non Sterile**
4. Glove Design & Feature : **Ambidextrous and palm textured.**
5. Cuff : **Beaded**
6. Usage : **For Single Use Only**
7. Colour : **Black**
8. Packaging : **100 ± 2 pcs/inner, 10 inners/carton**

9. Dimensions : (Available in 5 sizes)

Size	Glove Weight (g)	Palm Width (mm)		Length (mm)	
		ASTM D6319	MAXTER	ASTM D6319	MAXTER
XS	4.6 ± 0.2	70 ± 10	70 – 79	Min. 220	Min. 240
S	5.0 ± 0.2	80 ± 10	80 – 89	Min. 220	Min. 240
M	5.4 ± 0.2	95 ± 10	90 – 99	Min. 230	Min. 240
L	5.8 ± 0.2	110 ± 10	100 – 109	Min. 230	Min. 240
XL	6.2 ± 0.2	120 ± 10	110 – 119	Min. 230	Min. 240
XXL	7.0 ± 0.2	-	120 - 129	-	Min. 240

10. Thickness :

Location of Thickness Measurement	Single Wall (mm)	
	ASTM D6319	MAXTER
Finger	Min 0.05	Min 0.13
Palm	Min 0.05	Min 0.11
Cuff	N/A	Min 0.08

11. Physical Properties :


	Before Aging		After Aging	
	ASTM D6319	MAXTER	ASTM D6319	MAXTER
Tensile Strength (MPa)	Min. 14	Min. 14	Min. 14	Min. 14
Elongation (%)	Min. 500	Min. 500	Min. 400	Min. 400
Force at Break (N)	N/A	Min. 6	N/A	Min. 6

12. Protein Content : **Not applicable.**
13. Powder Level : **Max. 2 mg/ glove.**
14. Compliance Standards : **ASTM D6319, EN 455 Part 1, 2, 3 & 4.**

15. Inspection Criteria (Sampling & Inspection ISO 2859) :

	Inspection Level	AQL
Watertight Test	G1	1.5
Major Defects	G1	2.5
Minor Defects	G1	4.0
Dimensions	S2	4.0
Physical Properties	S2	4.0

16. Quality Assurance : **ISO 9001 certified by SGS (UK) and SIRIM (Malaysia)
 ISO 13485 certified by SGS (UK)**

Prepared by : 
 Yap Peak Geeh
 QA & RA Manager

Approved by : 
 Dato' Seri Stanley Thai
 Group MD

