MAXTER
GLOVE MANUFACTURING SDN BHD
(229862-H)
since 1989

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

20th October 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, Selangor, Malaysia, declares under our sole responsibility that the medical devices and PPE described hereafter as:-

- **Non Sterile Latex Examination Gloves**
- **Non Sterile Nitrile Examination Gloves**

are in conformity with:-

- The general safety and performance requirements of Medical Device Regulation (EU) 2017/745 for Class I medical devices.

- Classification: Class I based on Rule 5 transient use, Annex VIII of the Medical Device Regulation (EU) 2017/745

- With the national standard transposing harmonized standard EN455 and is self-certified as a Class I non-sterile medical device.

- The provisions of Personal Protective Equipment (PPE) – Regulation (EU) 2016/425 and the requirements of the European harmonized standard EN420:2003+A1:2009, EN ISO 374-1:2016, and EN ISO 374-5:2016, EN 374-2:2014, EN 16523-1:2015 and EN 374-4:2013.

- Is identical to the PPE which is subject to the EU Type Examination Certificate (Module B) issued by the Notified Body:
  SATRA (2777)
  Bracetown Business Park, Clonee D15YN2P, Republic of Ireland.

- Is subject to the procedure set out in Module D of regulation (EU) 2016/425 as a Category III product and under the supervision of the Notified Body:
  SGS FIMKO OY (0598)
  P.O. Box 30 (Särkiniementie 3), 00211 Helsinki, Finland.

- The gloves are manufactured according to ISO 9001:2015 and ISO 13485:2016 Quality Management Systems and certified by Notified Body, SGS United Kingdom Ltd Systems & Services Certification.

- Our Authorized EU 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 : **2.5 Mil (3.4g) Teal Powder Free Nitrile Examination Gloves**
2. Material : **Nitrile**
3. Type : Non Sterile
4. Glove Design & Feature : Ambidextrous and finger textured.
5. Cuff : Beaded
6. Usage : For Single Use Only
7. Colour : Teal
8. Packaging : 200 ± 4 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	2.9 ± 0.2	70 ± 10	70 – 79	Min. 220	Min. 240
S	3.2 ± 0.2	80 ± 10	80 – 89	Min. 220	Min. 240
M	3.4 ± 0.2	95 ± 10	90 – 99	Min. 230	Min. 240
L	3.7 ± 0.2	110 ± 10	100 – 109	Min. 230	Min. 240
XL	4.0 ± 0.2	120 ± 10	110 – 119	Min. 230	Min. 240

10. Thickness :

Location of Thickness Measurement	Single Wall (mm)	
	ASTM D6319	MAXTER
Finger	Min 0.05	Min 0.10
Palm	Min 0.05	Min 0.05
Cuff	N/A	Min 0.05

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 and 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

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