



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

LOT 6070

Jalan Haji Abdul Manan, 6th Miles Off Jalan Meru
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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 : 3.2 Mil (3.6g) Ice Blue 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 : Ice Blue
 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 | 3.0 ± 0.2 | 70 ± 10 | 70 – 79 | Min. 220 | Min. 240 |
| S | 3.3 ± 0.2 | 80 ± 10 | 80 – 89 | Min. 220 | Min. 240 |
| M | 3.5 ± 0.2 | 95 ± 10 | 90 – 99 | Min. 230 | Min. 240 |
| L | 3.8 ± 0.2 | 110 ± 10 | 100 – 109 | Min. 230 | Min. 240 |
| XL | 4.1 ± 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 0.06 |
| 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

