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
E-MAIL: info@maxter.com.my

2nd April 2020

To Whom It May Concern:

MANUFACTURER DECLARATION

We, MAXTER GLOVE MANUFACTURING SDN. BHD., located at Lot 6070, Jalan Haji Abdul Manan, 6th Miles off Jalan Meru, 41050 Klang, declare that the device manufactured by us,

- **"MAXTER" label, Non Sterile Powder Free Nitrile Examination Gloves**

are in conformity with:-

- **EEC regulations concerning the conformity of materials and products that has to get in touch with food:**
  1. **Reg. EEC 1935/2004**
  2. **Regulation EC 10/2011**
  3. **Regulation (EC) No 2023/2006**

- **The gloves are for contact of dry, fatty, alcoholic and aqueous food for short term contact based on the outcome of the overall migration test on the food simulants at 40°C for 2 hours.**

- **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.**

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Klang, Selangor
Malaysia

Yap Peak Geeh
QA & Regulatory Affairs Manager

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Date: 2 April 2020

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 :-

- **"MAXTER" Label, Non Sterile 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 United Kingdom Ltd Systems & Services Certification.
- Our Authorized Representative is Supermax Healthcare (Europe) Limited, 38 Main Street, Swords Co. Dublin, Ireland K67 E0A2.

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2nd April 2020

To Whom It May Concern:

EC DECLARATION OF CONFORMITY

We, **MAXTER GLOVE MANUFACTURING SDN. BHD., located at Lot 6070, Jalan Haji Abdul Manan, 6th Miles off Jalan Meru, 41050 Klang,** declare that the medical devices manufactured by us,

- "MAXTER" label, Non Sterile Powder Free Nitrile Examination Gloves

are PPE Category III and are in conformity with:

- The provisions of Regulation (EU) 2016/425 and, the requirements of the European harmonized standard EN420:2003+A1:2009 and EN374-1:2016, and it is identical to the PPE which is subject to the EC 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 under the supervision of the Notified Body:
  SGS UK Limited (0120)
  202B Worle Parkway, Weston-super-Mare, BS226WA, UK.

- The gloves are manufactured according to ISO 9001:2015 and 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 European Representative is Supermax Healthcare (Europe) Limited, 38 Main Street, Swords Co. Dublin, Ireland K67 E0A2.

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