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

Date: 2nd February 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 that the medical devices described hereafter as:-

- "**Maxter**" label, Non Sterile Powder Free Latex Examination Gloves
  UDI-DI code: 9 555002 105761, 9 555002 105778, 9 555002 105785,
  9 555002 105792 and 9 555002 105808

- 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

Yap Peak Geeh
QA & Regulatory Affairs Manager

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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,** declare that the devices manufactured by us,

- "**Maxter**" label, Non Sterile Powder Free Latex Examination Gloves
  UDI-DI code: 9 555002 105761, 9 555002 105778, 9 555002 105785,
  9 555002 105792 and 9 555002 105808
  -are PPE Category III covered by EU Type Examination Certificate No: 2777/12719-01/E00-00

are in conformity with:

- The provisions of Regulation (EU) 2016/425 and, the requirements of the European harmonized standard EN420:2003+A1:2009 and EN ISO 374-1:2016, and it 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 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 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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