M A X T E R
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

6th June 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,** declare that the devices manufactured by us,

- ñ**MAXTER**ò label, Non Sterile Cobalt Blue 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 EN ISO 374-1:2016, 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 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.

Klang, Selangor
Malaysia

Yap Peak Geeh
QA & Regulatory Affairs Manager