



M A X T E R

GLOVE MANUFACTURING SDN BHD
(229862-H)

LOT 6070

Jalan Haji Abdul Manan, 6th Miles Off Jalan Meru
41050 Klang, Selangor, Malaysia
Tel: 603-33929888 (8 lines) Fax: 603-33923328
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21st December 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,

- **öSuperguardö** label, Non Sterile 2.2Mil Purple Blue Powder Free Nitrile Examination Gloves
UDI-DI code: 9-555002-114497, 9-555002-114503 and 9-555002-114510
-are PPE Category III covered by EU Type Examination Certificate No:
2777/12706-01/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.



Klang, Selangor
Malaysia

Yap Peak Geeh
QA & Regulatory Affairs Manager