



**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  
E-MAIL: info@maxter.com.my

**23<sup>rd</sup> July 2020**

To Whom It May Concern:

**EU DECLARATION OF CONFORMITY**

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

- “**MAXTER**” label, Non Sterile Powder Free Latex Examination Gloves
  - “**MAXTER**” label, Non Sterile Powdered Latex Examination Gloves
- are PPE Category III covered by EU Type Examination Certificate No: 2777/12719-01/E00-00 and 2777/12636-01/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