



M A X T E R
GLOVE MANUFACTURING SDN BHD
(229862-H)

LOT 6070

Jalan Haji Abdul Manan, 6th Miles Off Jalan Meru
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Date: 23rd November 2023

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, Selangor, Malaysia declares under our sole responsibility that the devices described hereafter as :-

- “**PROMATES**” label, Non-Sterile 7.0mil Orange Powder Free Nitrile Examination Gloves
Product reference : **PFHN-GTO**
- “**PROMATES**” label, Non-Sterile 7.0mil Black Powder Free Nitrile Examination Gloves
Product reference : **PFHN-GTBK**

-are PPE Category III covered by EU Type Examination Certificate No: **2777/12710-02/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, EN ISO 374-1:2016+A1:2018 and EN ISO 374-5:2016 and it is subject to the EU Type Examination (Module B) by the Notified Body:
SATRA (2777)
Bracetown Business Park, Clonee D15YN2P, Republic of Ireland.
- Is subject to the conformity assessment procedure set out in Module D of Regulation (EU) 2016/425 under surveillance of the Notified Body:
SGS FIMKO OY (0598)
Takomotie 8, FI-00380 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 authorised representative is Supermax Healthcare (Europe) Limited, 38 Main Street, Swords Co. Dublin, Ireland K67 E0A2.

Signed for and on behalf of
Maxter Glove Manufacturing Sdn Bhd



Klang, Selangor
Malaysia

Yap Peak Geeh
QA & Regulatory Affairs Senior Manager