

Date: 28<sup>th</sup> June 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:-

- “**SUPERMAX**” label, Non Sterile 3.2mil Ice Blue Powder Free Nitrile Examination Gloves  
Product reference: **PFTN-FTIB**

-are PPE Category III covered by EU Type Examination Certificate No: **2777/12716-02/E00-00**

are in conformity with:

- The provisions of Regulation (EU) 2016/425 and the requirements of the European harmonized standard EN 420:2003+A1:2009, EN ISO 374-1:2016 and EN ISO 374-5:2016 and it is subject to the EU Type Examination (Module B) by 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**