



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: maxter@tm.net.my
www.maxter.com.my

Date: 28th 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 medical devices described hereafter as:-

- **“SUPERMAX”** label, Non Sterile 3.2mil Ice Blue Powder Free Nitrile Examination Gloves
Basic UDI-DI: **955 500211 638CT**

Single Registration Number (SRN): **MY-MF-000016719**

are in conformity with:-

- The general safety and performance requirements of Annex I Medical Device Regulation (EU) 2017/745 for Class I medical devices.
- Classification: Class I based on Rule 5 transient use, Annex VIII of the Medical Device Regulation (EU) 2017/745
- The national standard transposing harmonized standard EN455-1, EN455-2, EN455-3 and EN455-4
- The gloves are manufactured according to ISO 9001:2015 and ISO 13485:2016 Quality Management Systems and certified by Notified Body, SGS United Kingdom Ltd Systems & Services Certification.
- 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