MAXTER
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

Date: 13th July 2022

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

- "**KIMESTA**" Label, Non Sterile 7.0mil Orange Powder Free Nitrile Examination Gloves
  Product reference: PFHN-GTO

  -are PPE Category III covered by EU Type Examination Certificate No: 2777/12710-01/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, EN ISO 374-1:2016, 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 Representative is Supermax Healthcare (Europe) Limited, 38 Main Street, Swords Co. Dublin, Ireland K67 E0A2.

MAXTER GLOVE MANUFACTURING SDN BHD 229862-H

Klang, Selangor
Malaysia

Yap Peak Geeh
QA & Regulatory Affairs Manager

M A X T E R
GLOVE MANUFACTURING SDN BHD
(229862-H)
since 1989

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## 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:-

- **"KIMESTA" label, Non Sterile Powder Free Nitrile Examination Gloves, 7.0mil**
  Product Reference: **PFHN-GTO**
  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
- With the national standard transposing harmonized standard EN455-1, EN455-2, EN455-3 and EN455-4 and is self-certified as a Class I non-sterile medical device.
- 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 Authorized EU Representative is Supermax Healthcare (Europe) Limited, 38 Main Street, Swords, Co. Dublin, Ireland K67 E0A2


Klang, Selangor
Malaysia

Yap Peak Geeh
QA & Regulatory Affairs Senior Manager