MAXTER
GLOVE MANUFACTURING SDN BHD
(229862-H)
since 1989

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: 31st December 2024

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:

- **"SENSITEX"** label, Non-Sterile Powdered Latex Examination Gloves
  Basic UDI-DI: **955 500211 636CP**

- **"SENSITEX"** label, Non-Sterile Powder Free Latex Examination Gloves
  Basic UDI-DI: **955 500211 637CR**

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 EU Declaration of Conformity is assured according to the guidelines set out in Annex IV 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 Obelis S.A., Bd. General Wahis 53, 1030 Brussels, Belgium.

Signed for and on behalf of
Maxter Glove Manufacturing Sdn Bhd

Klang, Selangor
Malaysia

Yap Peak Geeh
QA & Regulatory Affairs Senior Manager

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- "**SENSITEX**" label, Non-Sterile Powder Free Latex Examination Gloves
  Product reference: **MTCLPF**

  -are PPE Category III covered by EU Type Examination Certificate No: **2777/12719-05/E00-00**

are in conformity with:

- The provisions of Regulation (EU) 2016/425 and the requirements of the European harmonized standard EN ISO 21420:2020, 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 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.

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