MAXTER
GLOVE MANUFACTURING SDN BHD
(229862-H)

Lot 6070, Jalan Haji Abdul Manan
6th Miles Off Jalan Meru
41050 Klang, Selangor, Malaysia
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Date: 18th January 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, Selangor, Malaysia, declares under our sole responsibility that the medical devices described hereafter as:-

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

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

- **Non Sterile 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

- With the national standard transposing harmonized standard EN455 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

Digitally signed by Chitic Ecaterina
Date: 2022.10.12 11:18:36 EEST
Reason: MoldSign Signature
Location: Moldova

MAXTER GLOVE MANUFACTURING SDN BHD 229862-H

Klang, Selangor
Malaysia

Yap Peak Geeh
QA & Regulatory Affairs Manager