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

LOT 6070
Jalan Haji Abdul Manan, 6th Miles Off Jalan Meru
41050 Klang, Selangor, Malaysia
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13th December 2021

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 medical devices described hereafter as :-

- "**MAXTER**" Label, Non Sterile 4.5Mil Long Cuff Regular Blue Powder Free Nitrile Examination Gloves, consists of the following product codes

Size	Product Code
XS	MX63885
S	MX63886
M	MX63887
L	MX63888
XL	MX63889

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 of Medical Device Regulation (EU) 2017/745 for Class I medical devices.

- Classification: Class I based on Rule 5 transient use, Annex VIII of Medical Device Regulation (EU) 2017/745.

- Are in conformity with the national standard transposing harmonized standard EN 455-1, EN 455-2, EN 455-3 and EN 455-4.

- The gloves are manufactured according to ISO 9001:2015 and EN ISO 13485:2016 Quality Management Systems and certified by Notified Body, SGS United Kingdom Ltd Systems & 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.

- Are imported by RE-GUARD KFT, Telki, Tücsök u. 16, 2089 Hungary to Hungary.

Klang, Selangor
Malaysia

Yap Peak Geeh
QA & Regulatory Affairs Manager