



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

LOT 6070

Jalan Haji Abdul Manan, 6th Miles Off Jalan Meru
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Date: 19th June 2020

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 that the medical devices described hereafter as:-

“BIMEL” Label, Non Sterile Blue Powder Free Nitrile Examination Gloves

- 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 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 EN455-4.
- The gloves are manufactured according to ISO 9001:2015 and EN 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 Authorized Representative is Supermax Healthcare (Europe) Limited, 38 Main Street, Swords Co. Dublin, Ireland K67 E0A2.

Klang, Selangor
Malaysia



Yap Peak Geeh
QA & Regulatory Affairs Manager