



**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: 24<sup>TH</sup> OCTOBER 2020

To Whom It May Concern

**EU DECLARATION OF CONFORMITY**

We, **MAXTER GLOVE MANUFACTURING SDN. BHD.** located at Lot 6070, Jalan Haji Abdul Manan, 6<sup>th</sup> Miles Off Jalan Meru, 41050 Klang, Selangor, Malaysia, declares under our sole responsibility that the medical devices described hereafter as: -

**“Maxter” Non-Sterile Latex Powdered Smooth Surface Examination Glove, delivered as per invoice SHK007662 (shipped on October 25, 2020)**

- 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 United Kingdom Ltd Systems & Services Certification.
- 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