



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

**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: info@maxter.com.my

Date: 21<sup>st</sup> December 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, declares that the medical devices described hereafter as:-

- **Superguard** label, Non Sterile 2.2Mil Purple Blue Powder Free Nitrile Examination Gloves  
UDI-DI code: 9-555002-114497, 9-555002-114503 and 9-555002-114510
- 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



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Yap Peak Geeh  
QA & Regulatory Affairs Manager