



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
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25th January 2019

To Whom It May Concern:

EC DECLARATION OF CONFORMITY

We, MAXTER GLOVE MANUFACTURING SDN. BHD., located at Lot 6070, Jalan Haji Abdul Manan, 6th Miles off Jalan Meru, 41050 Klang, declare that the devices manufactured by us,

➤ **NON STERILE POWDERED LATEX EXAMINATION GLOVES**

are PPE Category III and are in conformity with:

- **The provisions of Council Directive 89/686/EEC and, the requirements of the European harmonized standard EN420:2003+A1:2009 and EN374:2003, and it is identical to the PPE which is subject to the EC Type Examination Certificate Number 060/2014/1393 issued by the Notified Body:
Centexbel (0493)
Technologiepark 7,
BE-9052 Zwijnaarde.**
- **Is subject to the procedure set out in Article 11B of Directive 89/686/EEC under the supervision of the Notified Body:
SGS UK Limited (0120)
202B Worle Parkway, Weston-super-Mare, BS226WA, UK.**
- **The gloves are manufactured according to ISO 9001:2015 and 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 European Representative is Supermax Healthcare Limited, located at 12-16 Titan Drive, Fengate, Peterborough, PE1 5XN, United Kingdom.**

**Klang, Selangor
Malaysia**



**Yap Peak Geeh
QA & Regulatory Affairs Manager**