



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

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21st January 2017

EC DECLARATION OF CONFORMITY

To Whom It May Concern:

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

“ Sonic” Non Sterile Nitrile Examination Glove

is in conformity with :-

- **The essential requirements of Medical Device Directive (MDD) 93/42EEC as amended by Directive 2007/47/EC for Class 1 Medical Devices.**
- **EN 455-1, 2, 3 & 4 Standards.**
- **The gloves are manufactured according to ISO 9001:2008 and ISO 13485:2003 Quality Management Systems and certified by Notified Body, SGS United Kingdom Ltd Systems & Services Certification, UK.**
- **Our European Representative is Supermax Healthcare Limited, 12-16 Titan Drive, Fengate, Peterborough, PE1 5XN, United Kingdom. Tel: +44 (0) 1733 615215**
- **We have been selling our products in the European Union countries such as United Kingdom, Germany, Italy, Netherlands, Lithuania, Greece and etc since 1991 year.**

**Klang, Selangor
Malaysia**



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