



**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  
Email: info@maxter.com.my  
www.maxter.com.my

**21<sup>st</sup> 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 6<sup>th</sup> 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**