

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: maxter@tm.net.my www.maxter.com.my

16th August 2016

To Whom It May Concern:

DECLARATION OF CONFORMITY

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,

> Non Sterile Nitrile Examination Gloves

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 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.
- 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



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21th September 2016

To Whom It May Concern:

DECLARATION OF CONFORMITY

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,

> Non Sterile Latex Examination Gloves

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 & 3 Standards.
- The gloves are manufactured according to ISO 9001:2008 and ISO 13485:2003
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