

Lot 38, Putra Industrial Park, Bukit Rahman Putra 47000 Sungai Buloh, Selangor Darul Ehsan, Malaysia Tel: 603-61452328 (30 lines) Fax: 603-61562191 / 67307883 E-MAIL: smax@po.jaring.my www.supergloves.com

7th November 2017

To Whom It May Concern:

CERTIFICATE OF CONFORMITY

We, SUPERMAX GLOVE MANUFACTURING SDN. BHD., located at Lot 38, Putra Industrial Park, Bukit Rahman Putra 47000 Sungai Buloh, declare that the medical devices manufactured by us as,

"Aurelia Robust Grip" Label, Non Sterile Regular Blue **Powder Free Nitrile Examination Gloves**

are in conformity with:-

- The essential requirements of Medical Device Directive 93/42/EEC as amended by Directive 2007/47/EC for Class I medical devices and EN455-1, 2, 3 & 4 standards.
- The essential requirements of EN420 as per the PPE Directive 89/686/EEC, EN374-1, 2 & 3 standards & EN1186 Food Contact.
- The gloves are manufactured according to ISO 9001:2008 and ISO 13485:2003 Quality Management Systems and certified by Notified Body, SGS, United Kingdom.
- Our European Representative is Supermax Healthcare Ltd, 12-16 Titan Drive, Fengate, Peterborough UK, PE1 5XN.

E-mail: sales@supermax.co.uk

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

Sungai Buloh, Selangor Malaysia