

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

7<sup>th</sup> August 2014

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 Quest" Label, Non Sterile White 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, Supermax Suite, Stuart House East Wing, St Johns Street, Peterborough UK, PE1 5DD. E-mail: <u>sales@supermax.co.uk</u>

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

Sungai Buloh, Selangor Malaysia