

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 Distinct" Label, Non Sterile Honeycomb Textured Powder Free Latex 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>

2185080-1 (2010) 2185080-1 (2

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

Sungai Buloh, Selangor Malaysia