SUPERMAX
GLOVE MANUFACTURING SDN BHD
(218698-T)
since 1989

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22nd June 2017

To Whom It May Concern:

LETTER OF CONFIRMATION

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" Non Sterile Powdered Latex Examination Gloves**

- Are manufactured in a strict GMP environment with a certified quality management system to ISO 9001:2008 and ISO 13485:2003.

- Systematic procedures have been established in complying with the relevant regulatory requirements stated in the following international standards.

Document No.	Title of Document
BS EN ISO 9001 : 2008	Quality management systems - Requirements
ISO 13485 : 2003	Medical devices – Quality management systems – Requirements for regulatory purposes
BS EN ISO 14971 : 2009	Medical devices – Application of risk management to medical devices
BS EN 455-1 : 2000	Medical gloves for single use - Part 1 : Requirements and testing for freedom from holes
BS EN 455-2:2009+A1:2011	Medical gloves for single use - Part 2 : Requirements and testing for physical properties
BS EN 455-3 : 2006	Medical gloves for single use - Part 3 : Requirements and testing for biological evaluation
EN 10993 – Part 1	Biological evaluation of medical devices – Part 1 : Evaluation and testing
EN 1041 : 1998	Medical devices – Information supplied by the manufacturer
BS EN 980 : 2008	Graphical symbols for use in the labelling of medical devices

Sungai Buloh, Selangor,

Malaysia

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Yap Peak Geeh
QA & Regulatory Affairs Manager