



**M A X T E R**  
GLOVE MANUFACTURING SDN BHD  
(229862-H)

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30<sup>th</sup> April 2019

### DECLARATION OF CONFORMITY

We, MAXTER GLOVE MANUFACTURING SDN. BHD., located at Lot 6070, Jalan Haji Abdul Manan, 6<sup>th</sup> Miles Off Jalan Meru, 41050 Klang, Selangor, Malaysia, declare that the medical devices described hereafter,

**“Aurelia Bold-Max”, Non Sterile Black Powder Free Nitrile Examination Gloves**

are in conformity with:-

- The provisions of Personal Protective Equipment (PPE) – Regulation (EU) 2016/425 as a CAT III. product and, the requirement of the European harmonised standard EN420 and EN374.
- With the essential requirements of Medical Device Directive (MDD) 93/42/EEC as amended by Directive 2007/47/EC and with the National Standards transposing harmonised standards EN455-1, EN455-2, EN455-3, EN455-4 and is self-certified as a Class 1 non-sterile medical device.
- The gloves are manufactured according to ISO 9001:2015 and ISO 13485:2016 Quality Management Systems and certified by Notified Body, SGS, United Kingdom.
- EEC regulations concerning the conformity of materials and products that are allowed to come into contact with food. In accordance with Regulation EEC 1935/2004, Regulation EC 10/2011 & Regulation (EC) No 2023/2006. The gloves are suitable for contact with dry, fatty, alcoholic and aqueous food for short term contact based on the outcome of the overall migration test on the food simulants.
- User Information - This product does not contain natural rubber latex. Contains accelerators which may cause allergic reactions. You are advised to retain the packaging for reference.
- Storage: Store below 40°C/104°F in dry conditions and away from direct sunlight.
- Our UK Representative is Supermax Healthcare Limited., 12-16 Titan Drive, Fengate, Peterborough, PE1 5XN, United Kingdom.
- Our EU Representative is Supermax Healthcare (Europe) Limited, 38 Main Street, Swords, Co. Dublin, Ireland.



Klang, Selangor  
Malaysia

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