MAXTER
GLOVE MANUFACTURING SDN BHD
(229862-H)
since 1989

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30th April 2019

DECLARATION OF CONFORMITY

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

"Aurelia Ignite", Non Sterile Orange 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