



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

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8th January 2020

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, declares under our sole responsibility that the medical devices described hereafter as:-

“Aurelia Transform 100”, Non Sterile Ice Blue Powder Free Nitrile Examination Gloves

are in conformity with:-

- The general safety and performance requirements of Annex I, Medical Device Regulation (EU) 2017/745 for Class I medical devices.
- Classification: Class I based on Rule 5 transient use, Annex VIII of the Medical Device Regulation (EU) 2017/745
- With the national standard transposing harmonized standard EN455-1, EN455-2, EN455-3 and EN455-4 and is self-certified as a Class I non-sterile medical device.
- The provisions of Personal Protective Equipment (PPE) – Regulation (EU) 2016/425 Module D as a CAT III product and the requirement of the European harmonised standard EN420 and EN374 and certified by Notified Body CE0598 SGS Fimko OY, Finland.
- The gloves are manufactured according to ISO 9001:2015 and ISO 13485:2016 Quality Management Systems and certified by Notified Body, SGS United Kingdom Ltd Systems & Services Certification.
- 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 Authorised UK Representative is Supermax Healthcare Limited., 12-16 Titan Drive, Fengate, Peterborough, PE1 5XN, United Kingdom.
- Our Authorised EU Representative is Supermax Healthcare (Europe) Limited, 38 Main Street, Swords, Co. Dublin, Ireland K67 E0A2



**Klang, Selangor
Malaysia**

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