



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

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6th Miles Off Jalan Meru  
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**8<sup>th</sup> January 2020**

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

**“Aurelia Zero”, Non Sterile Ice Blue Accelerator Free 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 and is accelerator-free. If any allergic reaction is found 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**