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

Lot 6070, Jalan Haji Abdul Manan
6th Miles Off Jalan Meru
41050 Klang, Selangor, Malaysia
Tel: 603-33929888 (8 lines) Fax: 603-33923328
E-MAIL: maxter@tm.net.my
www.maxter.com.my

# Declaration of Conformity

Maxter Glove Manufacturing Sdn Bhd hereby confirms that the product mentioned below complies with EU Regulations and Standards and is manufactured according to ISO 9001 & ISO 13485 standard requirements.

**Aurelia Bold Max 6.0 mil Black Powder Free Nitrile Examination Glove**

| Size | Product Code | Inner case barcode | Outer case barcode |
|---|---|---|---|
| **Medium** | 9789A7 | 955-500211-3063 | 1955-500211-3060 |
| **Large** | 9789A8 | 955-500211-3070 | 1955-500211-3077 |
| **X-Large** | 9789A9 | 955-500211-3087 | 1955-500211-3084 |
| **XX-Large** | 9789A0 | 955-500211-3094 | 1955-500211-3091 |

**Classification of the product:**

- Class I Medical Device based on Rule 5 transient use, Annex VIII of Medical Device Regulation (EU) 2017/745
- CAT III PPE (EU) 2016/425

**Product mentioned above complies with:**

- The General Safety and Performance requirements of Annex I, Medical Device Regulation (EU) 2017/745 for Class I Medical Devices and with the Article 19 requirements.
- The provisions of Personal Protective Equipment (PPE) Regulation (EU) 2016/425, including the General Safety Requirements (Annex II), Module B EU-Type Examination Certification and Module D, Conformity to type, based on Quality Assurance of the production process.
- 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 2023/2006.
- Medical Device Regulation 2002 for Class I Medical Devices.

**Certification:**

- Module B, EU Type Examination Certificate issued by Notified Body : Satra (2777) – Certificate No. 2777/22622-02/E00-00
- Module D, Regulation (EU) 2016/425, Examination Certificate issued by Notified Body : SGS FIMKO OY, Notified Body CE0598 – Certificate No. MY19/1811030073
- ISO 9001:2015
- ISO 13485:2016

**Gloves tested according to Harmonised Standards:**

- EN 374-1 – chemical resistance
- EN 374-5 – microbiological resistance
- EN 455 – 1,2,3, 4 – medical devices
- EN 21420 – physical attributes or EN420 during the transition period

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**User Information:**

- 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.
- The product does not contain natural rubber latex. Contains accelerators which may cause allergic reactions. Please retain the packaging for reference.
- Store below 40°C/104°F in dry, clean condition and away from direct sunlight and fluorescent lighting.

**Responsibility**

- This Declaration of Conformity is issued under the responsibility of the Manufacturer, as indicated below:

**Manufacturer:**

- Maxter Glove Manufacturing Sdn Bhd, located at Lot 6070, Jalan Haji Abdul Manam, 6th Miles off Jalan Meru, 41050 Klang, Selangor, Malaysia
- SRN: MY-MF-000016719

**Importer & Authorised Representatives:**

- EU Representative is Supermax Healthcare (Europe) Limited, 38 Main Street, Swords Co. Dublin, K67 E0A2, Ireland
  - SRN: IE-AR-000013888
- UK Representative is Supermax Healthcare Limited, 12-16 Titan Drive, Fengate, PE1 5XN, Peterborough, United Kingdom

Maxter Glove Manufacturing Sdn Bhd, Malaysia

Authorised by:

Yap Peak Geeh
Senior Manager
QA & Regulatory Affairs

Date : 04/10/2023

***This declaration is valid for period of 2 years from the date of issue or until any changes to regulations or products are applicable.**