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 Delight Clear Powdered Vinyl Glove

Size	Product Code	Inner Boxes Barcode	Outer Boxes Barcode
Small	38826	955-500210-6027	195-55002-106024
Medium	38827	955-500210-6034	195-55002-106031
Large	38828	955-500210-6041	195-55002-106048
X-Large	38829	955-500210-6058	195-55002-106109

Classification of the product:

- Class I Medical Device based on Rule 5 transient use, Annex VIII of Medical Device Regulation (EU) 2017/745
- Basic UDI DI: 697306977VinylDU
- 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:

- ISO 9001:2015
- ISO 13485:2016

Gloves tested according to Harmonised Standards:

- EN ISO 374-1 – chemical resistance
- EN ISO 374-5 – microbiological resistance
- EN455 – 1,2,3, 4 – medical devices
- EN ISO 21420 – physical attributes

User Information:

- The gloves are suitable for contact with dry, fatty, alcoholic, acidic 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.

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Responsibility

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

Manufacturer:

- Supermax Healthcare Limited, 12-16 Titan Drive, Fengate, PE1 5XN, Peterborough, United Kingdom

Authorised Representatives:

- EU Representative is Supermax Healthcare (Europe) Limited, 38 Main Street, Swords Co. Dublin, K67 E0A2, Ireland

In Peterborough, UK, 02/10/2025

Authorised by:

Daniel Todd
Group QA/RA & Technical Manager
Supermax Healthcare Ltd, Supermax Healthcare (Europe) Ltd (Authorised Representative)