

Declaration of Conformity – EU

Maxter Glove Manufacturing Sdn Bhd hereby confirms that the product mentioned below complies with EU Regulations and Standards and is manufactured according to ISO9001 & ISO13485 standard requirements.

Aurelia Zero 3.2 mil Powder Free Nitrile Examination Glove

Size	Product Code	Barcode
X-Small	92775	955-500210-5617
Small	92776	955-500210-5624
Medium	92777	955-500210-5631
Large	92778	955-500210-5648
X-Large	92779	955-500210-5655

Classification of the product:

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

Product mentioned above complies with:

- The General Safety and Performance requirements of Annex I, Medical Regulation (EU)2017/745 for Class I Medical Devices and with the Article 19 requirements
- 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:

- ISO9001:2015
- ISO13485:2016

Gloves tested according to Harmonised Standards:

- EN455 – 1,2,3, 4 – medical devices
- EN21420- physical attributes or EN420 during the transition period

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.
- The product does not contain accelerators.
- Store below 40°C/104°F in dry, clean condition and away from direct sunlight.



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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: 22 March 2024

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