

Declaration of Conformity – UK

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 Sonic 200 2.2 mil Cobalt Blue Powder Free Nitrile Examination Glove

Size	Product Code	Barcode	UDI Code
X-Small	9377A5	955-500210-5662	1955-500210-5669
Small	9377A6	955-500210-5679	1955-500210-5676
Medium	9377A7	955-500210-5686	1955-500210-5683
Large	9377A8	955-500210-5693	1955-500210-5690
X-Large	9377A9	955-500210-5709	1955-500210-5706

Classification of the product:

- Class I Medical Device based on Rule 5 transient use, Annex IX of COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices, which is implemented into UK law by the Medical Device Regulations 2002, as amended.
- 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, which is directly implemented into UK law.

Product mentioned above complies with:

- Medical Device Regulation 2002 for Class I Medical Devices, implementing COUNCIL DIRECTIVE 93/42/EEC
- 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.
- 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.

Certification:

- Module B, UKCA Type Examination Certificate issued by Approved Body : Satra (0321) – Certificate No. AB0321/19867-01/E00-00

- Module D, Regulation 2016/425 as brought into the UK Law, Examination Certificate issued by Approved Body : SGS UK, Approved Body UKCA0120 – Certificate No. MY21/1811030640
- ISO9001:2015
- ISO13485:2016

Gloves tested according to Harmonised Standards:

- EN374-1 – chemical resistance
- EN374-5 microbiological resistance
- 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. 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.

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

Authorised Representatives:

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

Maxter Glove Manufacturing Sdn Bhd, Malaysia





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Authorised by:

Yap Peak Geeh
Senior Manager
QA & Regulatory Affairs

Date: 25-Jun-2022

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