



Declaration of Conformity – EU

Supermax Healthcare (Europe) Limited authorised representative hereby confirms that the product mentioned below complies with EU Regulations and Standards and is manufactured according to ISO9001 & ISO13485 standard requirements.

Aurelia Delight Blue Powdered Examination Gloves

Size	Product Code
Small	38896
Medium	38897
Large	38898
X-Large	38899

Classification of the product:

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

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
- The provisions of Personal Protective Equipment (PPE) Regulation (EU) 2016/425, including the General Safety Requirements (Annex II), Module A Internal production control.
- 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
- EN420- physical attributes

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.



SUPERMAX
Healthcare Limited

Supermax Healthcare Limited
38 Main Street
Swords Co. Dublin
K67E0A2
Ireland

- 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 and Authorised Representative, as indicated below:

Legal 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, 23/11/2023

Authorised by:

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

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