



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 Clear Powdered Examination Gloves

Size	Product Code
Small	38826
Medium	38827
Large	38828
X-Large	38829

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
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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.**