



Declaration of Conformity

Supermax Healthcare Ltd. 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 Powder Free Vinyl Glove

Size	Product Code	Inner Boxes Barcode	Outer Boxes Barcode
Small	38226	955-500210-6072	5056730301271
Medium	38227	955-500210-6089	5056730301288
Large	38228	955-500210-6096	5056730301295
X-Large	38229	955-500210-6102	5056730301301

Classification of the product:

- 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
- Basic UDI DI: 697521920EM0101147176BL

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 374-4 – chemical degradation
- 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, 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.



AURELIA[®] GLOVES

A SUPERMAX HEALTHCARE BRAND

- Store below 40°C/104°F in dry, clean condition and away from direct sunlight and fluorescent lighting.

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

In Peterborough, UK, 11/09/2026

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.**