SUPERMAX
Healthcare Limited

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

Declaration of Conformity – EU

Supermax Healthcare 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 Blush 2.5 mil Pink Powder Free Nitrile Examination Glove

Size	Product Code	Barcode	UDI Code
X-Small	78885	955-500210-5242	1955-500210-5249
Small	78886	955-500210-5259	1955-500210-5256
Medium	78887	955-500210-5266	1955-500210-5263
Large	78888	955-500210-5273	1955-500210-5270
X-Large	78889	955-500210-5280	1955-500210-5287

Classification of the product:

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

- Module B, EU Type Examination Certificate issued by Notified Body : Satra (2777) – Certificate No. 2777/12707-01/E00-00
- Module D, Regulation 216/425, Examination Certificate issued by Notified Body : SGS Fimko OY, Notified Body CE0598 – Certificate No. MY19/1811030073
- 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
- EN420- physical attributes

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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 and Authorised Representative, 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 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

In Peterborough, UK, 04/08/2021

Author:

Lucia Kralova
QA/RA & Technical Executive
Supermax Healthcare Ltd
Authorised Representative

Authorised by:

09/08/2021

Daniel Todd
Group QA/RA & Technical Manager
Supermax Healthcare 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.**