Declaration of Conformity

Supermax Healthcare Ltd. 12-16 Titan Drive, Fengate , Peterborough, PE1 5XN, United Kingdom hereby confirms that the product mentioned below complies with EU & UK Regulations and Standards and is manufactured according to ISO9001 & ISO13485 standard requirements.

Description

DexiPro X Examination Gloves Product codes 71996 (S/7) – 71999 (XL/10)

Disposable Powder-Free Nitrile Gloves, Black

Classification of the product:

- CAT III PPE (EU) 2016/425
- Class I Medical Device (EU 2017/745)
- Class I Medical Device (2002 UK Medical Device Regulations, as amended)
- Basic UDI : DI 697306977NitrileFR

Certification:

- Module B, EU Type Examination Satra (2777) – Certificate No. 2777/14815-05/E06-01
- Module D, Satra Certificate: STE2008999; SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, Dublin 15D15 YN2P Ireland ; Notified Body Number: 2777
- 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

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.
- 2002 UK Medical Device Regulations, as amended.
- 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.

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 in a cool dry place, avoid excessive heat (40^{o}C/104^{o}F) in dry, clean condition and away from direct sunlight.

Responsibility

- This Declaration of Conformity is issued under the responsibility of the Legal Manufacturer, as indicated below:

Manufactured in China on behalf of :

Supermax Healthcare Ltd
12-16 Titan Drive
Fengate
Peterborough
PE1 5XN
United Kingdom

Authorised by:

Daniel Todd
Group QA / RA & Technical Manager

Date: 02/06/2025

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