

Reff: SNS 030924

Declaration of Conformity

Manufacturer: Sterimax Global Ltd, Jubilee House, Whitwick Business Park, Stenson Road, Coalville LE67 4NA, United Kingdom

Product Identification

Disposable Nitrile Powder Free Gloves

SN100C	Blue
SN200C	Black
SN300	White
SN500C	Green
SN800C	Pink
SN900C	Purple
SN1200C	Grey
SN1300C	Burgundy
SN1400C	Rose Gold
SN1500C	Navy blue

Risk Class for Medical Devices

Device Classification Common Specifications / Standards Class: 1, Rule 5

EN455-1:2020 Medical gloves for single use: Freedom from holes

EN455-2:2015 Medical gloves for single use: Physical properties

EN455-3:2015 Medical gloves for single use: Biological evaluation

EN455-4:2009 Medical gloves for single use: Shelf-life determination

Risk Category of Personal Protective Equipment and Performance Levels:

- Personal Protective Equipment (PPE) Category III
- EN ISO 374-1:2016: Type B – K, P, T

- EN ISO 374-5:2016:
- Protection against bacteria and fungi: Pass
- Protection against viruses: Pass

Sterimax Global Ltd declares that the above-mentioned product meets the provision of the following EU legislation:

- Medical Devices Regulation (EU) 2017/745
- Is classed as Cat III PPE in conformity with the provisions of Regulation (EU) 2016/425 on personal protective equipment and with National Standards transposing harmonised standards EN 374-1:2016+A1:2018, EN 374-5:2016, and EN ISO 21420:2020.
- Is identical to the personal protective equipment which is the subject of EU Type-Examination Certificate number 2777/15669-02/E01-01, issued by SATRA Technology Europe Limited, Bracetown Business Park, Clonee, Dublin, D15 YN2P, Republic of Ireland (Notified Body number 2777), according to Annex V (Module B) of Regulation (EU) 2016/425.
- Is subject to the quality assurance conformity of the production process Module C2 set out in Annex VIII of Regulation (EU) 2016/425, under the surveillance of the notified body SATRA Technology Europe Limited, Bracetown Business Park, Clonee, Dublin, D15 YN2P, Republic of Ireland (Notified Body number 2777)

Date / Authorised

3rd September 2024

Title of Signatory:

Matthew Wilson



Commercial Lead