

Ref: SNPP 250701

EU Declaration of Conformity

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

Authorised representative:
Taylored Consultancy EU Ltd Forsyth House, Cromac Square,
Belfast, BT2 8LA

Product Identification

Five-fingered nitrile, powder-free, non-sterile examination glove

Available in blue, black, green, orange and purple.

Product references: SN100SG (Blue), SN200SG (Black), SN500SG (Green), SN600SG (Orange), SN900SG (Purple)

Sizes: S, M, L, XL

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+A1:2018: Type JKPTO

EN ISO 374-5:2016:

Protection against bacteria and fungi: Pass

Protection against viruses: Pass

Tested for use with Chemotherapy Drugs per ASTM D6978-05 (2019)

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 2777/23907-01/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

7th January 2025

Title of Signatory:

Matthew Wilson

Matthew Wilson

Commercial Lead