

Technical Sheet

Product: SERIX PROTECT Nitrile Powder-Free Protective Gloves
Manufacturer: Blue Sail Medical Co., Ltd
EC-REP: Lotus NL B.V.



SERIX PROTECT Nitrile Powder-Free Protective Gloves

Description

- Powder-Free Nitrile Protective Gloves
- This product is not made from natural rubber latex
- Textured finger. Non-sterile
- Design: ambidextrous with elastic cuff
- Protects against chemicals
- Protects against bacteria and fungi
- Color: black
- Packing: 50 pcs/box

Tested and certified for use in:

- Hospitality industry: hotels, restaurants, catering
- Cosmetics industry
- Cleaning
- Food production and processing
- Chemical industry
- General use

Instructions for use:

After use, wearers should visually check the gloves and remove any contamination from the outer surface before removing the gloves from the hands. Alternatively, carefully peel the gloves off the hands so that the contaminated outer gloves do not touch your skin.

Storage:

Store in original packaging in a dry and dark area, protected from ozone.

Technical data:

Size	Length (mm)	Width (mm)	Weight (g)	Thickness Cuff	Thickness Palm	Thickness Fingers
S	240	80 - 90	5.5 ± 0.3	0.07 mm	0.10 mm	0.12 mm
M		90 - 100	6.0 ± 0.3			
L		100 - 110	6.5 ± 0.3			
XL		110 - 120	7.0 ± 0.3			

Chemical Permeation:

Code letter	Chemical Permeation (EN ISO 374-1:2016)	Level	Mean Degradation (%) (En 374-4:2013)	Degradation levels indicate the change in Puncture Resistance of the glove after exposure to the tested chemical.
K	40% Sodium Hydroxide	6	-38.4	
P	30% Hydrogen Peroxide	2	17.6	
J	n-heptane	0	27.4	
O	25% Ammonium hydroxide	0	29.9	
T	37% Formaldehyde	5	46.6	

Certifications and standards:

- EN ISO 374-1:2016/Type B
- EN ISO 374-5:2016
- EN 16523-1, En 455-2,3
- EN ISO 21420:2020
- EN 420:2003 +A1:2009 (Palm Protection)
- 2777 Comply to PPE Regulation 2016/425 Cat III

SERIX PROTECT Nitrile Powder-Free Protective Gloves

EU DECLARATION OF CONFORMITY

Doc No.: M-PPE02-B00

Identification of the Legal Manufacturer & Address : Blue Sail Medical Co., Ltd
: No. 21 Qingtian Road, Qilu Chemical Industrial Park,
Zibo, Shandong 255414 China

European Authorized Representative : Lotus NL B.V.
: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague,
Netherlands
: Email: peter@lousnl.com

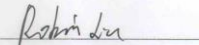
Product & Identification : Disposable Nitrile Gloves, Powder Free

Intended purpose of the product: The Disposable Nitrile Gloves, Powder Free are no-sterile and single use personal protective equipment, this gloves is used to prevent the contact between the user and dangerous chemicals and micro-organisms.

We hereby declare that our EU Type Examination Certificate conformity the requirements of Annex V (Module B) of the regulation (EU)2016/425 of the European Parliament and of the council. Follow the EU Type-Examination the product has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU)2016/425 as a Category III product.
The declaration of conformity is issued under the sole responsible of manufacturer.

Relevant Harmonized Standards: : EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016, EN ISO 21420:2020
Certification Body : SATRA Technology Europe Limited
Notified Body: : 2777
Expire Date: : 09 Nov 2023
Certificate number: : 2777/11521-02/E00-00

The Personal Protective Equipment is subject to the conformity assessment procedure conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the notified body SATRA Technology Europe Limited (2777).

Identification of the person authorized to sign on behalf of the Legal Manufacturer: : Signed by

: Print Name: Robin Liu
: Title: Quality Director
: Place of Issue: Shandong, China
: Date: 22 Feb 2021

SERIX PROTECT Nitrile Powder-Free Protective Gloves



Notified Body: 2777

Issued to:

Blue Sail Medical Co Ltd
Qilu Chemical Industrial Park,
No 21 Qinglian Road
Zibo
Shandong
China

SATRA customer number: P1543

EU Type-Examination Certificate

Certificate number: 2777/11521-02/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:
Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:	Description:
BS0102016-BS0102020	Disposable Powder-Free Nitrile Gloves
BS0102026-BS0102030	Available Colours in
BS0102036-BS0102040	Blue
BS0102046-BS0102050	Blue Purple
BS0102056-BS0102060	Cobalt Blue
	White
	Black

Sizes: 6 – 10 (XS – XL)	Classification:
	EN ISO 374-1:2016 /Type B
	Level
	EN ISO 374-4:2013 Degradation %
	40% Sodium Hydroxide (K) 6 -38.4
	30% Hydrogen Peroxide (P) 2 17.6
	n-heptane (J) 0 27.4
	25% Ammonium hydroxide (O) 0 29.9
	37% Formaldehyde (T) 5 46.6
	EN ISO 374-5:2016
	Level
	Protection against Bacteria and Fungi Pass
	Protection against Viruses Pass

Standards/Technical specifications applied:
EN 420: 2003+A1: 2009, EN ISO 374-1:2016, EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: CHT0269325/1814, CHT0269325/1814/SPT, CHT0269325/1814/EN/A, CHT0269325/1814/EN/B/Issue 2, CHT0273567/1830/LH/B, CHT0275700/1838/LH, CHT0269325/1814/EN/C, CHT0273567/1830/LH/A

Signed on behalf of SATRA: *Daisy He*

Date first issued: 09/11/2018

Date of issue: 09/08/2020

Daisy He

Expiry date: 09/11/2023

Geoff Graham

Geoff Graham

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TERMS AND CONDITIONS



The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement.

The certificate holder is licensed to mark the products detailed within this certificate in accordance with Annex V (Module B) of the Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment once you have drawn up an EU declaration of product conformity.

Please note:

1. Where the product is classified as category III then CE Marking of production is reliant on current compliance with Regulation 2016/425 module C2 or Module D. (Except that specifically produced to fit an individual user).
2. Full details of the scope of the certification and product(s) certified are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturers technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate.
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. Where results obtained during type testing are within the budget of uncertainty when compared to the pass requirement, classification or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications or performance levels.
8. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state government.
9. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
10. SATRA reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of Regulation 2016/425.

SERIX PROTECT Nitrile Powder-Free Protective Gloves

**PPE REGULATION (EU) 2016/425
MODULE C2 CERTIFICATE**


Issued to:

*Blue Sail Medical Co Ltd
Qilu Chemical Industrial Park
No 21 Qingtian Road
Zibo
Shandong
China*

This is to certify that the following products tested under SATRA reports referenced: STE0317596 & CHM0319556/2137/JH have been found to satisfy the requirement of PPE Regulation (EU) 2016/425 Module C2 EU quality control system for the final product for and on behalf of SATRA Technology Europe Limited

EU TYPE EXAMINATION CERTIFICATE NUMBER	PRODUCT GROUP REFERENCE	PRODUCT TYPE	CLASSIFICATION
2777/11521-02/E00-00	BS0102016-BS0102020 BS0102026-BS0102030 BS0102036-BS0102040 BS0102046-BS0102050 BS0102056-BS0102060	Disposable Powder free nitrile gloves in colours Blue Blue Purple Cobalt Blue VWhite Black	EN ISO 374-1:2016 Type B & EN ISO 374-5:2016

Dated: 11th November 2021



Signed By G Graham

This certificate is valid until:

October 2022

For and on behalf of SATRA Technology Europe Limited

The issuance of this certificate is subject to the company maintaining its manufacturing and quality system to the required standard
 SATRA Technology Europe Limited, Bracetown Business Park Clonoe Dublin 15 D15 YN2P, Republic of Ireland.
 (Notified Body number 2777)
 Tel: +353 (0) 1 437 2484 Web: www.satraeurope.com

Thank you!



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