

# 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  
 BS0102026-BS0102030  
 BS0102036-BS0102040  
 BS0102046-BS0102050  
 BS0102056-BS0102060

Disposable Powder-Free Nitrile Gloves  
 Available Colours in  
 Blue  
 Blue Purple  
 Cobalt Blue  
 White  
 Black

**Sizes: 6 – 10 (XS – XL)**

**Classification:**

**EN ISO 374-1:2016 /Type B**

40% Sodium Hydroxide (K)  
 30% Hydrogen Peroxide (P)  
 n-heptane (J)  
 25% Ammonium hydroxide (O)  
 37% Formaldehyde (T)

Level	EN ISO 374-4:2013 Degradation %
6	-38.4
2	17.6
0	27.4
0	29.9
5	46.6

**EN ISO 374-5:2016**

Protection against Bacteria and Fungi  
 Protection against Viruses

Level
Pass
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*

Daisy He

*Geoff Graham*

Geoff Graham

**Date first issued: 09/11/2018**

**Date of issue: 09/08/2020**

**Expiry date: 09/11/2023**

# 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.



# 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 White Black	EN ISO 374-1:2016 Type B & EN ISO 374-5:2016

Dated: 11<sup>th</sup> November 2021

This certificate is  
valid until:

*October 2022*

Signed By G Graham

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 Clonee Dublin 15 D15 YN2P. Republic of Ireland.  
(Notified Body number 2777)*

*Tel: +353 (0) 1 437 2484 Web: [www.satraeurope.com](http://www.satraeurope.com)*



PSB Singapore

# TEST CERTIFICATE

This Certificate is issued to

Blue Sail Medical Co., Ltd.  
Qilu Chemical Industrial Park,  
No. 21 Qingtian Rd.,  
255414, Zibo, Shandong,  
China.

## FOR

Product:	Disposable Nitrile Powder-Free Examination Gloves
Brand/Model:	<ol style="list-style-type: none"> <li>1. BS 020-N01</li> <li>2. BS 020-N02</li> <li>3. BS 020-N03</li> <li>4. BS 020-N04</li> <li>5. BS 020-N05</li> </ol>
Product Details:	<ol style="list-style-type: none"> <li>1. Sizes XS, S, M, L &amp; XL, Powder-Free, Blue, Nitrile, Examination Glove</li> <li>2. Sizes XS, S, M, L &amp; XL, Powder-Free, White, Nitrile, Examination Glove</li> <li>3. Sizes XS, S, M &amp; L, Powder-Free, Blue Purple, Nitrile, Examination Glove</li> <li>4. Sizes S, M, L &amp; XL, Powder-Free, Black, Nitrile, Examination Glove</li> <li>5. Sizes M &amp; L, Powder-Free, Cobalt Blue, Nitrile, Examination Glove</li> </ol>
Specification:	EN 455-1:2000 EN 455-2:2015 EN 455-3:2015
Test Report:	<ol style="list-style-type: none"> <li>1. 7191233436-EEC20/01-WBH</li> <li>2. 7191233436-EEC20/02-WBH</li> <li>3. 7191233436-EEC20/03-WBH</li> <li>4. 7191233436-EEC20/04-WBH</li> <li>5. 7191233436-EEC20/05-WBH</li> </ol>
Date of Test Report:	13 Apr 2020

## Summary

A sample of product submitted was tested and found to comply with the requirements of the above standards.

TÜV SÜD PSB Pte Ltd

Certificate No:	Date of Original Issue:	Date of Last Revision:	Date of Expiry:
04115	17 Apr 2020	-	16 Apr 2022

This Certificate is part of a full report and should be read in conjunction with it. This Certificate remains the property of TÜV SÜD PSB Pte Ltd and shall be returned upon request. The use of this Certificate is subjected to the terms and conditions of the Test Certification Scheme.

Note: This Certificate is issued pursuant to the terms set out overleaf.

**Please note that this Certificate is issued under the following terms:**

1. This certificate applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB in any way "guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific product/equipment.
2. The sample/s mentioned in this certificate is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.
3. Nothing in this certificate shall be interpreted to mean that TÜV SÜD PSB has verified or ascertained any endorsement or marks from any other testing authority or bodies that may be found on that sample.
4. This certificate shall not be reproduced wholly or in parts and no reference shall be made by the Client to TÜV SÜD PSB or to the report or results furnished by TÜV SÜD PSB in any advertisements or sales promotion unless with the prior written consent of TÜV SÜD PSB.
5. Unless otherwise stated, this certificate was issued pursuant to the test as reflected in the test report. This certificate shall be read in conjunction with the full test report carried out in TÜV SÜD PSB Pte Ltd, No.1 Science Park Drive Singapore 118221.