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:CHM0291439/1944/JH & STE0289547 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
2777/11521-01/E00-00	BS01020X	Disposable medical Nitrile examination glove	EN ISO 374-1:016

Dated: 14th November 2019

This certificate is valid until: November 2020

Signed By (Alan Weston)

For and on behalf of SATRA Technology Europe Limited

CE

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

Issued to:

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

Notified Body: 2777

SATRA customer number: P1543

EU Type-Examination Certificate

Certificate number: 2777/11521-01/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:
	Disposable Medical Nitrile Examination Gloves Available in
BS010201	Blue
BS010202	Blue Purple
BS010203	Cobalt Blue
BS010204	White
BS010205	Black

Sizes: 6 – 10 (XS – XL)

Classification:

EN ISO 374-1:2016 /Type B	Level	EN 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, CHT0271193/1821/JS/A, CHT0271193/1821/JS/B, CHT0269325/1814/EN/A, CHT0269325/1814/EN/B, CHT0271193/1821/SPT, CHT0271193/1821, CHT0273567/1830/LH/B, CHT0275700/1838/LH, CHT0269325/1814/EN/C, CHT0275700/1838/LH

Signed on behalf of SATRA: Tara Saunders Austin Simmons

Date first issued: 09/11/2018
Date of issue: 09/11/2018

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 certification and product 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. 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.
8. 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.
9. SATRA Technology 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.

EU DECLARATION OF CONFORMITY

Doc No.: D-MDR-02/08-A00

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 :Tel: +31 645171879 (English) +31626669008 (Dutch) :Email:
Basic UDI-DI	: Details please reference the Article 1.1 part (4) of the CE technical files
Product & Identification	: **Disposable Nitrile Patient Examination Gloves**
Intended purpose of the product:	The Disposable Nitrile Patient Examination Gloves is a disposable Product intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.
GMDN code and product:	**56286 Nitrile examination/treatment glove, non-powdered, non-sterile** : Detail of product code, common specification please reference to Doc# D-MDR-02/05-A00, Doc# D-MDR-02/02-A00 in the CE Technical Files
Risk Classification:	: Class I, Non-sterile, no measuring function and not surgical instrument

We hereby declare that the above mentioned devices comply with the European Medical Device Regulations (EU) MDR 2017/745. The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Conformity Assessment Procedure	: Article 4.1 Rule 1, Non-invasive device, and/or : Article 5.1 intended for transient use, Rule 5 of invasive device of Annex VIII
Conformity Route	: Self-Declaration
Relevant Harmonized Standards:	:EN ISO13485:2016 :EN 455-1: 2000, EN455-2:2015, EN455-3 2015, EN455-4:2009 :EN ISO 374-1:2016, EN374-2: 2014, EN16523-1:2015, EN374-4:2013, ENISO 374-5: 2016, EN420: 2003+A1:2009
Certification Body	:TUV SUD PSB Singapore
Registration Date	: March 23, 2018
Registration No.	: 03855
Quality System Certificate	: Certificate No: Q5 062837 0012 Rev. 01 : Certificate Body: TUV SUD Product Service GmbH : Issued Date: Aug 1, 2019
Identification of the person authorized to sign on behalf of the Legal Manufacturer:	:Singed by: Robin Liu :Print Name: Robin Liu :Title: Quality Director :Place of Issue: Zibo, Shandong, China :Date: 08/Aug/2019