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: 2777/11331-03/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 Vinyl gloves
BS0100116 – BS0100120	Powdered colour White
BS0100126 – BS0100130	Powdered free Colour White
BS0100186 – BS0100190	Powdered Colour Yellow
BS0100196 – BS0100200	Powdered free Colour Yellow
BS0100546 – BS0100550	Powdered Colour Clear
BS0100106 – BS0100110	Powdered free Colour Clear
BS0203716 – BS0203720	Powdered free Long cuff colour Clear
BS0100206 – BS0100210	Powdered Colour Blue
BS0100216 – BS0100220	Powdered free Colour Blue
BS0100306 – BS0100310	Powdered Colour Black
BS0100316 – BS0100320	Powdered free Colour Black

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Sizes:

6	XS
7	S
8	M
9	L
10	XL

Classification:

EN ISO 374-1:2016 / Type B	**Level**	**EN374-4:2013**
40% Sodium hydroxide (K)	6	0.4 %
30% Hydrogen peroxide (P)	5	-12.4 %
37% Formaldehyde solution (T)	6	7.9 %

EN ISO 374-5:2016	
Resistance to Bacteria and Fungi	Pass
Resistance to Virus	Pass

Standards/Technical specifications applied:
EN ISO 374-1:2016; EN 374-2: 2014; EN 374-4: 2013; EN ISO 374-5:2016; EN 420: 2003+A1: 2009

Technical reports/Approval documents:
SATRA: CHT0271193/1821 v2, CHT0271193/1821/JS/A Issue 3, CHT0271193/1821/JS/B issue 3 , CHT0271193/1821/SPT issue 3 , CHT0273393/1821/LC/C
CHT0288841/1934

Signed on behalf of SATRA: Gabriela Zajac Quincey Brown

Date first issued: 10/10/2018
Date of issue: 02/07/2020

Expiry date: 10/10/2023

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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.