

# Disposable inspection gloves

— Healthy and comfortable care for family —



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**RESULTS:**

Sample: Powder Free Nitrile Examination Gloves, BS0002

Table 1: Results for EN 455-1:2000

Clause	Tests	Size	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	XS	Shall not leak	10	315	1	Passed
		S		10	315	1	Passed
		M		10	315	2	Passed
		L		10	315	6	Passed
		XL		10	315	4	Passed

Table 2: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Size	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	a) Length (mm)	XS	$\geq 240$	13	250	Passed
		S		13	250	Passed
		M		13	255	Passed
		L		13	250	Passed
		XL		13	248	Passed
	b) Width (mm)	XS	$\leq 80$	13	73	Passed
		S	$80 \pm 10$	13	85	Passed
		M	$95 \pm 10$	13	96	Passed
		L	$110 \pm 10$	13	106	Passed
		XL	$\geq 110$	13	115	Passed
5	a) Force at break (N)	XS	For nitrile examination gloves: $\geq 6.0$	13	6.4	Passed
		S		13	8.6	Passed
		M		13	6.1	Passed
		L		13	6.1	Passed
		XL		13	6.6	Passed
	b) Force at break after challenge testing (N)	XS	For nitrile examination gloves: $\geq 6.0$	13	7.0	Passed
		S		13	9.0	Passed
		M		13	7.3	Passed
		L		13	6.6	Passed
		XL		13	7.1	Passed

Table 3: Results for EN 455-2:2015 Clause 7

Clause	Tests	Requirements	Results	Inferred results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Observed	Passed

**RESULTS (cont'd):**

Sample: Powder Free Nitrile Examination Gloves, BS0002

Table 4: Results for EN 455-3:2015 Clauses 4.2-4.5

Clause	Tests	Requirements	Results / Remarks	Inferred results
4.2	Chemicals	Gloves shall not be dressed with talcum powder (magnesium silicate).	Glove is powder-free glove, based on client's declaration letter version 2018001	NA
		Other chemicals	Manufacturer shall disclose upon request a list of chemical ingredients	NA
4.3 5.1	Endotoxins	< 20 EU/pair for gloves labelled with 'low endotoxin content'.	Not labelled with 'low endotoxin content'	NA
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	XS 0.61 mg per glove	Passed
			S 0.63 mg per glove	Passed
			M 0.97 mg per glove	Passed
			L 0.86 mg per glove	Passed
			XL 0.48 mg per glove	Passed
4.5 5.3	Proteins, leachable	The manufacturer shall strive to minimize the leachable protein level for gloves containing natural rubber latex.	Non-natural rubber latex glove	NA

Table 5: Results for EN 455-3:2015 Clause 4.6

Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex;	NA
		The labelling shall include the following or equivalent warning statement together with the symbol: '(Product) contains natural rubber latex which may cause allergic reactions, including anaphylactic responses'.	NA
		b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free;	Comply
		c) sterile powdered gloves shall be labelled with the following or equivalent: 'CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions'.	NA
		d) for any medical glove containing natural rubber latex the product labelling shall not include: - any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein; - any unjustified indication of the presence of allergens;	NA
e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given.	NA		
Inferred results			Passed

**Test Report No. 7191179419-EEC18-CSL**  
dated 23 Mar 2018



PSB Singapore

**REMARKS:**

1. Freedom from holes test for XS, S, M and L sizes were tested in manufacturer's site, witnessed by TÜV SÜD Certification and Testing (China) Co., Ltd. Beijing Branch on 22 Mar 2018.
2. For size XS, results for EN 455-2:2015 Clause 4 Dimensions is based on lot no. 03060511, while the rest of the results are based on lot no. 12150511.
3. Labelling requirements are assessed based on submitted packaging artwork together with client's declaration letter version number 2018003.
4. NA: Not applicable for the submitted sample.

A handwritten signature in black ink, appearing to read 'Shareen'.

Shareen Chan  
Engineer

A handwritten signature in black ink, appearing to read 'Wong Bee Hui'.

Wong Bee Hui  
Product Manager  
Medical Health Services (NAM)

**APPENDIX:**



Photo : Powder Free Nitrile Examination Gloves, BS0002

## DECLARATION OF CONFORMITY

DOC NO.: D-CE-02/18-01-A3

**Manufacturer's Name** : BLUE SAIL MEDICAL CO., LTD  
**Manufacturer's Address** : No. 21 Qingtian Road, Qilu Chemical Industrial Park,  
Zibo, Shandong 255414 China  
**European Authorized Representative** : Lotus Global Co., Ltd  
: West Drayton, Middlesex, London, UK, UB7 9GG  
: Tel: 0044-20-75868010 Fax: 0044-20-7906187  
: Email: lotus882@isosh.com  
**Type** : Nitrile examination glove, nitrile, Blue, Violet  
: Blue, Cobalt Blue, White and Black  
**Risk Classification** : Class 1, Non Sterile  
**Conformity Assessment Procedure** : Annex IX, Rules 12,  
: Annex VII.  
**Conformity Route** : Self-Declaration

We herewith declare with our own responsibility that above mentioned product(s) with CE mark are fully compliance with Essential Requirement of the EC Council Directive 93/42/EEC 14<sup>th</sup> June 1993 concerned medical devices, amended by Council Directive 2007/47/EC.

**Certification Body** : TÜV SÜD  
**Date** : Jan 18, 2018



Print Name: Robin Liu

Designation: RA/QA Manager

**blue**  
**sail+**  
蓝帆医疗



蓝帆医疗股份有限公司

山东省淄博市临淄区一清路48号

0533-7871015

lanfan@bluesail.cn

www.bluesail.cn



## Test Report

No. NGBHG1702376301

Date: 31 May 2017

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BLUE SAIL MEDICAL CO.,LTD

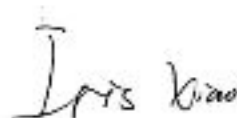
NO.21 QINGTIAN ROAD,QILU CHEMICAL INDUSTRIAL PARK,ZIBO CITY,SHANDONG  
PROVINCE,CHINA,255414The following sample(s) was/were submitted and identified on behalf of the clients as : POWDER FREE NITRILE  
EXAMINATION GLOVES

SGS Job No. : QDHL1705011377OT - QD  
Date of Sample Received : 24 May 2017  
Testing Period : 24 May 2017 - 31 May 2017  
Test Requested : Selected test(s) as requested by client.  
Test Method : Please refer to next page(s).  
Test Results : Please refer to next page(s).

### Result Summary :

Test Requested	Conclusion
FDA 21 CFR 177.2600- Total Extractives	PASS

Signed for and on behalf of  
SGS-CSTC Standards Technical Services Co., Ltd. Ningbo Branch



Iris Xiao  
Approved Signatory



**Test Report No. 7191179419-EEC18-CSL**  
dated 23 Mar 2018



PSB Singapore

Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.

**SUBJECT:**

Testing of Powder Free Nitrile Examination Gloves submitted by Blue Sail Medical Co., Ltd. on 25 Jan 2018 and 09 Mar 2018.

**TESTED FOR:**

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

**TEST DATE:**

26 Jan 2018 to 06 Feb 2018 and 22 Mar 2018

**DESCRIPTION OF SAMPLES:**

S/N	Product Description	Colour	Reference No.	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Powder Free Nitrile Examination Gloves	Blue	BS0002	12150511	XS	100	Blue Sail Medical Co., Ltd.
				03060511		89	
				12150521	S	100	
				12080311	M	100	
				12090411	L	100	
				12070611	XL	407	

Lot size as specified by client: 200,000 pieces

**METHOD OF TEST:**

1. EN 455-1:2000 Medical gloves for single use  
Part 1: Requirements and testing for freedom from holes
2. EN 455-2:2015 Medical gloves for single use  
Part 2: Requirements and testing for physical properties
3. EN 455-3:2015 Medical glove for single use  
Part 3: Requirements and testing for biological evaluation



Choose certainty.  
Add value.