

Test Report No. 7191227746-EEC20-WBH
dated 22 Jan 2020



PSB Singapore

**Add value.
Inspire trust.**

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 Power-Free Gloves submitted by Blue Sail Medical Co., Ltd
on 11 Dec 2019.

TESTED FOR:

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

TEST DATE:

11 Dec 2019 to 17 Jan 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Brand/Model	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Disposable Vinyl Powder-Free Examination Gloves	BS 015-02	Clear	11264312	XS	60	Blue Sail Medical Co., Ltd
				11264111	S	60	
				11294822	M	60	
				11165511	L	60	
				11256011	XL	400	

Lot size: 150,001 to 500,000 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



Laboratory:
TÜV SÜD PSB Pte. Ltd.
No.1 Science Park Drive
Singapore 118221

Phone : +65-6885 1333
Fax : +65-6776 8670
E-mail: enquiries@tuv-sud-psb.sg
www.tuv-sud-psb.sg
Co. Reg : 199002667R

Regional Head Office:
TÜV SÜD Asia Pacific Pte. Ltd.
1 Science Park Drive, #02-01
Singapore 118221
TUV®

Test Report No. 7191227746-EEC20-WBH
dated 22 Jan 2020



PSB Singapore

RESULTS:

Sample: Disposable Vinyl Powder-Free Examination Gloves, Brand/Model: BS 015-02

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	0	Passed
		S		10	315	0	Passed
		M		10	315	0	Passed
		L		10	315	0	Passed
		XL		10	315	1	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	Dimensions a) Length (mm)	XS	Median Length ≥ 240	13	243	Passed
		S		13	243	Passed
		M		13	240	Passed
		L		13	245	Passed
		XL		13	248	Passed
	b) Width (mm)	XS	≤ 80	13	76	Passed
		S	80 ± 10	13	87	Passed
		M	95 ± 10	13	95	Passed
		L	110 ± 10	13	107	Passed
		XL	≥ 110	13	114	Passed
5	Strength a) Force at break (N)	XS	For examination gloves: ≥ 3.6	13	4.8	Passed
		S		13	4.9	Passed
		M		13	4.6	Passed
		L		13	4.4	Passed
		XL		13	4.9	Passed
	b) Force at break after challenge testing (N) 7 days at $(70 \pm 2) ^\circ\text{C}$	XS	For examination gloves: ≥ 3.6	13	4.6	Passed
		S		13	4.8	Passed
		M		13	4.5	Passed
		L		13	4.2	Passed
		XL		13	4.8	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.	Comply	Passed

Test Report No. 7191227746-EEC20-WBH
dated 22 Jan 2020



PSB Singapore

RESULTS (cont'd):

Sample: Disposable Vinyl Powder-Free Examination Gloves, Brand/Model: BS 015-02

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 number: 2019001)	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	0.46 mg per glove	Passed
			S	0.66 mg per glove	
			M	0.70 mg per glove	
			L	0.63 mg per glove	
			XL	0.56 mg per glove	
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

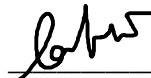
Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the 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

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 16 Jan 2020.
2. Labelling requirements are assessed based on submitted packaging artwork.
3. NA: Not applicable as the feature was not found on sample.



Yeo Poh Kwang
Associate Engineer



Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:



Photo: Disposable Vinyl Powder-Free Examination Gloves, Brand/Model: BS 015-02

Test Report No. 7191227746-EEC20-WBH
dated 22 Jan 2020



Please note that this Report is issued under the following terms :

1. This report 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 report 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 report 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 report 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.
5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, No.1 Science Park Drive Singapore 118221.

July 2011

