Test Report No. 7191179419 dated 23 Mar 2018

PSB Singapore

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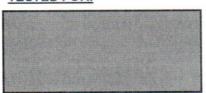
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Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.

SUBJECT:

Testing of Powder Free Nitrile Examination Gloves submitted by on 25 Jan 2018 and 09 Mar 2018.

TESTED FOR:



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		BS0002	12150511	VC	100	
				03060511	XS	69	
				12150521	S	100	
		Blue		12080311	М	100	
				12090411	L	100	
				12070611	XL	407	

Lot size as specified by client: 200,000 pieces

METHOD OF TEST:

- 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.sq Co. Reg: 199002667R

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

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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
	Freedom from holes	XS		10	315	1	Passed
		S		10	315	1	Passed
4 5		M	Shall not leak	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
	Dimensions a) Length (mm)	XS	≥ 240	13	250	Passed
		S		13	250	Passed
		M		13	255	Passed
		L		13	250	Passed
		XL		13	248	Passed
4	b) Width (mm)	XS	≤ 80	13	73	Passed
		S	80 ± 10	13	85	Passed
		M	95 ± 10	13	96	Passed
		L	110 ± 10	13	106	Passed
		XL	≥ 110	13	115	Passed
	Strength a) Force at break (N)	XS	For nitrile examination gloves: ≥ 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
5	b) Force at break after challenge testing (N)	XS	For nitrile examination gloves: ≥ 6.0	13	7.0	Passed
		S		13	9.0	Passed
		M		13	7.3	Passed
		L		13	6.6	Passed
		XL	100 (c5(3) 5.0	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

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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
	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
4.2		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
		duantity of nowder residues shall not	XS	0.61 mg per glove	Passed
			S	0.63 mg per glove	Passed
	Powder-		M	0.97 mg per glove	Passed
	free gloves		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

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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.

Shareen Chan Engineer Wong Bee Hui Product Manager Medical Health Services (NAM)

APPENDIX:



Photo: Powder Free Nitrile Examination Gloves, BS0002

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- 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.
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