

Test Report No. 7191179419- [REDACTED]
dated 23 Mar 2018



PSB Singapore

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SUBJECT:

Testing of Powder Free Nitrile Examination Gloves submitted by [REDACTED] 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	Blue	BS0002	12150511	XS	100	[REDACTED]
				03060511		69	
				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



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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	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
	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
5	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
	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		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

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.



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APPENDIX:



Photo : Powder Free Nitrile Examination Gloves, BS0002

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July 2011

