

Test Report No. 7191244410-EEC20/02-LDY
dated 12 Oct 2020

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SUBJECT:

Testing of Gloves submitted by Zhonghong Pulin Medical Products Co.,Ltd.
on 11 Sep 2020.

TESTED FOR:

Zhonghong Pulin Medical Products Co.,Ltd.
West Industrial Park,
Luannan County,
Tangshan City, China

TEST DATE:

11 Sep 2020 to 07 Oct 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Brand /Model	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Nitrile Disposable Exam Gloves	Z/Z	Blue	20200927	XS	400	Zhonghong Pulin Medical Products Co.,Ltd.

Lot size as specified by client: 150,001 to 500,000 pieces

METHOD OF TEST:

1. EN 455-1:2020 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@tuvsud.com
<https://www.tuvsud.com/en-sg>
Co. Reg : 199002667R

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

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RESULTS:

Sample: Nitrile Disposable Exam Gloves, Z/Z, Lot No. 20200927, Blue, Size XS

Table 1: Results for EN 455-1:2020

Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	Shall not leak	10	315	0	Passed

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

Clause	Tests	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	a) Length (mm)	≥ 240	13	243	Passed
	b) Width (mm)	For Size XS: ≤ 80	13	78	Passed
5	a) Force at break (N)	For nitrile examination gloves: ≥ 6.0	13	7.4	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	For nitrile examination gloves: ≥ 6.0	13	7.4	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: Nitrile Disposable Exam Gloves, Z/Z, Lot No. 20200927, Blue, Size XS

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 not dressed with talcum powder, based on client's declaration letter on 21 Sep 2020	Passed
		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.	0.08 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.	Not 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. Labelling requirements are assessed based on the submitted packaging artwork by client.
2. NA: Not applicable for the submitted sample.



Yeo Poh Kwang
Associate Engineer

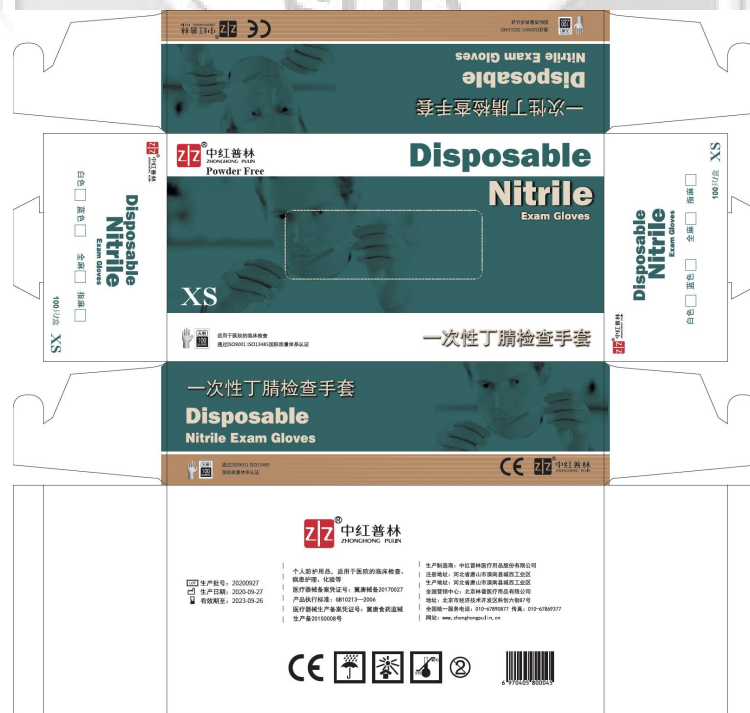


Lee Dai Yi
Engineer
Medical Health Services (NAM)

APPENDIX:



Photo 1: Nitrile Disposable Exam Gloves, Z/Z, Lot No. 20200927, Blue, Size XS



品牌: 北京林普-BNPF-200510-6无粉蓝丁腈手套 颜色: C M K 型号: XS 尺寸: 230*120*65mm 日期: 2020.09.08

Photo 2: Packaging artwork for Nitrile Disposable Exam Gloves, Z/Z, Lot No. 20200927, Blue, Size XS

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Effective 01 September 2020

