

Test Report No. 7191243138-EEC20-LDY_CR1
 (re-issue dated: 12 Mar 2021)
 dated 17 Sep 2020



PSB Singapore

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SUBJECT:

Testing of Gloves submitted by Changzhou Universal Medical Equipment Co., Ltd on 26 Aug 2020.

TESTED FOR:

Changzhou Universal Medical Equipment Co., Ltd
 No.6, Information Avenue
 Xinbei District, Changzhou City
 Jiangsu Province

TEST DATE:

26 Aug 2020 to 09 Sep 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Disposable Medical Protective Gloves (Non Sterile)	Blue	- (see Remark 1)	XL	400	Changzhou Universal Medical Equipment Co., Ltd

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

AMENDMENT:

The following amendment was made on 12 Mar 2021:
 The "Colour" was amended from "Purple" to "Blue" due to typographical error.



		LA-2007-0380-A LA-2007-0381-F LA-2007-0382-B LA-2007-0383-G LA-2007-0384-G LA-2007-0385-E	LA-2007-0386-C LA-2010-0464-D LA-2018-0702-B LA-2018-0703-G LA-2020-0747-L	The results reported herein have been performed in accordance with the terms of accreditation under the Singapore Accreditation Council. Inspections/Calibrations/Tests marked "Not SAC-SINGLAS Accredited" in this Report are not included in the SAC-SINGLAS Accreditation Schedule for our inspection body/laboratory.
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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
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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
 - Clause 4 Dimensions
 - Clause 5 Strength
3. EN 455-3:2015 Medical glove for single use
Part 3: Requirements and testing for biological evaluation
 - Clause 4.4 Powder-free gloves

RESULTS:

Sample: Disposable Medical Protective Gloves (Non Sterile), Blue, Size XL

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	8	Passed

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

Clause	Tests	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions a) Length (mm)	≥ 240	13	243	Passed
	b) Width (mm)	For Size XL: ≥ 110	13	114	Passed
5	Strength a) Force at break (N)	For nitrile examination gloves: ≥ 6.0	13	7.1	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	For nitrile examination gloves: ≥ 6.0	13	7.3	Passed

Table 3: Results for EN 455-3:2015 Clause 4.4

Clause	Tests	Requirements	Results / Remarks	Inferred results
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	0.27 mg per glove	Passed

REMARKS:

1. The Lot No. was not provided by client.



Yeo Poh Kwang
Associate Engineer



Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:



Photo: Disposable Medical Protective Gloves (Non Sterile), Blue, Size XL

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Effective 01 September 2020

