

# BRIGHTWAY HOLDINGS SDN.BHD.

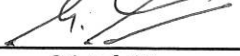
## CERTIFICATE OF ANALYSIS

P.O No	: EMAIL ORDER	Certificate No:	23G26 46B
P.I No	: BHSB/033/M/2023	Lot /Batch No:	CG100/04.2023
Container No	: BMOU 4248996	Seal No:	CEN 224391
Shipping Agent	: TRANSCARGO WORLDEIDE (M) SDN BHD	Container Size:	40" HQ
Customer	: COMPANY ALFA-LAB LIMITED LIABILITY COMPANY		
Brand	: Neutrino Cleanroom i3 - CG-100		
Product	: NACFT 300 P CL 100		
Description	: NITRILE AMBIDEXTROUS POWDER FREE GLOVES 300MM FINGER TEXTURED PURPLE COLOUR / CL 100		

Description		NITRILE AMBIDEXTROUS POWDER FREE GLOVES		
No.	Inspection Item	Inspection Methods & Criteria	Specification	Results
1	Freedom From Holes	EN 455 - 1	G1 AQL 1.5	COMPLIES
2	Physical Dimension Test	EN 455 - 2	<u>Width</u> Size Small : $87 \pm 3$ mm Size Medium : $97 \pm 3$ mm Size Large : $110 \pm 3$ mm Size X-Large : $116 \pm 3$ mm  <u>Length</u> 300mm +/- 10mm  <u>Thickness</u> Cuff : $0.08 \pm 0.02$ mm Palm : $0.11 \pm 0.02$ mm Finger : $0.17 \pm 0.02$ mm	COMPLIES

Attachments : A) LPC and IC Test Report (where applicable)

The Device History Records are inspected and verified to comply with good manufacturing practice and conform to customer's requirements. This Consignment has Passed the preshipment inspection and the order is approved for release.

Verified By :   
Date : 26-Jul-23

Name : S.Ganesh  
Position : Group QA/RA Manager

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## PRESHIPMENT REPORT

### A) PRODUCT BREAKDOWN LIST

Breakdown of Size	Quantity		Lot/Batch Number
	Pairs/Pieces	Cartons	
Small	441,000	294	CG100/04.2023
Medium	822,000	548	CG100/04.2023
Large	496,500	331	CG100/04.2023
X-Large	75,000	50	CG100/04.2023

### B) WATER TIGHT TEST / VISUAL INSPECTION

Inspection Criteria	Sampling	Insp. Level	AQL	Sample Size	Defects	(Acc/Rej)	Status
Pin hole Defects	Random Sampling Based on ISO 2859	G1	1.5	500	5	(10/11)	Pass
Visual Inspection for Major Defect		G1	2.5	500	7	(14/15)	Pass
Visual Inspection for Minor Defect		G1	4.0	315	3	(21/22)	Pass
Dimension		S2	4	13	0	(1/2)	Pass

### C) DIMENSION


Glove Size	Length (mm)		Glove Size	Palm Width (mm)	
	Spec	Actual		Spec	Actual
Small	300mm +/- 10mm	300 - 308	Small	87 ± 3mm	85 - 86
Medium		300 - 305	Medium	97 ± 3mm	96 - 98
Large		300 - 306	Large	110 ± 3mm	108 - 110
X-Large		300 - 305	X-Large	116 ± 3mm	115 - 116

### D) THICKNESS

Location of Thickness Measurement	Single wall (mm)	Actual
Cuff (at 25 mm from cuff end)	0.08 ± 0.02mm	0.08 - 0.09
Palm (at centre of palm)	0.11 ± 0.02mm	0.11 - 0.12
Finger (at 15 mm from the extreme tip)	0.17 ± 0.02mm	0.16 - 0.18

### E) QUANTITY PER PACKING UNIT

1) Gloves per Bag	250 pcs per bag
2) Bags per Export Carton	6 bags per export carton

Verified By:   
Date: 26-Jul-23

Name: S.Ganesh  
Position: Group QA/RA Manager

**BRIGHTWAY HOLDINGS SDN. BHD.**  
(Manufacturers & Exporters of Medical & Industrial Gloves)Lot 1559, Jalan Istimewa, Batu Belah, 42100 Klang, Selangor Darul Ehsan, Malaysia.  
Tel: (603) 33431007, 33431094 Co. No: 169521-T Fax: (603) 33414800, 87367455**BRIGHTWAY HOLDINGS SDN. BHD.**  
**TESTING SERVICES****Certificate of Analysis**Sample Received On : 22-Jul-23  
Test Result Reported On : 22-Jul-23Certificate No. : 23G22 14**PRODUCT DESCRIPTION**

Product Code	: NACFT 300 P (CL 100)	Length	: 300 mm
Size	: S / M / L / XL	Finishing	: Finger Textured
Type	: NITRILE AMBIDEXTROUS POWDER FREE GLOVES	Orientation	: Ambidextrous
300MM/FINGER TEXTURED/PURPLE/CL 100			

**CUSTOMER INFORMATION**

Customer	: ALFA-LAB LIMITED LIABILITY COMPANY	Lot No.	: CG100/04.2023
PI No.	: BHSB / 033 / M / 2023	PO No.	: EMAIL ORDER
Brand	: NEUTRINO CLEANROOM i3-CG-100	Batch No.	: N/A

**LIQUID PARTICLE COUNTS (LPC)**Volume of Water : 750 ml (Option B) Method : IEST-RP-CC005.4 Surface Area (cm<sup>2</sup>) : 1270

No. of Sample	Total Particle ( $\mu\text{m}$ ) per cm <sup>2</sup>	Specification (Particle per cm <sup>2</sup> )	Disposition
	> 0.5 $\mu\text{m}$ particle size		
AVE of 3	1051	1200	PASS

**IONIC BURDEN (IC)**Volume of Water : 700 ml (Option B) Method : IEST-RP-CC005.4 Surface Area (cm<sup>2</sup>) : 1270  
Glove weight : 6.33 g No of Sample : 1

Anion	Fluoride	Chloride	Nitrite	Bromide	Nitrate	Phosphate	Sulphate
$\mu\text{g}/\text{cm}^2$	ND	0.124	ND	ND	0.317	ND	0.017
SPEC ( $\mu\text{g}/\text{cm}^2$ )	0.01	0.20	0.10	0.05	0.40	0.05	0.05
Disposition	PASS	PASS	PASS	PASS	PASS	PASS	PASS

Cations	Sodium	Ammonium	Potassium	Magnesium	Calcium
$\mu\text{g}/\text{cm}^2$	0.016	0.021	0.023	0.002	0.349
SPEC ( $\mu\text{g}/\text{cm}^2$ )	0.05	0.10	0.05	0.01	0.50
Disposition	PASS	PASS	PASS	PASS	PASS

The test results are only related to the above sample(s) submitted for testing. This certificate shall not be reproduced except in full without the written approval of the company.

Remark :

Prepared by,  
Praveen

Clean Room Lab Technician

Verified By,  
S. Malathi

Clean Room Chemist

Approved By,  
T. Raj

Clean Room Manager