

BRIGHTWAY HOLDINGS SDN.BHD.


CERTIFICATE OF ANALYSIS

P.O No	: EMAIL ORDER	Certificate No: 23G26 47B
P.I No	: BHSB/033/M/2023	Lot /Batch No: CGS200/04.2023
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	: PURE TECH (Neutrino Cleanroom i5 - CG-200)	
Product	: NSCT 300 S CL100	
Description	: NITRILE HAND SPECIFIC POWDER FREE GLOVES 300MM TEXTURED	
	: DOUBLE CHLORINATED / CLEANROOM CLASS 100 / STERILE	

Description		NITRILE HAND SPECIFIC 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 6.0 : 75 ± 3mm Size 6.5 : 82 ± 3mm Size 7.0 : 89 ± 3mm Size 7.5 : 95 ± 3mm Size 8.0 : 102 ± 3mm Size 8.5 : 107 ± 3mm Size 9.0 : 115 ± 3mm Size 10.0 : 121 ± 3mm <u>Length</u> 295mm (min) <u>Thickness</u> Cuff : 0.08 ± 0.02mm Palm : 0.13 ± 0.02mm Finger : 0.16 ± 0.02mm	COMPLIES

Attachments : A) LPC and IC Test Report (where applicable)
B) Certificate of Irradiation(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

BRIGHTWAY HOLDINGS SDN.BHD.

PRESHIPMENT REPORT

A) PRODUCT BREAKDOWN LIST

Breakdown of Size	Quantity		Lot/Batch Number
	Pairs/Pieces	Cartons	
6.0	-	-	-
6.5	21,120	88	CGS200/04.2023
7.0	42,720	178	CGS200/04.2023
7.5	46,560	194	CGS200/04.2023
8.0	29,040	121	CGS200/04.2023
8.5	16,560	69	CGS200/04.2023
9.0	5,280	22	CGS200/04.2023
10.0	-	-	-

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	(14/15)	Pass
Visual Inspection for Major Defect		G1	2.5	500	7	(21/22)	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
6.0	295mm (Min)	-	6.0	75 ± 3mm	-
6.5		300 - 306	6.5	82 ± 3mm	84 - 85
7.0		302 - 308	7.0	89 ± 3mm	90 - 92
7.5		302 - 308	7.5	95 ± 3mm	96 - 98
8.0		300 - 308	8.0	102 ± 3mm	104 - 105
8.5		298 - 305	8.5	107 ± 3mm	109 - 110
9.0		305 - 308	9.0	115 ± 3mm	117 - 118
10.0		-	10.0	121 ± 3mm	-

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	0.12 - 0.14
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	30 pairs per bag
2) Bags per Export Carton	8 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-23

Certificate No. : 23G22 16

PRODUCT DESCRIPTION

Product Code : NSCT 300 S (CL100) Length : 300 mm
Size : 6.5 / 7.0 / 7.5 / 8.0 / 8.5 / 9.0 Finishing : Textured
Type : NITRILE HAND SPECIFIC POWDER FREE GLOVES/300M Orientation : Hand Specific
TEXTURED/DOUBLE CHLORINATED/CL 100/STERILE

CUSTOMER INFORMATION

Customer : ALFA-LAB LIMITED LIABILITY COMPANY Lot No. : CGS200/04.2023
PI No. : BHSB / 033 / M / 2023 PO No. : EMAIL ORDER
Brand : PURE TECH (Neutrino Cleanroom i5-CG-200) Batch No. : N/A

LIQUID PARTICLE COUNTS (LPC)

Volume of Water : 750 ml (Option B) Method : IEST-RP-CC005.4 Surface Area (cm²) : 1320

No. of Sample	Total Particle (μ m) per cm ²	Specification (Particle per cm ²)	Disposition
	> 0.5 μ m particle size		
AVE of 3	1023	1200	PASS

IONIC BURDEN (IC)

Volume of Water : 700 ml (Option B) Method : IEST-RP-CC005.4 Surface Area (cm²) : 1320
Glove weight : 6.84 g No of Sample : 1

Anion	Fluoride	Chloride	Nitrite	Bromide	Nitrate	Phosphate	Sulphate
μ g/cm ²	ND	0.136	ND	ND	0.151	ND	0.023
SPEC (μ g/cm ²)	0.01	0.20	0.05	0.05	0.20	0.05	0.05
Disposition	PASS	PASS	PASS	PASS	PASS	PASS	PASS

Cations	Sodium	Ammonium	Potassium	Magnesium	Calcium
μ g/cm ²	0.019	0.022	0.021	0.001	0.356
SPEC (μ g/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



<http://www.steris-ast.com>

Certificate of Irradiation

Date Issued: 23-Jun-2023

MY01S12748505-1-1

This is to certify that Synergy Sterilisation Rawang (M) Sdn. Bhd., a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
ISO 9001 Quality Management System
EN ISO 13485 Quality System - Medical Devices

Brightway Holding Sdn Bhd
Lot 1559 Jalan Istimewa
Batu Belah
SELANGOR
42100 Klang

Noraini 23/06/2023
Noraini binti Sudin
Senior Executive QA
Synergy Sterilisation Rawang (M) Sdn. Bhd
(234258-U)

Order Information

Account Number:	101044														
Synergy Health Sales Part Reference:	1137722														
Customer Reference Number:	85495														
Product Description:	Nitrile Hand-Specific Powderfree Gloves - 300mm/ Textured/ Cleanroom CL100/ Sterile														
Validation Reference:	R220027 Rev.1														
Quantity Received:	672														
Customer Minimum Specification kGy:	25.0														
Customer Maximum Specification kGy:	40.0														
Customer Unit Lot/Batch Number:	ALFA-LAB														
Other Process Details:	LOT NO :CGS200/04.2023														
	<table> <tr> <th>SIZE</th><th>QTY</th></tr> <tr> <td>6.5</td><td>88</td></tr> <tr> <td>7.0</td><td>178</td></tr> <tr> <td>7.5</td><td>194</td></tr> <tr> <td>8.0</td><td>121</td></tr> <tr> <td>8.5</td><td>69</td></tr> <tr> <td>9.0</td><td>22</td></tr> </table>	SIZE	QTY	6.5	88	7.0	178	7.5	194	8.0	121	8.5	69	9.0	22
SIZE	QTY														
6.5	88														
7.0	178														
7.5	194														
8.0	121														
8.5	69														
9.0	22														

Irradiation Data

Date and Time of Irradiation:	23-Jun-2023 07:44
Reference Dose Range kGy:	32.1 - 35.3
Calculated Minimum Dose kGy:	28.8

Processing Site: Lot 42 Jalan Industrial 2/1, Rawang Integrated Industrial Park, Rawang, 48000 Phone No: +60(0)3 6099 9600

Registered Office: 170-09-01, Livingston Tower, Jalan Argyll, 10050 George Town, Pulau Pinang, MALAYSIA

VAT Number: 000878280704



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Brightway Holding Sdn Bhd
Lot 1559 Jalan Istimewa
Batu Belah
SELANGOR
42100 Klang

Calculated Maximum Dose kGy:	39.5
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Irradiation Release Authorised By Synergy Sterilisation Rawang (M) Sdn. Bhd, a STERIS Company

Processing Site: Lot 42 Jalan Industrial 2/1, Rawang Integrated Industrial Park, Rawang, 48000 Phone No: +60(0)3 6099 9600

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