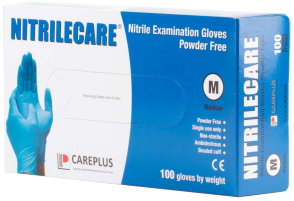

CAREPLUS
NITRILEGLOVES
CarePlus Nitrilecare® Examination Gloves - Powder Free

CAREPLUS NitrileCare®

Nitrile Examination Gloves

The NitrileCare® nitrile examination glove is manufactured in Malaysia by CarePlus Global, who for over 30 years have produced top quality gloves with consistency and reliability.

The NitrileCare® nitrile examination glove has a premium finish, meeting the ASTM Chemo/ Viral Barrier/ ISO quality standards and has FDA 510(k) approval. It has been tested for use with Chemotherapy Drugs for ultimate hand protection you can always trust.



Multi-Purpose

Hospital · Dental · Laboratory · Cleaning

Industry · Hotel · Cosmetic · Food

NitrileCare® Examination Gloves

Specifications & Certifications

Multi-Purpose

Hospital · Dental · Laboratory · Cleaning · Industry · Hotel · Cosmetic · Food

The NitrileCare® glove is manufactured in Malaysia and distributed to North America. This 3.5gm indigo blue glove meets ISO quality and ASTM Chemo/ Viral Barrier standards and holds FDA 510(k) approval.

Product Technical Data Sheet	
Type	Powder-Free, Examination Glove
Specification	Non-Sterile/Disposable
Cuff	Beaded
Weight	3.5gm +/- 0.3gm (0.12 fl oz.)
Colour	Indigo Blue
Primary Material	Nitrile
Surface	External: Finger Textured
Powder Control	<=2mg/glove
Packaging	100 pcs/box
Size & Product Code	Small: MS60412 Medium: MS60413 Large: MS60414 Extra-large: MS60415
Product Name	NirtileCare® Examination Gloves
Hand Design	Ambidextrous
Origin of Manufacturer	Mayalsia

Product Properties

Test Method	Characteristics			Requirement	Median
ATSM D6319	Dimensions (mm)	Width (M)		95 ± 10	95
		Length (M)		Min 230	240 (9,5*)
		Thickness single (mm)	Finger	Min 0.05	0.10 (4.0mils)
			Palm	Min 0.05	0.08 (3.1mils)
ASTM D5151	Freedom from holes			No leakage	NA
ASTM D412	Before accelerated aging.				
	Tensile Strength (MPa)			Min 14	30
	Ultimate elongation (%)			Min 500	650
ASTM D573	After accelerated aging at (70±2˚C 166±2 hr).				
	Tensile Strength (MPa)			Min 14	14
	Ultimate elongation (%)			Min 400	400

US Standards	ASTM 6319, ASTM 6978 Chemo/ ASTM F1671 Viral Barrier
FDA Information	FDA 510(k) - K172015
Quality Standards	ISO 9001:2015, EN ISO 13485:2016

Certifications

FDA · CE · LATEX · 2 · NON STERILE

510(k) Premarket

FDA

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510(k) Premarket Notification

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Device Classification Name	Polymer Patient Examination Glove[22]
510(K) Number	K172015
Device Name	POWDER FREE NITRILE EXAMINATION GLOVES, BLUE (COLORED)
Applicant	Careglove Global Sdn Bhd Lot 17479, Lrg Senawang 3/2, Off Jln Senawang 3, Senawang In Seremban, MY 70450
Applicant Contact	Lim Kwee Shyan
Correspondent	Careglove Global Sdn Bhd Lot 17479, Lrg Senawang 3/2, Off Jln Senawang 3, Senawang In Seremban, MY 70450
Correspondent Contact	Lim Kwee Shyan
Regulation Number	880.6250[23]
Classification Product Code	LZA[24]
Date Received	07/03/2017
Decision Date	09/26/2017
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Summary	Summary[25]
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

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25. http://www.accessdata.fda.gov/cdrh_docs/pdf17/K172015.pdf

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FDA Establishment

FDA

Establishment Registration & Device Listing

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Proprietary Name:	POWDER FREE NITRILE EXAMINATION GLOVES BLUE (COLORED)
Classification Name:	POLYMER PATIENT EXAMINATION GLOVE
Product Code:	LZA[6]
Device Class:	1
Regulation Number:	880.6250[7]
Medical Specialty:	General Hospital
Registered Establishment Name:	CAREGLOVE GLOBAL SDN BHD[8]
Registered Establishment Number:	3014164734
Premarket Submission Number:	K172015[9]
Owner/Operator:	Careglove Global Sdn Bhd[10]
Owner/Operator Number:	10051431
Establishment Operations:	Contract Manufacturer; Manufacturer

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FDA

U.S. Food and Drug Administration
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Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)

ASTM D6978 (1)

AKRON RUBBER DEVELOPMENT LABORATORY, INC.

Testing. Development. Problem Solving.

September 14, 2020

▪TEST REPORT▪

PN 155473

PHARMACEUTICAL SERVICES

Prepared For:

Murni Razali
CareGlove Global Sdn. Bhd.
Lot 17479 Senawang Industrial Estate
Lorong Senawang 3/2 Kawasan Perusahaan Senawang Seremban, Nageri Sembilan 70450
Malaysia

Prepared By: Tiffany Heller
Manager, Pharmaceutical Services

Approved By: Ana C Barbur, M.S.
Vice President, Analytical & Chemical Services

Rev 101218

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ISO 9001:2015

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AKRON RUBBER DEVELOPMENT LABORATORY, INC.

Testing. Development. Problem Solving.

September 14, 2020

Murni Razali
CareGlove Global Sdn. Bhd.

SUBJECT: Permeation testing per ASTM D6978 on sample submitted by the above company.

RECEIVED: One (1) glove type identified as; Blue Nitrile Examination Gloves, Powder Free, Sample ID; M29070

TEST CHEMICALS:
Table 1. List of the Testing Drugs and their Sources

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	USP; Lot# R116Y0; Expiration 07/2021
Cisplatin, 1.0 mg/ml (1,000 ppm)	Accord; Lot# P2001296; Expiration 01/2022
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000 ppm)	Accord; Lot# 19112225; Expiration 10/2021
Dacarbazine, 10.0 mg/ml (10,000 ppm)	Teva; Lot# 31325414B; Expiration 09/2021
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	WestWard; Lot# BJ0051; Expiration 06/2021
Etoposide, 20.0 mg/ml (20,000 ppm)	Teva; Lot# 31325485B; Expiration 07/2021
Fluorouracil, 50.0 mg/ml (50,000 ppm)	Accord; Lot# P2001167; Expiration 01/2022
Ifosfamide, 50 mg/ml (50,000 ppm)	Baxter Healthcare; Lot# 9A018G; Expiration 01/2022
Mitoxantrone, 2 mg/ml (2,000 ppm)	USP; Lot# J0F278; Expiration 07/2021
Paclitaxel, 6.0 mg/ml (6,000 ppm)	Teva; Lot# 19K24KA; Expiration 11/2021
ThioTepa, 10.0 mg/ml (10,000 ppm)	USP; Lot # R11380; Expiration 04/2021
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	Hospira; Lot# G057139AA; Expiration 03/31/2021

COLLECTION MEDIA:
Table 2. Collection Media for Test Drug

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	10% Ethanol Aqueous Solution
Cisplatin, 1.0 mg/ml (1,000 ppm)	Distilled Water
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000 ppm)	Distilled Water
Dacarbazine, 10.0 mg/ml (10,000 ppm)	Distilled Water
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	Distilled Water
Etoposide, 20.0 mg/ml (20,000 ppm)	Distilled Water
Fluorouracil, 50.0 mg/ml (50,000 ppm)	9.20 pH Sodium Hydroxide Solution
Ifosfamide, 50 mg/ml (50,000 ppm)	Distilled Water
Mitoxantrone, 2 mg/ml (2,000 ppm)	Distilled Water
Paclitaxel, 6.0 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
ThioTepa, 10.0 mg/ml (10,000 ppm)	Distilled Water
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	Distilled Water

ASTM D6978 (2)

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D6978
Analytical Method:	UV/VIS Spectrometry
Testing Temperature:	35.0°C ± 2.0
Collection System:	Closed Loop
Specimen Area Exposed:	5.067 cm2
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff

DETECTION METHOD OF CHEMICAL PERMEATION:

UV/VIS ABSORPTION SPECTROMETRY:
Instrument: Perkin Elmer UV/VIS Spectrometer Lambda 25

UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals, which permeated through the specimens into the collection medium. The collection medium was circulated in a closed loop through the testing period. Data collection was performed according to the programmed schedule by means of UV Winlab software from the Perkin Elmer Corporation. The list of the characteristic wavelengths is shown below.

Table 3. Characteristic Wavelengths used in UV/VIS Absorption Spectrometry

TESTING DRUG	WAVELENGTH (nm)
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	229
Cisplatin, 1.0 mg/ml (1,000 ppm)	199
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000 ppm)	200
Dacarbazine, 10.0 mg/ml (10,000 ppm)	320
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	232
Etoposide, 20.0 mg/ml (20,000 ppm)	205
Fluorouracil, 50.0 mg/ml (50,000 ppm)	269
Ifosfamide, 50 mg/ml (50,000 ppm)	200
Mitoxantrone, 2 mg/ml (2,000 ppm)	242
Paclitaxel, 6.0 mg/ml (6,000 ppm)	232
ThioTepa, 10.0 mg/ml (10,000 ppm)	199
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	220

SAMPLE CHARACTERISTICS:
Table 4. Thickness characteristics for the tested: Blue Nitrile Examination Gloves, Powder Free, Sample ID: M29070.

Testing Drug	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Carmustine (BCNU)	0.059	0.064	0.066	0.063
Cisplatin	0.060	0.063	0.059	0.061
Cyclophosphamide (Cytoxan)	0.058	0.062	0.059	0.059
Dacarbazine	0.060	0.062	0.062	0.061
Doxorubicin	0.063	0.058	0.068	0.063
Etoposide	0.057	0.063	0.062	0.060
Fluorouracil	0.062	0.061	0.063	0.062
Ifosfamide	0.062	0.066	0.061	0.063
Mitoxantrone	0.060	0.059	0.067	0.062
Paclitaxel	0.060	0.063	0.064	0.062
ThioTepa	0.067	0.063	0.061	0.064
Vincristine Sulfate	0.065	0.067	0.061	0.064
Weight/Unit Area (g/m2)	57.0			

RESULTS:
Table 5. Permeation Test Results on testing of: Blue Nitrile Examination Gloves, Powder Free, Sample ID: M29070.

TEST CHEMOTHERAPY DRUGS	AVERAGE BREAKTHROUGH DETECTION TIME (Specimen1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen1/2/3) (µg/cm²/minute)	OTHER OBSERVATIONS
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	22.6 (22.6,23.0,23.2)	0.4 (0.4,0.4,0.4)	Moderate swelling and degradation
Cisplatin, 1.0 mg/ml (1,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Dacarbazine, 10.0 mg/ml (10,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Etoposide, 20.0 mg/ml (20,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Fluorouracil, 50.0 mg/ml (50,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Ifosfamide, 50 mg/ml (50,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Mitoxantrone, 2 mg/ml (2,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Paclitaxel, 6.0 mg/ml (6,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
ThioTepa, 10.0 mg/ml (10,000 ppm)	43.9 (44.3,43.9,48.7)	1.5 (1.5,1.9,1.2)	Slight swelling and degradation
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	>240 min.	N/A	Slight swelling and no degradation

Prepared By: _____
Tiffany Heller
Manager, Pharmaceutical Services

Approved By: _____
Ana C Barbur, M.S.
Vice President, Analytical & Chemical Services

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NOTE: Non-ISO 17025 accredited test methods are designated with the ^ symbol to differentiate from ISO 17025 accredited methods in the body of the test report.*

ASTM F1671 Viral Barrier

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The Rubber Industry's Catalyst For Rubber Sector Related Samples

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GLOBAL TESTING AND CONSULTANCY FOR RUBBER

TEST REPORT

REPORT NO	: VPT/2009/0007
SUBJECT	: VIRUS PENETRATION
SUBMITED BY	: **CAREGLOVE GLOBAL SDN BHD** **Lot 17479, Lorong Senawang 3/2** **Off Jalan Senawang 3, Senawang Industrial Estate** **70450 Seremban, Negeri Sembilan.**
RECEIVED ON	: September 28th, 2020

These results have been obtained on sample(s) submitted to us.

Condition of samples	: Unused gloves with no wear or abrasion
Expected	: No penetration of viral solution from inside the glove; any penetration above 10 pfu is considered failed. Expected recovery; 100 ± 2%
Test objective	: To determine that the viral solution did not penetrate > 10 pfu within the test period (viral leak < 10 pfu)

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TEST REPORT

REPORT NO	: VPT/2009/0007
SAMPLE DESRIPTION	: Blue Nitrile Examination, Powder Free 3.5g Product Code: M0-0820048
STANDARD TEST METHOD	: *ASTM F1671-07*, Phi-X174 Bacteriophage Penetration Test
DATE OF TESTING	: 05th - 06th October 2020
DATE OF REPORT	: 07st October 2020

Sample Id	Plague Forming Unit	Requirement Virus Leak (Pfu)	Status
M0-0820048	NP	<10	PASS

Note
NP : No plaque formed
VSF : Test results are acceptable if VSF > 0.8*

Disclaimer
***Test is performed** to required specification (s) of the said standard (where applicable). Results reflect data obtained and/or observed from the samples provided for testing only. Results do not reflect shipment prior to the stated lot numbers, or condition of future shipment, nor does it reflect the quality of future production and manufacturing. Our organization is not liable for any mis-used of data or information*

Yours Sincerely;

(TAJUL ANUAR YAAKOB)
Technical Manager
Biological Laboratory
Global Testing and Consultancy for Rubber (G-TACR)
47000 Sg Buloh, Selangor, Malaysia

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G-TACR/TR2/Issue No.2

FDA Food Grade Test Report (1)

CAREGLOVE GLOBAL SDN. BHD.
LOT 17479, LORONG SENAWANG 3/2, OFF JALAN SENAWANG 3,
SENAWANG INDUSTRIAL ESTATE, 70450 SEREMBAN, NEGERI SEMBILAN.

The following sample(s) was/were submitted and identified by the applicant as:

Blue Nitrile Examination Glove, Powder Free 3.5g

Job Ref No. : 2020-09-14-018
Date of Sample Received : 14th September 2020
Testing Period : 14th September 2020 – 24th September 2020

Test Requested : Please refer to the results summary

Test Method & Results : Please refer to next page(s).

Result Summary :

Test Requested	Conclusion
US FDA 21 CFR 177.2600 (Rubber Articles) – Determination of Amount of Extractives	**PASS**

SIGNED FOR AND ON BEHALF OF
SGS (MALAYSIA) SDN BHD

CHEE TUCK CHOON
SECTION HEAD
IKM No. M/3983/6401/12/14

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Test Results :

US FDA 21 CFR 177.2600 (Rubber Articles) – Determination of Amount of Extractives

Method : With reference to US FDA 21 CFR 177.2600.

For use in contact with aqueous food:

Extractant	Test Condition	Result ($mg/inch^2$)	Reporting Limit ($mg/inch^2$)	Permissible Limit ($mg/inch^2$)
Distilled Water	Reflux temperature for 7 hours	1.4	0.2	20
	Succeeding 2 hours of extraction	N.D.	0.2	1
Comment	--	**PASS**	--	--

For use in contact with fatty food:

Extractant	Test Condition	Result ($mg/inch^2$)	Reporting Limit ($mg/inch^2$)	Permissible Limit ($mg/inch^2$)
n-Hexane	Reflux temperature for 7 hours	1.2	0.2	175
	Succeeding 2 hours of extraction	0.3	0.2	4
Comment	--	**PASS**	--	--

Sample Description : **Blue Nitrile Examination Glove, Powder Free 3.5g**

Note : 1. $mg/inch^2$ = milligram per square inch
2. N.D. = Not Detected

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CHEE TUCK CHOON
SECTION HEAD
IKM No. M/3983/6401/12/14

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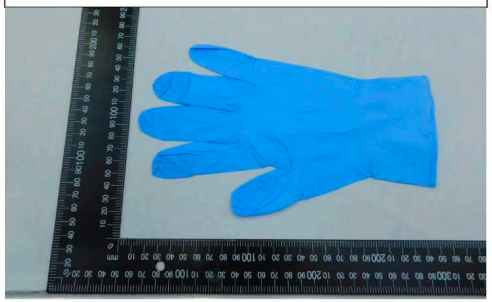
FDA Food Grade Test Report (2)

Sample Photo:

CAREGLOVE GLOBAL SDN. BHD. CA46743



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CHEE TUCK CHOON
SECTION HEAD
IKM No. M/3983/6401/12/14

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ISO 9001

CERTIFICATE

This is to certify that

Careglove Global Sdn. Bhd.

Lot 17479, Lorong Senawang 3/2,
Off Jalan Senawang 3,
Senawang Industrial Estate,
70450 Seremban, Negeri Sembilan,
Malaysia.Senawang 3/2,

has implemented and maintains a **Quality Management System**.

Scope:
Manufacture of Non-sterile Powdered and Powder Free Latex Examination Gloves.

Manufacture of Sterile Powdered and Powder Free Latex Surgical Gloves.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 9001 : 2015

Certificate registration no.	496791 QM15
Date of certification	2018-05-28
Valid until	2021-05-27

QS 02062017 CB 18

DQS Certification (M) Sdn Bhd

Danny Ng
Regional Managing Director

Accredited Body: DQS Malaysia, Suite 43-4 Setia Avenue, Jalan Setia Prima S U 13/S,
Setia Alam Seksyen U 13, 40170 Shah Alam, Selangor - Malaysia

ISO 13485

CERTIFICATE

This is to certify that the company

Careglove Global Sdn. Bhd.

Lot 17479, Lorong Senawang 3/2,
Off Jalan Senawang 3,
Senawang Industrial Estate,
70450 Seremban, Negeri Sembilan
Malaysia

has implemented and maintains a **Quality Management System.**

Scope:
Manufacture and supply of non-sterile powdered and powder free latex and nitrile examination gloves.
Manufacture and supply of sterile powdered and powder free latex surgical gloves.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

EN ISO 13485 : 2016

Certificate registration no.	496791 MP2016
Certificate unique ID	170707485
Effective date	2018-06-09
Expiry date	2021-06-08
Frankfurt am Main	2018-06-09

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

IQNet

E 10.22 Version 3.0

EC Declaration

CAREGLOVE GLOBAL SDN BHD (933760-W)
Lot 17479, Lorong Senawang 3/2, Off Jalan Senawang 3,
Senawang Industrial Estate, 70450 Seremban, Negeri Sembilan, Malaysia.
Tel: 60-6-6782377, 60-6-6788377 Fax: 60-6-6785377
Email: info@careglove.com

EC Declaration of Conformity

according to the Medical Devices Directive 93/42/EEC

Manufacture: **CAREGLOVE GLOBAL SDN. BHD.**

Address: Lot 17479, Lorong Senawang 3/2, Off Jalan Senawang 3, Senawang Industrial Estate, 70450 Seremban, Negeri Sembilan, Malaysia.

EC Representative: Welkang Ltd.
Suite B, 29 Harley Street, London WIG 9QR, UK.

We, the manufacture, declare under our sole responsibility that the medical device (s)

Product Name: **Nitrile Examination Glove, Powdered and Powder Free**

Class: **I**

is in conformity with the relevant provisions and requirements of directive 93/42/EEC, as amended by Directive 2007/47/EEC.

Standards Applied: EN 455 Part 1, 2 & 3
ISO 11193-1
ASTM D6319

Authorised Signatory:

Lim Kwee Shyan
Managing Director

08th April 2020
Date

Negeri Sembilan, Malaysia
Place of Issue