

CAREGLOVE GLOBAL SDN BHD

Quality and Relationship You Can Trust

Nitrile Examination Glove (Powder-Free) (Chemotherapy)

An ideal alternative for chemotherapy applications which require a high level of protection. A nitrile glove provides protection from common chemicals, with good puncture resistance and tear strength

Functional Benefits

- O Excellent fit and soft feel for outstanding comfort and protection
- O Textured fingertip enhances grip in wet and dry condition
- Latex Free for users who suffer from natural rubber latex allergies
- Ambidextrous
- Beaded cuff and easy donning

■ Shelf Life

3 years from the date of manufacturing

Storage

Avoid excessive heat (40°C, 104°F). Open box should be shielded from exposure to direct sun or fluorescent lighting.

NITRILEGARE WITRILECARE

Product Description

- Weight
 - 3.5g
- **AQL** 1.5

Light Blue

Light Diuc

Colour

Glove Sizes

XS, S, M, L, XL, XXL

Quality Standards & System

- Conforms to ASTM D6319 and EN455-1, 2, 3 Standards
- Manufactured under QSR (GMP), ISO 9001:2015 and ISO 13485:2016 Quality Management System & ISO 14001:2015 Environmental Management System

Physical Dimensions

	Standards		
Dimensions	Careglove Global	ASTM D6319	EN 455
Length (mm)	Min 240	Min 220 (XS, S) Min 230 (M, L, XL, XXL)	Min 240
Palm Width (mm)			
• XS	70 ± 5	70 ± 10	≤ 80
• S	85 ± 5	80 ± 10	80 ± 10
• M	95 ± 5	95 ± 10	95 ± 10
• L	105 ± 5	110 ± 10	110 ± 10
• XL	115 ± 5	120 ± 10	≥ 110
• XXL	120 ± 5	130 ± 10	-
Thickness: Single			
Wall (mm)			
 Finger 	Min 0.05	Min 0.05	N/A
• Palm	Min 0.05	Min 0.05	N/A

Physical Properties

Property	ASTM D6319	EN 455
Tensile Strength (MPa)		
Before Aging	Min 14	N/A
After Aging	Min 14	N/A
Elongation at Break (%)		
Before Aging	Min 500	N/A
After Aging	Min 400	N/A
Median Force at Break (N)		
Before Aging	N/A	Min 6
After Aging	N/A	Min 6

Product Safety Conformance

BISPHENOL A (BPA) TESTED

Pass

Standard Reference: Liquid Chromatography-Mass Spectrometry System (LC-MS), JETRO

Purpose: To ensure the glove are free from Bisphenol A and safe to use.

Bisphenol A (BPA)	Test Results	
	Not Detected	

If you have any enquiries on our products, please contact: Manufactured by:

CAREGLOVE GLOBAL SDN BHD

(A Member of Careplus Group of Companies)

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











VIRAL PENETRATION TESTED

CHEMOTHERAPY DRUGS TESTED

Pass

Standard Reference: ASTM F1671 - Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood - Borne Pathogens Using Phi-X 174 Bacteriophage Penetration

as a Test System

Purpose: To test the barrier protection of the gloves from the passages of the viruses

Viral Penetration	Test Results
virai Penetration	Pass

BIO-COMPATIBILITY TESTED

Pass

Standard Reference: Reference: ISO 10993-10 (Test for Skin Irritation and Skin Sensitization)

Purpose: Biological evaluation for medical devices for irritation and

delayed type hypersensitivity.

Biocompatibility Test	Test Results
	PASSES
Primary Skin Irritation	Not a primary skin irritant under
	condition of the study
Skin Sensitization	PASSES
	Not a contact sensitizer under
	condition of the study

Assessment of Medical Gloves to Permeation by Chemotherapy Drugs Purpose: To examine the glove's barrier protection against

Standard Reference: ASTM D6978-05 Standard Practice for

virus passage to the test

In the second se	
	Concentration Breakthrough
Chemotherapy Drugs	Detection Time in
	(Minutes)
Carmustine (BCNU) 3.3mg/ml	22.6
Cisplatin 1.0mg/ml	>240 min
Cyclophosphamide (Cytoxan) 20.0mg/ml	>240 min
Dacarbazine 10.0mg/ml	>240 min
Doxorubicin HCL 2.0mg/ml	>240 min
Etoposide 20.0mg/ml	>240 min
Fluorouracil 50.0mg/ml	>240 min
Ifosfamide 50.0mg/ml	>240 min
Mitoxantrone 2mg/ml	>240 min
Paclitaxel 6.0mg/ml	>240 min
Thio Tepa 10.0mg/ml	43.9
Vincristine Sulfate 1.0mg/ml	>240 min

FOOD MIGRATION TESTED

Pass

Purpose: To ensure the gloves are comply with regulation and safe to use for handling food.

Standard	Property	External Lab Test Results		Artwork Labelling
National Food		Simulant	Overall Migration	
Safety Standard- Food Contact Rubber	Overall Migration	50% Ethanol	PASS	St
Materials and		Test Condition: 40°C	C, 10 mins	This product is suitable for milk and
Products GB 4806.11-2016		Standard: <10mg/dm2		dairy products, alcoholic food, and beverages of more than 20% of alcohol and oil in water emulsion
		Simulant	Overall Migration	
		Distilled water at reflux temperature for 7 hours	PASS	ניור דו
Legislation CFR US FDA 21 CFR	CFR US FDA Overall	Distilled water at reflux temperature for succeeding 2 hours	PASS	Sci
177.2600	-	n-Hexane at reflux temperature for 7 hours	PASS	
		n-Hexane at reflux temperature for succeeding 2 hours	PASS	This product is suitable for food handling under US FDA 21 CFR 177.2600
Materials and Articles in		Simulant	Overall Migration	
Contact With		10% Ethanol	PASS	()7
Food Stuffs-		20% Ethanol	PASS	771
Plastics-EN	Overall	Iso-octane	PASS	
1186-1	Migration	Test Condition : 40°C	C, 30 mins	
		Standard : <10mg/dm2		This product is suitable for pastries, alcoholic food, and beverages of more than 20% of alcohol and oil in water emulsion

Personal Protective Equipment Regulation (EU) 2016/425

Standard Reference: EN ISO 374-1:2016 + AI:2018

Purpose: To ensure the requirements for protective gloves intended to protect the user against dangerous chemicals

	EN ISO 374-1:2016 + AI:2018
40% Sodium Hydroxide	6
37% Formaldehyde	2
96% Sulphuric Acid	0
30% Hydrogen Peroxide	0
99% Acetic Acid	0
N-Heptane	6

Standard Reference: EN ISO 374-5:2016

Purpose: To ensure the requirements and test methods for protective gloves intended to protect the user against micro-

organisms

Phi-X174	Pass
Bacteriophage	

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Certificate No: CE 760946 Certificate Body No: 2797 UK CA

Certificate No: UKCA 766514 Certificate Body No: 0086