



CAREGLOVE GLOBAL SDN BHD

Quality and Relationship You Can Trust

Nitrile Examination Glove (Powder-Free)

A nitrile glove provides protection from common chemicals, with good puncture resistance and tear strength

Functional Benefits

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



Product Description

- **Weight**
4.6g
- **AQL**
1.5
- **Colour**
Green, Black, White, Purple, Orange, Indigo Blue
- **Glove Sizes**
XS, S, M, L, XL, XXL
- **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.

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

| Dimensions | Standards | | |
|-----------------------------|------------------|--|----------|
| | 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)

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VIRAL PENETRATION 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 |
|-------------------|--------------|
| | Pass |



PHTHALATES TESTED**Pass****Standard Reference:** RoHS Directive (EU) 2015/863 amending Annex II to Directive 2011/65/EU**Purpose:** Compliance on REACH Regulation (EC) 1907/2006 Annex XVII requirements for phthalates

| Chemical Test (s) | Test Results (µg/g) |
|-----------------------------------|---------------------|
| Dibutyl Phthalate (DBP) | Not Detected |
| Di(2-ethylhexyl) Phthalate (DEHP) | Not Detected |
| Di-isobutyl Phthalate (DIBP) | Not Detected |
| Benzyl butyl Phthalate (BBP) | Not Detected |

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 |
|-------------------------|--|
| Primary Skin Irritation | PASSES Not a primary skin irritant under condition of the study |
| Skin Sensitization | PASSES Not a contact sensitizer under condition of the study |


FOOD MIGRATION TESTED**Pass****Purpose:** To ensure the gloves are comply with regulation and also safe to use for handling food.

| Standard | Property | External Lab Test Results | | Artwork Labelling |
|--|-------------------|--|--------------------------|---|
| National Food Safety Standard-Food Contact Rubber Materials and Products GB 4806.11-2016 | Overall Migration | Simulant | Overall Migration |  |
| | | 50% Ethanol | PASS | |
| | | Test Condition : 40°C, 10 mins | | This product is suitable for milk and dairy products, alcoholic food, and beverages of more than 20% of alcohol and oil in water emulsion |
| | | Standard : <10mg/dm2 | | |
| Federal Legislation CFR US FDA 21 CFR 177.2600 | Overall Migration | Simulant | Overall Migration |  |
| | | Distilled water at reflux temperature for 7 hours | PASS | |
| | | Distilled water at reflux temperature for succeeding 2 hours | PASS | |
| | | 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 |

Personal Protective Equipment Regulation (EU) 2016/425

Standard Reference: EN ISO 374-1:2016 + AI:2018 & EN ISO 374-4:2019 (%)

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

|  | EN ISO 374-1:2016 + AI:2018 | EN ISO 374-4:2019 (%) |
|---|-----------------------------|-----------------------|
| 40% Sodium Hydroxide | 6 | -6.9 |
| 37% Formaldehyde | 2 | 13.4 |
| 96% Sulphuric Acid | 1 | 100.0 |
| 30% Hydrogen Peroxide | 2 | 4.1 |

Standard Reference: EN ISO 374-1:2016

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

| Level | 1 | 2 | 3 | 4 | 5 | 6 |
|-------|-----|-----|-----|------|------|------|
| Time | >10 | >30 | >60 | >120 | >240 | >480 |

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 Bacteriophage | Pass |
|------------------------|------|



Certificate No: CE 760946
Certificate Body No: 2797



Certificate No: UKCA 766514
Certificate Body No: 0086