



# 6.0g Black | Blue | Violet-Blue Powder-Free Nitrile Gloves

## Powder-Free Nitrile Gloves (ASTM | EN) Specifications

### Product Specification

|                   |                                                                                                                                                                                                                                                                 |
|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Type      | Powder-Free, Non-sterile, Single-use                                                                                                                                                                                                                            |
| Material          | Nitrile Butadiene Rubber (NBR)                                                                                                                                                                                                                                  |
| Color             | Black, Blue, Violet-Blue                                                                                                                                                                                                                                        |
| Gloves Size       | XS, S, M, L, XL                                                                                                                                                                                                                                                 |
| Weight (g)        | 6.0 ± 0.5                                                                                                                                                                                                                                                       |
| Design & Features | <ul style="list-style-type: none"><li>• Tested for Chemotherapy Drugs &amp; Fentanyl Resistance</li><li>• Biocompatibility Tested</li><li>• Not made with natural rubber latex</li><li>• Ambidextrous</li><li>• Finger Textured</li><li>• Beaded cuff</li></ul> |
| Shelf-life        | 3 years from the date of manufacturing                                                                                                                                                                                                                          |

### Quality Standards

- Conforms to ASTM D6319 and EN 455 Standards
- Manufactured under ISO 9001:2015 and ISO 13485:2016 Quality Management System

|              |                                                                                                                                                                                                                                                                                                                |
|--------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Medical      | <ul style="list-style-type: none"><li>• Conforms to Medical Device Regulation (EU) 2017/745 Class I</li><li>• Cleared under FDA 510(k) Premarket Notification Class I</li></ul>                                                                                                                                |
| PPE          | <ul style="list-style-type: none"><li>• Conforms to Personal Protective Equipment Regulation (EU) 2016/425 Category III (Type B) in accordance with EN ISO 21420 and EN ISO 374</li></ul>                                                                                                                      |
| Food Contact | <ul style="list-style-type: none"><li>• Conforms to Federal Legislation US FDA 21 CFR 177.2600</li><li>• Conforms to Regulation (EU) No 1935/2004 (Italian D.M. 21/03/73, EC Directive 93/11/EEC &amp; Council of Europe Resolution AP(2004)4)</li><li>• *Conforms to JETRO and Korea MFDS standards</li></ul> |

\*On selected color variants.

### Physical Dimension

| DIMENSIONS                 |                                    | STANDARDS |                                        |          |
|----------------------------|------------------------------------|-----------|----------------------------------------|----------|
|                            |                                    | One Glove | ASTM D6319                             | EN455    |
| Length (mm)                |                                    | Min 240   | Min 220 (XS, S),<br>Min 230 (M, L, XL) | Min 240  |
| Palm Width (mm)            | XS                                 | 75 ± 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     |
| Single Wall Thickness (mm) | Finger (13 ± 3 mm from finger tip) | Min 0.17  | Min 0.05                               | N/A      |
|                            | Palm (33 ± 5 mm from crotch)       | Min 0.10  | Min 0.05                               | N/A      |
|                            | *Cuff (25 ± 5 mm from cuff edge)   | Min 0.08  | N/A                                    | N/A      |

\*For reference only.  
Single Wall Thickness represents the typical thickness value measured.

### Quality Assurance for Pre-Shipment Inspection

| Characteristic   | Dimension | Physical Properties | Freedom from Holes | Visual Defects |       |
|------------------|-----------|---------------------|--------------------|----------------|-------|
|                  |           |                     |                    | Major          | Minor |
| Inspection Level | S2        | S2                  | G1                 | G1             | G1    |
| AQL              | 4.0       | 4.0                 | 1.5                | 2.5            | 4.0   |

\*This pre-shipment inspection follows our standard guidelines and is subjected to change according to agreed requirements and specifications.  
For further information, please contact our sales team.

### Physical Properties

| PROPERTY                   | STANDARDS    |             |              |             |
|----------------------------|--------------|-------------|--------------|-------------|
|                            | ASTM D6319   |             | EN 455       |             |
|                            | Before Aging | After Aging | Before Aging | After Aging |
| Tensile Strength (MPa)     | Min 14       | Min 14      | N/A          | N/A         |
| Elongation at Break (%)    | Min 500      | Min 400     | N/A          | N/A         |
| Median Force at Break (N)  | N/A          | N/A         | Min 6        | Min 6       |
| Powder Content (mg/glove)  | ≤ 2.0        |             | ≤ 2.0        |             |
| Protein Content (mg/glove) | N/A          |             | Not detected |             |

### Product Performance

#### EN ISO 374-1: 2016+A1:2018

Classification of Permeation Performance Level:

| Level               | 1   | 2   | 3   | 4    | 5    | 6    |
|---------------------|-----|-----|-----|------|------|------|
| Breakthrough (mins) | >10 | >30 | >60 | >120 | >240 | >480 |

| Code Letter | Chemical Permeation (EN ISO 374-1: 2016+A1:2018) | Level | Mean Degradation (%) (EN ISO 374-4:2019) |
|-------------|--------------------------------------------------|-------|------------------------------------------|
| J           | n-Heptane                                        | 6     | 52                                       |
| K           | Sodium hydroxide 40%                             | 6     | -21.7                                    |
| P           | Hydrogen peroxide 30%                            | 5     | 43                                       |
| T           | Formaldehyde 37%                                 | 5     | 32.8                                     |

#### EN ISO 374-5: 2016

Protection against bacteria and fungi  
Protection against viruses

Pass  
Pass

#### ASTM D6978

Resistance to Permeation by Chemotherapy Drugs and Fentanyl

| Chemotherapy Drugs and Concentration                              | Breakthrough Time (Min) |
|-------------------------------------------------------------------|-------------------------|
| Carboplatin (10 mg/ml)                                            | >240                    |
| Carmustine (3.3 mg/ml)                                            | Do not use              |
| Cisplatin (1 mg/ml)                                               | >240                    |
| Cyclophosphamide (20 mg/ml)                                       | >240                    |
| Dacarbazine (10 mg/ml)                                            | >240                    |
| Docetaxel (20 mg/ml)                                              | >240                    |
| Doxorubicin HCl (2 mg/ml)                                         | >240                    |
| Etoposide (20 mg/ml)                                              | >240                    |
| Fluorouracil (50 mg/ml)                                           | >240                    |
| Gemcitabine (38 mg/ml)                                            | >240                    |
| *Gluteraldehyde (80 mg/ml)                                        | >240                    |
| Ifosfamide (50 mg/ml)                                             | >240                    |
| *Methotrexate (25 mg/ml)                                          | >240                    |
| *Mitomycin C (0.5 mg/ml)                                          | >240                    |
| Paclitaxel (6.0 mg/ml)                                            | >240                    |
| Thiotepa (10 mg/ml)                                               | Do not use              |
| Vincristine Sulfate (1 mg/ml)                                     | >240                    |
| Additional Agents                                                 |                         |
| Fentanyl Citrate Injection (100mcg/2ml)                           | >240                    |
| Gastric Acid Fluid/ Fentanyl Citrate Injection Mix 50/50 Solution | >240                    |
| Simulated Gastric Acid                                            | >240                    |

\*FDA 510(k) clearance is currently in process for Gluteraldehyde, Methotrexate, Mitomycin C (Black), and all Chemotherapy Drugs (Blue).

#### Biocompatibility Testing

Acute Systemic Toxicity (ISO 10993-11)  
Sensitization (ISO 10993-10)  
Irritation (ISO 10993-10)

Pass  
Pass  
Pass

\*All test reports are available upon request



One Glove Group Berhad

Lot 73-86, Jalan Logam 5, Perindustrian Kamunting 3, Kamunting Raya Industrial Estate, 34600 Kamunting, Perak Darul Ridzuan, Malaysia

T/F (+605) 891 3333 | E info@oneglovegroup.com | W oneglovegroup.com