



**PRODUCT SPECIFICATION**  
***Generic Black Nitrile Industrial***

**PRODUCT**

Nitrile disposable glove  
Industrial grade  
Non-sterile  
Powder-free  
Textured surface

**COUNTRY OF ORIGIN**

Malaysia

**INTENDED USE**

This is a disposable product intended for non-medical purposes

**MATERIAL**

Synthetic nitrile rubber

**OUTER SURFACE**

No donning powder used

**COMPONENTS**

Synthetic rubber nitrile (NBR)  
Potassium Hydroxide  
Titanium Dioxide  
Sulfur  
Organic accelerators (dithiocarbamate-based)  
Zinc Oxide

**SHAPE**

Straight fingers  
Thumb and fingers in one plane  
Ambidextrous

**CUFF**

Beaded (rolled rim)

**COLOR**

Black

**SIZES**

Extra small (XS), small (S), medium (M), large (L), extra large (XL), extra extra large (XXL)

**MARKING**

Packaging marked to designated size (gloves not marked)

**PACKAGING AND LABELING**

Reorder Number GBLK101-106

100 pieces per box, 1000 pieces per case; 90 pieces per box, 900 pieces per case (XXL)

**CONTROL NUMBER (LOT NO.)**

Each packing unit (dispenser box) and outer carton bears a control number

EXAMPLE: 328012531NCZ

Key: 3           ..... Fixed code  
 28           ..... Manufacturing plant  
 012531       ..... Sales order number  
 NC           ..... Type of glove  
 Z           ..... Size

**QUALITY CHARACTERISTICS**

All listed standards are used in their latest edition. Current test data on physical properties is available upon request.

| <b>DESCRIPTION</b>                           | <b>SPECIFICATION</b>  | <b>ASSURANCE ACTION</b> |
|--|---|-------------------------|
| <u>Dimensions</u>                            | 240 mm min (S)  | <i>ASTM D 6319</i>      |
| <i>Overall length</i>                        |   |                         |
| <i>Width</i>                                 | 76 mm +/- 3 mm (XS)<br>84 mm +/- 3 mm (S)<br>94 mm +/- 3 mm (M)<br>105 mm +/- 3 mm (L)<br>113 mm +/- 3 mm (XL)<br>123 mm +/- 3 mm (XXL) |                         |
| <i>Thickness (single wall)</i>               | <i>Finger:</i> 0.08 mm/3.2 mils min.<br><i>Palm:</i> 0.05 mm/2.0 mils min.  |                         |
| <u>Biocompatibility</u>                      |   |                         |
| <i>Inside pH</i>                             | 7.0 +/- 1   | <i>Test method A1</i>   |
| <u>Physical properties</u>                   |   | <i>ASTM D 412</i>       |
| <i>Tensile strength (before/after aging)</i> | 14 MPa min.   |                         |
| <i>Elongation (before aging)</i>             | 500% min.   |                         |
| <i>(after aging)</i>                         | 400% min.   |                         |

**PERFORMANCE REQUIREMENTS FOR QUALITY CHARACTERISTICS**

For reference purpose in accordance with ISO 2859 "Sampling Procedures for Inspection by Attributes"

**INTERNAL ATTRIBUTIVE RELEASE INSPECTION**

Sampling for examination in accordance with ISO 2859-1.

Unit for *inspection*: one (1) glove

If several defects are found on one glove, only the most serious defect (i.e. lowest category) is evaluated

The acceptance criteria is based on the number of defectives observed in a sample

**FINAL GLOVE RELEASE**

**Assurance action**

ISO 2859-1: "Sampling Procedures for Inspection by Attributes – Part 1: Sampling Schemes Indexed by Acceptance Quality Limit (AQL) for Lot-by-Lot Inspection"

**Sampling inspection and final release information**

*Major defects:* highest concern non-conformities which prevent correct use of the product. AQL 4.0 (inspection level GI for leaks)

**PACKAGING, MARKING, GOOD DELIVERY INSPECTION**

**Assurance Action**

Set-up and patrol inspection at packaging

Supervision of vehicle or vessel loading

***Sempermed USA, Inc. is a certified participant of C-TPAT (U.S. Customs-Trade Partnership Against Terrorism)***

**GOOD MANUFACTURING PRACTICE**

The gloves are manufactured in compliance with ISO 9001 and ISO 13485

**STORAGE**

According to ISO 2230 for Vulcanized Rubber

Store in a dry, ventilated area

Avoid direct sunlight, fluorescent lighting, heat, and moisture

Do not store above 100° F (38° C) as this will lead to accelerated aging

Long-term storage can result in pleats and stickiness

**END OF DOCUMENT**

