



PRODUCT SPECIFICATION

SemperGuard® Nitrile General Purpose Gloves

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 (carbamate-based)
Zinc Oxide

SHAPE

Straight fingers
Thumb and fingers in one plane
Ambidextrous

CUFF

Beaded (rolled rim)

COLOR

Blue

SIZES

Small (S), medium (M), large (L), extra large (XL)

MARKING

Packaging marked to designated size (gloves not marked)

PACKAGING AND LABELING

Reorder Number INIPFT102-INIPFT105
 100 pieces per box, 1000 pieces per case

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.

DESCRIPTION	SPECIFICATION	ASSURANCE ACTION
<u>Dimensions</u>	240 mm min (S)	ASTM D 6319
Overall length		
Width	84 mm +/- 3 mm (S) 94 mm +/- 3 mm (M) 105 mm +/- 3 mm (L) 113 mm +/- 3 mm (XL)	
Thickness (single wall)	Finger: 0.10 mm/4.0 mils min. Palm: 0.07 mm/2.8 mils min.	
Weight (size M)	4.4 g min.	
<u>Physical properties*</u>		ASTM D 412
Tensile strength (before/after aging)	14 MPa min.	
Elongation (before aging)	500% min.	
(after aging)	450% min.	

*minimum acceptable requirements of ASTM and FDA where applicable. Gloves offered by Sempermed USA, Inc. exceed these physical requirements.

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

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