Sempermed®
We are people protection.®

**PRODUCT SPECIFICATION**

# SemperShield™ Nitrile

## PRODUCT
Nitrile examination glove
Medical grade
Non-sterile
Powder-free
Textured surface

## COUNTRY OF ORIGIN
Thailand

## INTENDED USE
This is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner where natural rubber latex should be avoided

## SPECIAL USE
Tested for use with chemotherapy drugs. Drugs tested:, Cisplatin, Cyclophosphamide, Dacarbazine, Doxorubicin Hydrochloride, Etoposide, 5-Fluorouracil, Mitomycin, Methotrexate, Paclitaxel, Thiotepa, Vincristine Sulfate.
CAUTION: Gloves used for protection against chemotherapy drug exposure must be selected specifically for the type of drugs used. Review material safety data sheets for the drug being used to determine the required level of protection.

## MATERIAL
Synthetic nitrile rubber. This product does not contain proteins found in natural rubber goods.

## OUTER SURFACE
No donning powder used

## COMPONENTS
Synthetic rubber nitrile (NBR)
Titanium Dioxide
Sulfur
Organic accelerators (carbamate-based and thiozole-based)
Zinc Oxide

## SHAPE
Straight fingers
Thumb and fingers in one plane
Ambidextrous

## CUFF
Beaded (rolled rim)

## COLOR
Blue

**Sempermed USA, Inc.,** 13900 49th Street North, Clearwater, Florida 33762
Tel: 800.366.9545 Fax: 800.763.5491

## SIZES
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 SSNF102-SSNF106
50 pieces per box, 500 pieces per case

## CONTROL NUMBER (LOT NO.)
Each packing unit (dispenser box) and outer carton bears a control number that includes the month and year of production. Each also bears a control number:
EXAMPLE: 160913180115
Key: 16 …… Production year
09 …… Production month
13 …… Production day
180115 … Batch number

## QUALITY CHARACTERISTICS
All listed standards are used in their latest edition.

| DESCRIPTION | SPECIFICATION | ASSURANCE ACTION |
|---|---|---|
| Dimensions | | *ASTM D 6319* |
| *Overall length* | 280 mm min. | |
| *Width* | 86 mm +/- 4 mm (S)<br>98 mm +/- 4 mm (M)<br>107 mm +/- 4 mm (L)<br>115 mm +/- 4 mm (XL)<br>122 mm +/- 4 mm (XXL) | |
| *Thickness (single wall)* | *Finger:* 0.14 mm/5.6 mils max.<br>*Palm:* 0.11 mm/4.4 mils max.<br>Cuff: 0.10 mM/4.0 mils max. | |
| Physical properties | | |
| *Tensile strength (before aging)* | 36 MPa max. | *ASTM D 412 / ASTM D 5273* |
| *Tensile strength (after aging)* | 27 MPa max. | |
| *Elongation (before aging)* | 996% max. | |
| *(after aging)* | 841% max. | |

## 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
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**

ASTM D 6319: “Standard Specification for Nitrile Examination Gloves for Medical Application”
ASTM D 5151: “Standard Test Method for Detection of Holes in Medical Gloves”

***Sampling inspection and final release information***

*Major defects:* highest concern non-conformities which prevent correct use of the product. AQL 1.5 (inspection level GI for leaks)
*Minor defects*: non-conformities of a lesser degree of concern, which do not prevent correct use of the product. AQL 4.0 (inspection level GI for visual defects aggregated)

## 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 (Customs-Trade Protection Against Terrorism)***

## GOOD MANUFACTURING PRACTICE

The gloves are manufactured in compliance with ISO 13485 and US FDA 21 CFR part 820

## MICROBIOLOGICAL CLEANLINESS CONTROL

The bioburdens of the finished gloves are monitored and recorded. Unusual contaminants are identified.
**CAUTION:** Non-sterile examination gloves are used in a variety of circumstances, including procedures where the surface of the glove contacts wounds, body cavities, or other possible routes of contamination. If conditions warrant, the user may wish to minimize the risk of infection. In this case we recommend the decontamination of the gloves prior to use by disinfectants or other effective methods.

## 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**