



**PRODUCT SPECIFICATION**

***SemperSure® Black Nitrile Examination Gloves***

**PRODUCT**

Nitrile examination glove  
Medical grade  
Non-sterile  
Powder-free  
Textured fingertips  
Low dermatitis potential

**COUNTRY OF ORIGIN**

Malaysia

**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

**SPECIAL USE**

Tested for use with chemotherapy drugs and fentanyl. Drugs tested: Cisplatin, Cyclophosphamide, Cytarabine, Cyclophosphamide, Dacarbazine, Doxorubicin Hydrochloride, Etoposide, Fluorouracil, Ifosfamide, Methotrexate, Mitomycin, Mitoxantrone, Paclitaxel, Vincristine Sulfate; fentanyl Citrate Injection.

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**

Halogenation/siliconization and extensive washing in water  
No donning powder used

**COMPONENTS**

Synthetic Rubber Nitrile  
Titanium Oxide  
Zinc Oxide  
Polymeric sterically hindered phenol  
Potassium Hydroxide

**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)

**MARKING**

Packaging marked to designated size (gloves not marked)

**PACKAGING AND LABELING**

Reorder Number SUNB101-SUNB105

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: 2022-01/100100131782

Key: 2022-01..... Production year and month  
 10..... Production year  
 01..... Production month  
 001..... Sequential numbers of the month  
 3..... Size (XS/1, S/2, M/3, L/4, XL/5)  
 1782..... Vender code

**QUALITY CHARACTERISTICS**

All listed standards are used in their latest edition.

DESCRIPTION	SPECIFICATION	ASSURANCE ACTION
<u>Dimensions</u>		<i>ASTM D 6319</i>
<i>Overall length</i>	230 mm min	
<i>Width</i>	75 mm +/- 5 mm (XS) 85 mm +/- 5 mm (S) 95 mm +/- 5 mm (M) 106 mm +/- 5 mm (L) 116 mm +/- 5 mm (XL)	
<i>Thickness (single wall)</i>	<i>Finger:</i> 0.06 mm/2.4 mils min. <i>Palm:</i> 0.05 mm/2.0 mils min.	
<i>Weight (size M)</i>	3.0 g min.	
<u>Physical properties*</u>		<i>ASTM D 412</i>
<i>Tensile strength (before aging)</i>	18 MPa min.	
<i>(after aging)</i>	14 MPa min.	
<i>Elongation (before aging)</i>	500% min.	
<i>(after aging)</i>	400% 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

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)

### **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, 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**