



PRODUCT SPECIFICATION

SemperShield® Nitrile Examination Gloves

PRODUCT

Nitrile examination glove
Medical grade
Non-sterile
Powder-free
Textured

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.

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 (NBR)
Titanium Dioxide
Sulfur
Organic accelerators (carbamate-based)
Zinc Oxide
Paraffin wax

SHAPE

Straight fingers
Thumb and fingers in one plane
Ambidextrous

CUFF

Beaded (rolled rim)

COLOR

Blue

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

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: 2021-01/0207703132602

Key: 2021 Production year
 01 Production month
 02 Factory code
 07 Production month
 7 Production year
 031 Order number
 32 Glove type
 60 Color code
 2 Size 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>	240 mm min	
<i>Width</i>	76 mm +/- 3 mm (XS) 84 mm +/- 3 mm (S) 94 mm +/- 3 mm (M) 105 mm +/- 3 mm (L) 113 mm +/- 3 mm (XL)	
<i>Thickness (single wall)</i>	<i>Finger:</i> 0.15 mm/6.0 mils min. <i>Palm:</i> 0.11 mm/4.4 mils min.	
<i>Weight (size M)</i>	7.0 g min.	
<u>Physical properties*</u>		<i>ASTM D 412</i>
<i>Tensile strength</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 2859-1 "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

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

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