Sempermed®
We are people protection.®

PRODUCT SPECIFICATION
FILE NO: US-NCMC-6F

SemperCare® Tender Touch™ Nitrile PF

PRODUCT
Nitrile examination glove
Inner coating
Medical grade
Non-sterile
Powder-free
Textured fingertips

COUNTRY OF ORIGIN
Thailand

INTENDED USE
Medical activities except surgery where presence of glove powder should be avoided.

SPECIAL USE
Tested for use with chemotherapy drugs. Drugs tested: Amethopterin Hydrate, Cisplatin, Cyclophosphamide, Dacarbazine, Doxorubicin Hydrochloride, Etoposide, 5-Fluorouracil, Paclitaxel, 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
Nitrile latex. This product does not contain Proteins found in Natural Rubber goods.

OUTER SURFACE
Halogenation/siliconization and extensive washing in water
Inside coated with synthetic material
No donning powder used

COMPONENTS
Synthetic rubber nitrile (NBR)
Titanium Oxide
Sulfur
Organic accelerators
Zinc Oxide
Polymeric sterically hindered phenol
Potassium Hydroxide

SHAPE
Straight fingers
Thumb and fingers in one plane
Ambidextrous

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

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
Reorder Number TTNF201-TTNF205
200 pieces per box (180 pieces XL), 2000 pieces per case (1800 pieces XL)

CONTROL NUMBER (LOT NO.)
Each packing unit (dispenser box) and outer carton bears a control number
EXAMPLE: 092009 1234 0098
Key: 092009 …… Production month and year
1234 …… Internal running order number
0098 …… Carton number

QUALITY CHARACTERISTICS*
All listed standards are used in their latest edition

DESCRIPTION	SPECIFICATION	ASSURANCE ACTION
Dimensions		*ASTM D 6319-00a*
Overall length	220 mm min (S) 230 mm min (S, M, L, XL)	
Width	70 mm +/- 10 mm (XS) 80 mm +/- 10 mm (S) 95 mm +/- 10 mm (M) 110 mm +/- 10 mm (L) 120 mm +/- 10 mm (XL)	ASTM D6319
Thickness (single wall)	*Finger:* 0.05 mm/2.0 mils min. *Palm:* 0.05 mm/2.0 mils min.	
Physical properties		*ASTM D 412*
Tensile strength (before/after aging)	14 MPa min.	
Elongation (before aging) *(after aging)*	500% min. 400% min.	*ASTM D 412*

*minimum acceptable requirements of ASTM and FDA where applicable. Gloves offered by Sempermed USA, Inc. meet or exceed these physical requirements. Independent laboratory test results are available upon request.

PERFORMANCE REQUIREMENTS FOR QUALITY CHARACTERISTICS
For reference purpose in accordance with ISO 2859 “Sampling Procedures for Inspection by Attributes”. All standards listed in this specification are applied to medical gloves non-sterile.

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 Nitrlie 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 in C-TPAT (U.S. Customs-Trade Partnership Against Terrorism)

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

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