sempermed®
YOUR GLOBAL GLOVE EXPERT™

PRODUCT SPECIFICATION

SemperForce® Black Nitrile Examination Gloves

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

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 31 chemotherapy drugs, including Cisplatin, Cyclophosphamide, Cytarabine, Dacarbazine, Doxorubicin Hydrochloride, Etoposide, Fluorouracil, Ifosfamide, Methotrexate, Mitomycin C, Paclitaxel, and 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.
Also tested for use with Chloroquine, Cyclosporin A, Fentanyl, Gastric Acid, and Retrovir.

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 Oxide
Sulfur
Organic accelerators (carbamate-based; no Thiurams)
Zinc Oxide
Polymeric sterically hindered phenol
Potassium Hydroxide

SHAPE
Straight fingers
Thumb and fingers in one plane
Ambidextrous

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CUFF
Beaded (rolled rim)

COLOR
Black

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 BKNF102 – BKNF106
100 pieces per box (90 pieces XXL), 1000 pieces per case (900 pieces XXL)

CONTROL NUMBER (LOT NO.)
Each packing unit (dispenser box) and outer carton bears a control number
EXAMPLE: F23S001
Key: F …… Powder-free
23 …… Year of manufacture
S …… Month of manufacture (Dec.)
001 …… Running number

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

DESCRIPTION	SPECIFICATION	ASSURANCE ACTION
Dimensions		
Overall length	240 mm min.	*ASTM D 6319*
Width	85 mm +/- 5 mm (S) 95 mm +/- 5 mm (M) 110 mm +/- 5 mm (L) 105 mm +/- 5 mm (XL) 125 mm +/- 5 mm (XXL)	
Thickness (single wall)	*Finger:* 0.10 mm/4.0 mils min. *Palm:* 0.08 mm/3.2 mils min. Cuff: 0.06 mm/2.4 mils min.	
Weight (size M)	5.0 g min. (M)	
Physical properties*		
Tensile strength (after aging)	18 MPa min.	*ASTM D 412 / ASTM D 5273*
Elongation (after aging)	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 1.0 (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, 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