PRODUCT SPECIFICATION
FILE NO: US-NQMC-6FE

**Patterson Nitrile Exam Gloves with Aloe and Vitamin E**

**PRODUCT**
Nitrile examination glove
Inner coating with aloe and vitamin E
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.

**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 aloe and vitamin E
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

**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 041-2205, 041-2213, 041-2221, 041-2239, 041-2247
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: 022013 1234 0098
Key: 09 2009 ...... Production month and year
  1234 ...... Internal running order number
  0098 ...... Carton number

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

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

*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 Nitrile Examination Gloves for Medical Application”

Patterson Dental, 1031 Mendota Heights Road, Saint Paul, MN 55120
Tel: 800.328.5536   Fax: 651.686.0288
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