PRODUCT SPECIFICATION
FDA 510(k) NO: 071910
Patterson Tactile Guard Nitrile PF

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

MATERIAL
Synthetic Nitrile Rubber (NBR)

OUTER SURFACE
No donning powder used

COMPONENTS
Synthetic Nitrile Rubber (NBR)
Compounding Agents

SHAPE
Straight fingers
Thumb and fingers in one plane
Ambidextrous

CUFF
Beaded (rolled rim)

COLOR
Periwinkle (Lavender 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 088-4478, 088-4486, 088-4494, 088-4502, 088-4510
200 pieces per box, 2000 pieces per case
CONTROL NUMBER (LOT NO.)
Each packing unit (dispenser box) and outer carton bears a control number
EXAMPLE: 0703300044
Key: 07 ...... Production Year
     03 ...... Production Month
     30 ...... Date of Manufacturing
     0044 ...... Batch packed for day

QUALITY CHARACTERISTICS
All listed standards are used in their latest edition. Current test data on physical properties is available upon request.

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>SPECIFICATION</th>
<th>ASSURANCE ACTION</th>
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<tbody>
<tr>
<td>Dimensions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall length</td>
<td>240 mm min</td>
<td>ASTM D 6319-00a</td>
</tr>
<tr>
<td>Width</td>
<td></td>
<td></td>
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<tr>
<td>76 mm +/- 4 mm (XS)</td>
<td>86 mm +/- 4 mm (S)</td>
<td></td>
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<tr>
<td>98 mm +/- 4 mm (M)</td>
<td>107 mm +/- 4 mm (L)</td>
<td></td>
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<tr>
<td>115 mm +/- 4 mm (XL)</td>
<td></td>
<td></td>
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<tr>
<td>Thickness (single wall)</td>
<td>Finger: 0.10 mm/4.0 mils</td>
<td></td>
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<tr>
<td></td>
<td>Palm: 0.08 mm/3.2 mils</td>
<td></td>
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<tr>
<td>Biocompatibility</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inside pH</td>
<td>7.0 +/- 1</td>
<td>Test method A1</td>
</tr>
<tr>
<td>Physical properties</td>
<td></td>
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<tr>
<td>Tensile strength (before aging)</td>
<td>18 MPa min.</td>
<td>ASTM D 412</td>
</tr>
<tr>
<td>(after aging)</td>
<td>16 MPa min.</td>
<td></td>
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<tr>
<td>Elongation (before aging)</td>
<td>500% min.</td>
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</tr>
<tr>
<td>(after aging)</td>
<td>400% min.</td>
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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 ANSI/ASQCZ1.4

FINAL GLOVE RELEASE
Assurance action

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

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 bioburden of the finished gloves are monitored and recorded. Unusual contaminants are identified. Tests are performed by an approved Institute for Microbiological Control

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
Store in a dry, ventilated area
Avoid direct sunlight, fluorescent lighting, storage close to photocopy equipment, heat and moisture
Do not store above 100° F (40° C) as this will lead to accelerated aging
Long-term storage can result in pleats, stickiness and early aging of the gloves
Copper ions discolor the glove

END OF DOCUMENT