PRODUCT SPECIFICATION
FDA 510(k) NO: K970794

Patterson Latex PF

PRODUCT
Latex examination glove
Polymer coating
Medical grade
Non-sterile
Powder-free
Textured surface

COUNTRY OF ORIGIN
Thailand

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
Natural rubber latex
CAUTION: This product contains natural rubber latex which may cause allergic reactions

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

COMPONENTS
Natural rubber latex
Sulfur
Zinc Oxide
Organic accelerators (dithiocarbamates)

SHAPE
Straight fingers
Thumb and fingers in one plane
Ambidextrous

CUFF
Beaded (rolled rim)

COLOR
Natural (white)

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 088-4718, 088-4726, 088-4734, 088-4742, 088-4759
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: 092002 1234 0098
Key: 092002 …… Production month and year
1234 …… Internal running order number
0098 …… Carton number

QUALITY CHARACTERISTICS

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

DESCRIPTION	SPECIFICATION	ASSURANCE ACTION
Dimensions		*ASTM D 3578*
Overall length	220 mm min (XS, S) 230 mm min (M, L, XL)	
Width	75 mm +/- 5 mm (XS) 83 mm +/- 5 mm (S) 93 mm +/- 5 mm (M) 106 mm +/- 5 mm (L) 116 mm +/- 5 mm (XL)	
Thickness (single wall)	*Finger:* 0.08 mm/3.2 mils min. *Palm:* 0.08 mm/3.2 mils min. *Cuff:* 0.08 mm/3.2 mils min.	
Biocompatibility		*ASTM D 5712*
Proteins	50 micrograms or less of total water-extractable proteins per gram	
Inside pH	7.0 +/- 1	*Test method A1*
Physical properties		*ASTM D 412*
Tensile strength (before aging) *(after aging)*	18 MPa min. 14 MPa min.	
Elongation (before aging) *(after aging)*	650% min. 500% min.	

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 3578: "Standard Specification for Rubber Examination Gloves"
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
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
According to ISO 2230 for Vulcanized Rubber
Store in a dry, ventilated area
Avoid direct sunlight, fluorescent lighting, storage close to photocopy equipment, heat and moisture
Do not store above 86° F (30° 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