PRODUCT SPECIFICATION
FDA 510(k) NO: K080520

Patterson Nitrile PF

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

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

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
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)
Color (Titanium oxide)
Vulcanizing agent (Sulfur)
Organic Accelerators (Zu-Dithiocarbamate type, Zn-Mercapto-benzothiazol)
Cure activator (Zinc Oxide)
Antioxidant (Polymeric sterically hindered phenol)
pH Preservative (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 088-4411, 088-4429, 088-4437, 088-4445, 088-4452
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 test data on physical properties is available upon request.

DESCRIPTION	SPECIFICATION	ASSURANCE ACTION
Dimensions		*ASTM D 6319*
Overall length	240 mm min (XS, S, M, L, XL)	
Width	80 mm +/- 5 mm (XS) 86 mm +/- 5 mm (S) 97 mm +/- 5 mm (M) 109 mm +/- 5 mm (L) 118 mm +/- 5 mm (XL)	
Thickness (single wall)	*Finger:* 0.05 mm/2.0 mils min. *Palm:* 0.05 mm/2.0 mils min. *Cuff:* 0.05 mm/2.0 mils min.	
Biocompatibility		
Inside pH	7.0 +/- 1	*Test method A1*
Physical properties		*ASTM D 412 / ASTM D 5273*
Tensile strength	14 MPa min.	
Elongation (before aging) *(after aging)*	500% min. 400% 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 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 1.5 (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