

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.

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

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

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