

**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	230 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) ± 0.02mm	Finger: 0.10 mm/4.0 mils Palm: 0.07 mm/2.8 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**