PRODUCT SPECIFICATION
FDA 510(k) NO: K895642

Patterson Powdered Latex

PRODUCT
Latex examination glove
Medical grade
Non-sterile
Powdered
Smooth (Micro rough)

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
U.S.P Absorbable Dusting Powder or equivalent

Donning powder caution: If conditions warrants, the user may wish to remove residual powder from the gloves prior to use in order to minimize the potential for adverse effects.
Caution: Users should consider the circumstances of use in deciding whether to remove residual powder on gloves after donning. Powder can be removed by wiping gloves thoroughly with a sterile wet sponge, sterile wet towel or other effective methods.

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

SHAPE
Straight fingers
Thumb and fingers in one plane
Ambidextrous

CUFF
Beaded (rolled rim)

COLOR
Natural

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 088-6242, 088-6218, 088-6226, 088-6234, 088-6192
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

DESCRIPTION	SPECIFICATION	ASSURANCE ACTION
Dimensions		*ASTM D 3578*
Overall length	220 mm min (S) 230 mm min (M, L, XL)	
Width	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		
Proteins	≤ 10 mg/dm^2	*ASTM D 5712*
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 (Customs-Trade Protection 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 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