PATTERSON DENTAL

PRODUCT SPECIFICATION

Patterson® TactileGuard Ultra 3G™ Nitrile Examination Gloves

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 rubber nitrile (NBR)
Titanium Dixide
Zinc Oxide
Sulfur
Organic accelerators (carbamates, thiazolates)

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)

Patterson Dental, 1031 Mendota Heights Road, Saint Paul, MN 55120
Tel: 800.328.5536 Fax: 651.686.0288

Revised 9/16

PACKAGING AND LABELING

Reorder Number 088-5714, 088-5723, 088-5731, 088-5749, 088-5756
300 pieces per box (250 pieces XL), 3000 pieces per case (2500 pieces XL)

CONTROL NUMBER (LOT NO.)

Each packing unit (dispenser box) and outer carton bears a control number
EXAMPLE: 130913180115
Key: 13 …… Production Year
09 …… Production Month
13 …… Production Day
180115 …… Batch Number

QUALITY CHARACTERISTICS*

All listed standards are used in their latest edition

DESCRIPTION	SPECIFICATION	ASSURANCE ACTION
Dimensions		*ASTM D 6319-00a*
Overall length	230 mm min (S, M, L, XL)	
	76 mm +/- 10 mm (XS)	
Width	86 mm +/- 10 mm (S)	ASTM D6319
	98 mm +/- 10 mm (M)	
	107 mm +/- 10 mm (L)	
	115 mm +/- 10 mm (XL)	
Thickness (single wall) ± 0.02mm	*Finger:* 0.09 mm/3.6 mils min.	
	Palm: 0.07 mm/2.8 mils min.	
Physical properties		*ASTM D 412*
Tensile strength (before/after aging)	18 MPa min. / 16 MPa min.	
Elongation (before aging)	500% min.	*ASTM D 412*
(after aging)	400% min.	

*minimum acceptable requirements of ASTM and FDA where applicable. Gloves offered by Sempermed USA, Inc. meet or exceed these physical requirements. Independent laboratory test results are available upon request.

PERFORMANCE REQUIREMENTS FOR QUALITY CHARACTERISTICS

For reference purpose in accordance with ISO 2859 “Sampling Procedures for Inspection by Attributes”. All standards listed in this specification are applied to medical gloves non-sterile.

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
Sempermed USA, Inc. is a certified participant in C-TPAT (U.S. Customs-Trade Partnership Against Terrorism)

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 bioburdens of the finished gloves are monitored and recorded. Unusual contaminants are identified.
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, heat, and moisture
Do not store above 100° F (38° C) as this will lead to accelerated aging
Long-term storage can result in pleats and stickiness

END OF DOCUMENT

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