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DELTA® RXN Series Stretch NITREX®

NITREX® Examination Glove

Powder-Free, Non-Sterile, Textured Nitrile

INTENDED USE

Medical activities (except surgery) to reduce contamination between patient and examiner where glove powder and latex proteins should be avoided.

COUNTRY OF ORIGIN

MALAYSIA

MATERIAL

Nitrile

OUTER SURFACE

Free from glove powder

DONNING POWDER

No donning powder is used

COMPONENTS

Nitrile Butadiene Rubber - 95.8%

Sulfur - 1.0%

Zinc Oxide - 1.2%

Accelerators - 1.0%

Others - 1.0%

SHAPE

Ambidextrous, straight fingers, thumb and fingers in one plane. Beaded cuff.

SIZES

X-Small (XS), Small (S), Medium (M), Large (L), X-Large (XL)

COLOR

White

MARKING

Gloves are not marked to designated size. Interior boxes are size specific and marked on top and ends of box.

PACKAGING AND LABELING

100 pieces per box, 1000 pieces per case. As per packaging specifications; FDA Final Rule September 30, 1997 Device Labeling Guidance #G91-1

Reorder Numbers RXN-010 X-Small
 RXN-100 Small
 RXN-110 Medium
 RXN-120 Large
 RXN-130 X-Large

Control Number

Each packing unit (dispenser box) and outer carton bears a Control number, e.g. 098 09 PF 4055

Key: 098 09 Production Year and Month

 PF Internal running order number (LOT)

 4055 Carton Number

QUALITY CHARACTERISTICS

A. Physical Characteristics				
Width	X-Small	75mm	+/-5mm	ASTM D 5250-00
	Small	85mm	+/-5mm	
	Medium	95mm	+/-5mm	
	Large	105mm	+/-5mm	
	X-Large	115mm	+/-5mm	
Length	All sizes	240mm	minimum	
Thickness	Cuff	0.08mm	3.15 mils	
	Palm	0.08mm	3.15 mils	
	Finger	0.10mm	3.94 mils	
B. Physical Properties				
Tensile Strength		25 MPa	minimum	ASTM D 5250-00
Elongation	Before Aging	560%	minimum	
Modulous	At 500% Mpa	15.2	minimum	
C. Performance Requirements				
Water Tight	AQL 1.5			
Dimension	AQL 1.5			
Physical Properties	AQL 1.5			

PERFORMANCE REQUIREMENTS FOR QUALITY CHARACTERISTICS

For reference purpose in accordance with ISO 2859 Sampling Procedures and Tables for Inspection Attributes.

INTERNAL ATTRIBUTIVE RELEASE INSPECTION

Sampling for examination in accordance with ISO 2859 Sampling Procedures and Tables for inspection by Attributes. If several defects are found on one glove, only the most serious defect (i.e. lowest category) is evaluated. The acceptance criteria are based on the number of defectives observed in a sample.

PIN HOLES AND VISUAL DEFECTS

Assurance Action

Sampling Inspection by destructive and visual test procedures.

FINAL GLOVE RELEASE

Sampling Inspection

AQL 1.5 for leaks

AQL 1.5 for leaks and visual defects aggregated.

Inspection Level 1, normal inspection, multiple sampling.

Assurance Action

U.S. FDA "Sample plans and test method for leakage defects: adulteration." (21 CFR Part 800.20) April 1, 1993

ASTM D-5151-99 "Standard test method for detection of holes in medical gloves."

GOOD MANUFACTURING PRACTICE

the gloves are manufactured in compliance with the Current Good Manufacturing Practice (GMP) requirements in the United States of America as appropriate for patient examination gloves.

ISO 9000

Quality System Certified to International Standards Organization 9002 **Model for Quality Assurance in Production, Installation and Servicing.**

Accreditation Number : QSC-4674