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DELTA® MAG Series Black Magic MAGNUM™ NITREX®
NITREX® Examination Glove

Powder-Free, Non-Sterile, Textured Nitrile

INTENDED USE

Medical activities (except surgery) to reduce contamination between patient and examiner and Industrial/General Purpose use 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

100% Acrylonitrile-butadiene (nitrile), a synthetic co-polymer

SHAPE

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

SIZES

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

COLOR

Black

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 for sizes small thru large. 90 pieces per box, 900 pieces per case for sizes x-large & xx-large. As per packaging specifications; FDA Final Rule September 30, 1997
Device Labeling Guidance #G91-1

Reorder Numbers	MAG-100 Small
	MAG-110 Medium
	MAG-120 Large
	MAG-130 X-Large
	MAG-140 XX-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	Small	85mm	+/-5mm
	Medium	95mm	+/-5mm
	Large	105mm	+/-5mm
	X-Large	115mm	+/-5mm
	XX-Large	120mm	+/-5mm
Length	All sizes	245-255mm	minimum
Thickness	Cuff	4.6 mil	
	Palm	4.6 mil	
	Finger	4.6 mil	
B. Physical Properties			
Tensile Strength	Before Aging	18 MPa	minimum
	After Aging	18 MPa	minimum
Elongation	Before Aging	750%	minimum
	After Aging	750%	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

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