DATA SHEET
NITRILE EXAMINATION GLOVES, POWDER FREE, NON-STERILE

Reorder #	Size: :	XS S M L XL	
Product Part #			112xx.112111930
510K # / MDL #			N/A
Design and Feature			Ambidextrous, textured surface at fingers (E1) and beaded cuff
Type			Powder free and non-sterile examination gloves
Material			100% nitrile (Acrylonitrile-butadiene)
Color			Blue (PMS2726)
Surface Treatment			Chlorination on donning side
Powder Free Residue (mg/glove)			≤ 2
Dimension	Size: :	XS S M L XL	Palm Width (mm) ≤80 / Length (mm) Min. 240; 80 ± 10 / Min. 240; 95 ± 10 / Min. 240; 110 ± 10 / Min. 240; ≥110 / Min. 240
Weight	Size: :	XS S M L XL	2.5 ± 0.3; 3.0 ± 0.3; 3.5 ± 0.3; 4.0 ± 0.3; 4.5 ± 0.3
Single-wall Thickness (mm) *All sizes	Finger Palm Cuff		Spec; Min. 0.05; Min. 0.05; Min. 0.05
Physical Properties	Before Aging Tensile Strength (MPa) Elongation (%) Force at Break (N)		EN/ASTM Spec; Min 14; Min 500; Min 6
Physical Properties	After Aging Tensile Strength (MPa) Elongation (%) Force at Break (N)		EN/ASTM Spec; Min 14; Min 400; Min 6
Packing Mode			200 gloves by weight per dispenser and 10 dispensers per carton
Glove Marking			No marking.
Lot # identification on Finished Goods			Lot Number Structure: YMMPPPPSS (9 digits) Y = Year of Packing; MM = Month of Packing; PPPP = WRP's Packing Work Order # (PWO); SS = Size (00=XS, 01=S, 02=M, 03=L and 04=XL)
Recommended Shelf Life			5 years upon manufactured date.
Pre-shipment Inspection *Single-Normal Sampling Plan	Dimension Physical Properties 1000ml Water Leak Powder Free Residue Major Visual Inspection Minor Visual Inspection		N=13, Median; N=13, Median; G-I, AQL 1.5; N=5; G-I, AQL 2.5; G-I, AQL 4.0
Product Conformance			• Medical Device: in compliance with European Medical Device Directive 93/42/EEC (CE Class I) • EN455 Parts 1, 2, 3 and 4 • Personal Protective Equipment of Complex Design Category III, in European Regulation (EU) 2016/425, type tested to EN 420:2003+A1:2009, EN ISO 374-1:2016 Type b, EN 374-2:2014, EN 374-4:2013, EN 374-5:2016 & EN 16523-1:2015, CE 2797 • ASTM D6319
Quality Assurance			• US FDA Quality System Regulation (QSR) • ISO9001 Quality Management Systems • ISO13485 Quality Management Systems

Note: The above information is a guideline of typical performance values and characteristic of the product; and not to be used as actual product specifications.

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