



DATA SHEET

DERMAGRIP[®] Black

Nitrile Examination Gloves, Powder Free, Non-Sterile

Size	Reorder #	Dimension		
		Target weight (g/pcs)	Palm Width (mm)	Length (mm)
Extra Small	D1100-65	3.5 ± 0.3	≤ 80	Min. 240
Small	D1101-65	4.0 ± 0.3	80 ± 10	Min. 240
Medium	D1102-65	4.5 ± 0.3	95 ± 10	Min. 240
Large	D1103-65	5.0 ± 0.3	110 ± 10	Min. 240
Extra Large	D1104-65	5.5 ± 0.3	≥ 110	Min. 240
		<i>*non-release criteria</i>		
Product Part #	112xx.115511924			
510K # / MDL #	K210330 & D468140 (Chemotherapy Drugs and Fentanyl Resistance)			
Design and Feature	Ambidextrous, textured surface at fingertip (E1) and beaded cuff			
Type	Powder free and non-sterile examination gloves			
Material	100% Nitrile (Acrylonitrile-butadiene)			
Colour	Black			
Surface Treatment	Chlorination on donning side			
Powder Residue (mg/glove)	≤ 2			
Single-wall Thickness (mm) <i>*All sizes</i>	Finger Palm Cuff	Specification 0.13 ± 0.03 Min. 0.07 0.07 ± 0.03		
Physical Properties	Tensile Strength (MPa) Ultimate Elongation (%) Stress at 300% (MPa) Force at break (N)	Unaged Min.14 Min. 500 Max. 3 ≥ 6	Aged Min.14 Min. 400 N/A ≥ 6	
Packing Mode	100 gloves by weight and 10 dispenser per carton (Size XS - XL)			
Glove Marking	No marking			
Lot # Identification on Finished Goods	Lot Number Structure : YMMPPPPSS (9 Digits) Y = Year of packing (e.g. 2 for year 2022, 3 for year 2023, etc.) MM = Month of packing (e.g. 09 for Sept., 10 for Oct., etc.) PPPP = WRP's Packing Work Order# (PWO) SS = Size (00=XS, 01=S, 02=M, 03=L, 04=XL and 05=XXL)			
Shelf Life Claim	5 years upon manufacturing date			
Pre-shipment Inspection <i>*Single-Normal Sampling Plan</i>	Dimension Physical Properties 1000ml Water Leak Powder Residue Major Visual Inspection Minor Visual Inspection	N=13, Median; S-2, AQL 4.0 N=13, Median; S-2, AQL 4.0 G-1, AQL 1.5 N=5 G-1, AQL 2.5 G-1, AQL 4.0		
Product Conformance	<ul style="list-style-type: none"> Medical Device in compliance with MDR (EU)2017/745 (CE Class I) EN 420:2003+A1:2009, EN ISO 374-1:2016 + A1:2018 Type B, EN ISO 374:2:2019, EN ISO 374-4:2019, EN ISO 374-5:2016 & EN 16523-1:2015 + A1:2018, CE2797 EN 455 PART 1/2/3/4 ASTM D6319 ASTM D6978 (Chemotherapy & Fentanyl Compliance) Food Safe Compliance (FDA 21 CFR 177.2600) Health Canada Compliance 			
Quality Assurance	<ul style="list-style-type: none"> MDSAP ISO 13485:2016 Quality Management System ISO 9001:2015 Quality Management System EN ISO 13485:2016 			

Note: The above information is a guideline of typical performance values and characteristics of the product.

WRP ASIA PACIFIC SDN. BHD.

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