



DATA SHEET

**DERMAGRIP<sup>®</sup> Classic**

**NR LATEX EXAMINATION GLOVES, POWDER FREE, NON-STERILE**

Size	Reorder #	Dimension		
		Target weight (g/pcs)	Palm Width (mm)	Length (mm)
Extra Small	D1500-10	6.8 ± 0.3	≤ 80	Min. 240
Small	D1501-10	7.1 ± 0.3	80 ± 10	Min. 240
Medium	D1502-10	7.7 ± 0.3	95 ± 10	Min. 240
Large	D1503-10	8.6 ± 0.3	110 ± 10	Min. 240
Extra Large	D1504-10	9.3 ± 0.3	≥ 110	Min. 240
		<i>*non-release criteria</i>		
Product Part No.		155xx.10301031		
510K # / MDL #		K953213 / D036480		
Design and Feature		Ambidextrous, textured overall surface and beaded cuff		
Type		Powder free and non-sterile examination gloves		
Material		Natural rubber latex		
Colour		Natural (i.e. off white to yellow)		
Surface Treatment		Online Chlorination and offline chlorination		
Protein Content		This latex glove contains 50 microgram or less of total extractable protein per gram		
Powder Residue (mg/glove)		≤ 2		
Single-wall Thickness (mm)	Finger	Specification		
	Palm	0.16 ± 0.03		
*All sizes	Cuff	0.14 ± 0.03		
		0.11 ± 0.03		
Physical Properties	Tensile Strength (MPa) Ultimate Elongation (%) Stress at 500% (MPa) Force at Break (N)	Unaged	Aged	
		Min. 18 Min. 650 Max. 5.5 ≥ 6	Min. 14 Min. 500 N/A ≥ 6	
Packing Mode		100 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 (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 (01=S, 02=M, 03=L and 04=XL)		
Shelf Life Claim		3 years upon manufacturing date		
Pre-shipment Inspection	Dimension Physical Properties 1000ml Water Leak Protein Content 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-I, AQL 1.5 N=8 (EN 455); N=3 (ASTM D3578) N=5 G-I, AQL 2.5 G-I, AQL 4.0		
Product Conformance		<ul style="list-style-type: none"> <li>Medical Device: in compliance with MDR (EU)2017/745 (CE Class I)</li> <li>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</li> <li>EN 455 Part 1/2/3/4</li> <li>ASTM D3578</li> <li>Health Canada Compliance</li> </ul>		
Quality Assurance		<ul style="list-style-type: none"> <li>MDSAP ISO 13485:2016 Quality Management System</li> <li>ISO 9001:2015 Quality Management System</li> <li>EN ISO 13485:2016</li> </ul>		

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

WRP ASIA PACIFIC SDN. BHD.  
  
  
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