



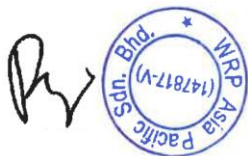
**SPECIFICATION SHEET**

**DERMAGRIP<sup>®</sup> Chemo Protection Gloves**

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

Size	Reorder #	Dimension		
		Target weight (g/pcs)	Palm width (mm)	Length (mm)
Small (6.5)	D3165-18	23.0 ± 3	83 ± 5	Min.290
Medium (7.5)	D3175-18	25.0 ± 3	95 ± 5	Min.290
Large (8.5)	D3185-18	27.0 ± 3	108 ± 6	Min.290
Extra Large (9.0)	D3190-18	29.0 ± 3	114 ± 6	Min.290
		<i>*non-release criteria</i>		
Product Part No.	312xx.10941018			
510K # / MDL #	K083409 / D080612			
Design and Feature	Hand specific, straight fingers, textured surface at the front part of palm and fingers area (SBS) and beaded cuff			
Type	Powder free, extra-thick, hand specific and non-sterile exam gloves			
Material	Natural rubber latex			
Colour	Blue (PMS 307U)			
Surface Treatment	Chlorination (i.e., SBS-HP)			
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) <i>*All sizes</i>	Finger Palm Cuff	<u>Specification</u> 0.48 ± 0.03 0.41 ± 0.03 0.28 ± 0.03		
Physical Properties	Tensile Strength (MPa) Ultimate Elongation (%) Stress at 500% (MPa) Force at Break (N)	<u>Unaged</u> Min. 18 Min. 650 Max. 5.5 ≥ 6	<u>Aged</u> Min. 14 Min. 500 N/A ≥ 6	
Packing Mode	50 left gloves and 50 right gloves per dispenser, 6 dispensers per carton			
Glove Marking	The cuff of each glove is marked with 'Hand & Size'			
Lot # Identification on Finished Goods	Lot Number Structure : YMMPPPPSS (9 Digits) Y = Year of packing (e.g. 3 for year 2023, 4 for year 2024, etc.) MM = Month of packing (e.g. 09 for Sept., 10 for Oct., etc.) PPPP = WRP's Packing Work Order# (PWO) SS = Size (65=6.5, 75=7.5, 85=8.5 and 9.0)			
Shelf Life Claim	3 years upon manufacturing date			
Pre-shipment Inspection  <i>*Single-Normal Sampling Plan</i>	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 1.5 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>Personal Protective Equipment of Complex Design Category III, in compliance with European Regulation (EU) 2016/425, tested to EN ISO 420:2003+A1:2009, EN ISO 374-1:2016 Type B, EN 374-2:2014, EN ISO 374-4:2013, EN ISO 374-5:2016, EN 16523-1:2015, CE2797</li> <li>EN 455 Part 1/2/3/4</li> <li>ASTM D3578, ASTM D6978 (Chemotherapy testing)</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> <li>ISO 14001:2015, Environmental Management System</li> </ul>			

WRP ASIA PACIFIC SDN. BHD.



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