



DATA SHEET

**DERMAGRIP**

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

Size	Reorder #	Dimension		
		Target weight (g/pcs)	Palm width (mm)	Length (mm)
Small	D3165-18	23.0 ± 3	83 ± 5	Min.290
Medium	D3175-18	25.0 ± 3	95 ± 5	Min.290
Large	D3185-18	27.0 ± 3	108 ± 6	Min.290
Extra Large	D3190-18	29.0 ± 3	114 ± 6	Min.290
		<i>*non-release criteria</i>		
Product Part No.		312xx.10941018		
510K # / MDL #		K083408 & D081667		
Design and Feature		Ambidextrous, 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 Free Residue (mg/glove)		≤ 2		
Single-wall Thickness (mm) <i>*All sizes</i>	Finger Palm Cuff	<u>Specification</u> Min. 0.46 Min. 0.39 Min. 0.26		
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	
		50 left gloves and 50 right gloves 6 dispensers per carton		
Packing Mode		The cuff of each glove is marked with 'Hand & Size'		
Glove Marking		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)		
Lot # Identification on Finished Goods		3 years upon manufacturing date		
Shelf Life Claim		N=13, Median; S-2, AQL 4.0 N=13, Median; S-2, AQL 4.0 G-I, AQL 1.5 N=8 N=5 G-I, AQL 2.5 G-I, AQL 4.0		
Pre-shipment Inspection  <i>*Single-Normal Sampling Plan</i>	Dimension Physical Properties 1000ml Water Leak Protein Content Powder Free Residue Major Visual Inspection Minor Visual Inspection	<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, ASTM D6978 (Chemotherapy testing)</li> </ul>		
Product Conformance		<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>		
Quality Assurance				

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

WRP ASIA PACIFIC SDN. BHD.



Name : Rosnaini Binti Rosli  
Title : Product Management Manager