



**DATA SHEET**

**DERMAGRIP®**

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

Reorder #	Small (6½) S-Medium (7) Medium (7½) Large (8½) Extra-large (9)	D3165-19 D3170-19 D3175-19 D3185-19 D3190-19
Product Part #	312xx.10942038	
510K # / MDL #	N/A	
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 sterile exam gloves	
Material	Natural rubber latex	
Color	Blue (PMS307U)	
Surface Treatment	Chlorination (i.e. SBS-HP)	
Powder Free Residue (mg/glove)	Max.2	
Protein Content (µg/g)	<50	
Dimension - Palm Width (mm)	Small (6½) : 83 ± 5 Small-Medium (7) : 89 ± 5 Medium (7½) : 95 ± 5 Large (8½) : 108 ± 6 Extra-large (9) : 114 ± 6	
Dimension - Length (mm)	Small (6½) : min. 290 Small-Medium (7) : min. 290 Medium (7½) : min. 290 Large (8½) : min. 290 Extra-large (9) : min. 290	
Single-wall Thickness (mm)	Finger Palm Cuff	Min 0.46 Min 0.39 Min 0.26
Physical Properties	Tensile Strength (MPa) Elongation (%) Modulus 500% (MPa) Force at Break (N)	<b>Before Aging</b> Min. 18 Min. 650 Min. 5.5 ≥ 6 <b>After Aging</b> Min. 14 Min. 500 Not Applicable ≥ 6
Packing Mode	Inner Wrapper Pouch Dispenser Carton	1 pair of gloves 1 inner wrapper 25 pouches 4 dispensers
Glove Marking	The cuff of each glove is marked with 'Hand & Size'	
Lot # identification on Finished Goods	Lot Number Structure: <b>YMMPPPPSS</b> Y = Year of Packing      P = WRP's PWO MM = Month of Packing      SS = Size	
Product Shelf Life	3 years upon manufactured date.	
Pre-shipment Inspection	Dimension Physical Properties 1000ml Water Leak Protein Content Powder Free Residue Major Visual Inspection Minor Visual Inspection	N=13 N=13 G-I, AQL 1.5 N=8 N=3 (pairs) G-I, AQL 1.5 G-I, AQL 4.0
Product Conformance	<ul style="list-style-type: none"> <li>• Medical Device: in compliance with 93/42/EEC (CE Class I Sterile)</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> <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 13485:2016s</li> </ul>	

*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*