



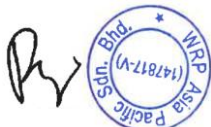
SPECIFICATION SHEET



NR LATEX EXAMINATION GLOVES, POWDER FREE, NON-STERILE

Size	Reorder #	Dimension		
		Target weight (g/pc)	Palm Width (mm)	Length (mm)
Small	D1401-14	14.0 ± 1.5	85 ± 4	290 ± 5
Medium	D1402-14	16.0 ± 1.5	95 ± 4	290 ± 5
Large	D1403-14	17.3 ± 1.5	105 ± 4	290 ± 5
Extra Large	D1404-14	18.3 ± 1.5	115 ± 4	290 ± 5
		<i>*non-release criteria</i>		
Product Part No.	142xx.10401034 / 145xx.10401034			
510K # / MDL #	K962188 / D036482			
Design and Feature	Ambidextrous, finger textured and beaded cuff			
Type	Powder free, thick (14mil), extra-long and non-sterile protection gloves			
Material	Natural rubber latex			
Colour	Blue (PMS 307U)			
Surface Treatment	Chlorination on glove surfaces (HRB)			
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> 0.36 ± 0.04 0.28 ± 0.03 0.20 ± 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 gloves by weight 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. 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 (01=S, 02=M, 03=L and 04=XL)			
Shelf Life Claim	5 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 2.5 G-I, AQL 4.0		
Product Conformance	<ul style="list-style-type: none"> Medical Device: in compliance with MDR (EU)2017/745 (CE Class I) Personal Protective Equipment of Complex Design Category III, in compliance with European Regulation (EU) 2016/425, Regulation 2016/425 on personal protective equipment, as amended to apply in GB, tested to EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018 Type A, 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 D3578, ASTM D6978 (Chemotherapy testing) Food Safe Compliance (EU No. 10/2011) 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 ISO 14001:2015, Environmental Management System 			

WRP ASIA PACIFIC SDN. BHD.



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