SPECIFICATION SHEET

DERMAGRIP® EXTRA

NR LATEX EXAMINATION GLOVES, POWDER FREE, NON-STERILE

Size	Reorder #	Dimension		
		Target weight (g/pcs)	Palm Width (mm)	Length (mm)
X-Small	D1400-04	11.7 ± 1.0	< 80	300 ± 10
Small	D1401-04	12.5 ± 1.0	85 ± 4	300 ± 10
Medium	D1402-04	13.7 ± 1.0	95 ± 4	300 ± 10
Large	D1403-04	15.0 ± 1.5	105 ± 4	300 ± 10
Extra Large	D1404-04	16.0 ± 1.5	115 ± 4	300 ± 10
		***non-release criteria**		

Product Part No.		145xx.100411771	
510K # / MDL #		K083410 / D479985	
Design and Feature		Ambidextrous, finger textured and beaded cuff	
Type		Powder free, extra thick (12mil), extra-long and non-sterile protection gloves	
Material		Natural rubber latex	
Colour		Natural (off white to yellow)	
Surface Treatment		Chlorination on glove surfaces (UO)	
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) **All sizes*	Finger Palm Cuff	Specification 0.30 ± 0.04 0.25 ± 0.03 0.17 ± 0.02	
Physical Properties	Tensile Strength (MPa) Ultimate Elongation (%) Force at Break (N)	Unaged Min. 21 Min. 750 ≥ 6	Aged Min. 18 Min. 600 ≥ 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 (00=XS, 01=S, 02=M, 03=L and 04=XL)	
Shelf Life Claim		3 years upon manufacturing date	
Pre-shipment Inspection **Single-Normal Sampling Plan*	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		• 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 B, 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 • Health Canada Compliance	
Quality Assurance		• 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.

Name : Rosnaini Binti Rashidin
Title : Product Management Manager

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