SPECIFICATION SHEET

DERMAGRIP® *Ultra*

NR LATEX EXAMINATION GLOVES, POWDER FREE, NON-STERILE

Size	Reorder #	Dimension		
		Target weight (g/pcs)	Palm Width (mm)	Length (mm)
Extra Small	D1000-20	5.3 ± 0.3	≤ 80	Min. 240
Small	D1001-20	6.0 ± 0.3	80 ± 10	Min. 240
Medium	D1002-20	6.5 ± 0.3	95 ± 10	Min. 240
Large	D1003-20	6.7 ± 0.3	110 ± 10	Min. 240
Extra Large	D1004-20	7.2 ± 0.3	≥ 110	Min. 240
		***non-release criteria**		

Product Part No.		116xx.10021033
510K # / MDL #		K211601 / D479985
Design and Feature		Ambidextrous, textured finger-tip surface and beaded cuff
Type		Powder free and non-sterile examination gloves
Material		Natural rubber latex
Colour		Natural (i.e., off white to yellow)
Surface Treatment		Strip & Pack
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	Specification	
	Finger	0.14 ± 0.03
	Palm	0.12 ± 0.03
	Cuff	0.10 ± 0.02

Physical Properties		Unaged	Aged
	Tensile Strength (MPa)	Min. 18	Min. 14
	Ultimate Elongation (%)	Min. 650	Min. 500
	Stress at 500% (MPa)	Max. 5.5	N/A
	Force at Break (N)	≥ 6	≥ 6

Packing Mode		100 gloves by weight per dispenser 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	N=13, Median; S-2, AQL 4.0
	Physical Properties	N=13, Median; S-2, AQL 4.0
	1000ml Water Leak	G-I, AQL 1.5
	Protein Content	N=8
	Powder Residue	N=5
	Major Visual Inspection	G-I, AQL 2.5
	Minor Visual Inspection	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

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