SPECIFICATION SHEET

DERMAGRIP *Ultra LS*

Nitrile Examination Gloves, Powder Free, Non-Sterile

Size	Reorder #	Dimension		
		Target weight (g/pcs)	Palm Width (mm)	Length (mm)
Extra Small	D1100-25	2.5 ± 0.3	≤ 80	Min. 240
Small	D1101-25	3.0 ± 0.3	80 ± 10	Min. 240
Medium	D1102-25	3.5 ± 0.3	95 ± 10	Min. 240
Large	D1103-25	4.0 ± 0.3	110 ± 10	Min. 240
Extra Large	D1104-25	4.5 ± 0.3	≥ 110	Min. 240
		***non-release criteria**		

Product Part #		112xx.110111068	
510K # / MDL #		K161422 & D278303 (with chemo claim)	
Design and Feature		Ambidextrous, textured surface at fingertip and beaded cuff	
Type		Powder free and non-sterile examination gloves	
Material		100% Nitrile (Acrylonitrile-butadiene)	
Colour		Blue	
Surface Treatment		Chlorination on donning side	
Powder Residue (mg/glove)		≤ 2	
Single-wall Thickness (mm) *All sizes*	Finger	Specification Min. 0.05	
	Palm	Min. 0.05	
	Cuff	Min. 0.05	
Physical Properties	Tensile Strength (MPa)	Unaged Min.14	Aged Min.14
	Ultimate Elongation (%)	Min. 500	Min. 400
	Stress at 300% (MPa)	Max. 3	N/A
	Force at break (N)	≥ 6	≥ 6
Packing Mode		100 gloves by weight and 10 dispenser 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, 04=XL and 05=XXL)	
Shelf Life Claim		5 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	
	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 D6319, ASTM D6978 (Chemotherapy testing) • Food Safe Compliance (FDA 21 CFR 177.2600 & EU No. 10/2011) • 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.

WRP Asia Pacific Sdn. Bhd. (147817-V)

Name : Rosnaini Binti Rashidin
Title : Product Management Manager

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DERMAGRIP® *Ultra LS*

Nitrile Examination Gloves, Powder Free, Non-Sterile

Size	Reorder #	Dimension		
		Target weight (g/pcs)	Palm Width (mm)	Length (mm)
Extra Small	D1100-24	2.5 ± 0.3	≤ 80	Min. 240
Small	D1101-24	3.0 ± 0.3	80 ± 10	Min. 240
Medium	D1102-24	3.5 ± 0.3	95 ± 10	Min. 240
Large	D1103-24	4.0 ± 0.3	110 ± 10	Min. 240
Extra Large	D1104-24	4.5 ± 0.3	≥ 110	Min. 240
		***non-release criteria**		

Product Part #		112xx.11011799
510K # / MDL #		K161422 & D278303 (with chemo claim)
Design and Feature		Ambidextrous, textured surface at fingertip and beaded cuff
Type		Powder free and non-sterile examination gloves
Material		100% Nitrile (Acrylonitrile-butadiene)
Colour		Blue
Surface Treatment		Chlorination on donning side
Powder Residue (mg/glove)		≤ 2
Single-wall Thickness (mm) *All sizes*	Specification	
	Finger	Min. 0.05
	Palm	Min. 0.05
	Cuff	Min. 0.05
Physical Properties		Unaged / Aged
	Tensile Strength (MPa)	Min.14 / Min.14
	Ultimate Elongation (%)	Min. 500 / Min. 400
	Stress at 300% (MPa)	Max. 3 / N/A
	Force at break (N)	≥ 6 / ≥ 6
Packing Mode		200 gloves by weight and 10 dispenser per carton (Size XS - L) 180 gloves by weight and 10 dispenser per carton (Size XL)
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, 04=XL and 05=XXL)
Shelf Life Claim		5 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
	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 D6319, ASTM D6978 (Chemotherapy testing) • Food Safe Compliance (FDA 21 CFR 177.2600 & EU No. 10/2011) • 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.

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