



DATA SHEET



DERMAGRIP[®] Ultra LT

Nitrile Examination Gloves, Powder Free, Non-Sterile

Size	Reorder #	Dimension		
		Target weight (g per pcs)	Palm Width (mm)	Length (mm)
Extra Small	D1100-23	2.7 ± 0.3	≤ 80	Min. 240
Small	D1101-23	3.2 ± 0.3	80 ± 10	Min. 240
Medium	D1102-23	3.7 ± 0.3	95 ± 10	Min. 240
Large	D1103-23	4.2 ± 0.3	110 ± 10	Min. 240
Extra Large	D1104-23	4.7 ± 0.3	≥ 110	Min. 240
		<i>*non-release criteria</i>		
Product Part #		112xx.112111009		
510K # / MDL #		K161422 & D278303 (with chemo claim)		
Design and Feature		Ambidextrous, textured surface at fingertip (E1) 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		<u>Specification</u>		
Thickness (mm)	Finger	Min. 0.07		
	Palm	Min. 0.06		
<i>*All sizes</i>	Cuff	Min. 0.05		
Physical Properties	Tensile Strength (MPa)	<u>Unaged</u>	<u>Aged</u>	
	Ultimate Elongation (%)	Min.14	Min.14	
	Stress at 300% (MPa)	Min. 500	Min. 400	
	Force at break (N)	Max. 3	N/A	
		≥ 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. 2 for year 2022, 3 for year 2023, 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	Dimension	N=13, Median; S-2, AQL 4.0		
	Physical Properties	N=13, Median; S-2, AQL 4.0		
<i>*Single-Normal Sampling Plan</i>	1000ml Water Leak	G-1, AQL 1.5		
	Powder Residue	N=5		
	Major Visual Inspection	G-1, AQL 2.5		
	Minor Visual Inspection	G-1, AQL 4.0		
Product Conformance		<ul style="list-style-type: none"> Medical Device: in compliance with MDR (EU)2017/745 (CE Class I) 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 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		<ul style="list-style-type: none"> MDSAP – ISO 13485:2016 Quality Management Systems ISO9001:2015 Quality Management Systems EN ISO 13485:2016 		

Note: The above information is a guideline of typical performance values and characteristic of the product.

WRP ASIA PACIFIC SDN. BHD.

Name : Rosnaini Binti Rashidin
 Title : Product Manager



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DERMAGRIP[®] Ultra LT
Nitrile Examination Gloves, Powder Free, Non-Sterile

Size	Reorder #	Dimension		
		Target weight (g per pcs)	Palm Width (mm)	Length (mm)
Extra Small	D1500-20	2.7 ± 0.3	≤ 80	Min. 240
Small	D1501-20	3.2 ± 0.3	80 ± 10	Min. 240
Medium	D1502-20	3.7 ± 0.3	95 ± 10	Min. 240
Large	D1503-20	4.2 ± 0.3	110 ± 10	Min. 240
Extra Large	D1504-20	4.7 ± 0.3	≥ 110	Min. 240
		<i>*non-release criteria</i>		
Product Part #		112xx.11211743		
510K # / MDL #		K161422 & D278303 (with chemo claim)		
Design and Feature		Ambidextrous, textured surface at fingertip (E1) 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) <i>*All sizes</i>	Finger Palm Cuff	Specification Min. 0.07 Min. 0.06 Min. 0.05		
Physical Properties	Tensile Strength (MPa) Ultimate Elongation (%) Stress at 300% (MPa) Force at break (N)	Unaged Min. 14 Min. 500 Max. 3 ≥ 6	Aged Min. 14 Min. 400 N/A ≥ 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. 2 for year 2022, 3 for year 2023, 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 <i>*Single-Normal Sampling Plan</i>	Dimension Physical Properties 1000ml Water Leak 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-1, AQL 1.5 N=5 G-1, AQL 2.5 G-1, AQL 4.0		
Product Conformance		<ul style="list-style-type: none"> Medical Device: in compliance with MDR (EU)2017/745 (CE Class I) 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 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		<ul style="list-style-type: none"> MDSAP – ISO 13485:2016 Quality Management Systems ISO9001:2015 Quality Management Systems EN ISO 13485:2016 		

Note: The above information is a guideline of typical performance values and characteristic of the product.

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Name : Rosnaini Binti Rashid
 Title : Product Management

