



SPECIFICATION SHEET

Product Name		Dermagrip Ultra Nitrile Long Powder Free Exam Gloves		
Reorder Number		D14xx-26		
Product Part Number		142xx.111911046		
Product Description				
Design and Feature		Ambidextrous, textured surface at finger and beaded cuff		
Type		Powder free and non-sterile examination glove		
Material		Nitrile		
Colour		Blue (PMS 285)		
Surface Treatment		Chlorination on donning side		
Product Quality Requirement				
Dimension	Size	Target weight (g/pc)	Palm Width (mm)	Length (mm)
	XS	5.5 ± 0.3	≤ 80	Min. 290
	S	6.0 ± 0.3	80 ± 10	Min. 290
	M	6.5 ± 0.3	95 ± 10	Min. 290
	L	7.0 ± 0.3	110 ± 10	Min. 290
	XL	7.5 ± 0.3	≥ 110	Min. 290
	XXL	8.0 ± 0.3	≥ 120	Min. 290
		*Non-release criteria		
Single-wall Thickness (mm) *All sizes		Finger	0.16 ± 0.02	
		Palm	0.09 ± 0.02	
		Cuff	0.08 ± 0.02	
Powder Residue (mg/glove)		≤ 2		
Physical Properties	Standard	Parameters	Before Aging	After Aging
	EN 455 Part 2	Force at break (N)	≥ 6	≥ 6
	ASTM D6319	Tensile Strength (MPa)	Min. 14	Min. 14
		Ultimate Elongation (%)	Min. 500	Min. 400
Shelf life (upon manufacturing date)		5 years		
Glove Cuff Printing		No marking		
Packing configuration		100 gloves by weight and 10 dispensers per carton		
Pre - shipment Inspection *Single-Normal Sampling Plan	Standard/Parameters		EN 455 Part 1,2,3	ASTM D6319
	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	G-I, AQL 1.5
	Powder Residue		N=5	N=5
	Visual Inspection (Major Defects)		G-I, AQL 2.5	G-I, AQL 2.5
	Visual Inspection (Minor Defects)		G-I, AQL 4.0	G-I, AQL 4.0
Product Conformance				
Medical Device		EU Compliance: MDR (EU) 2017/745 (CE Class I)		EN 455 Part 1,2,3,4
		UK Compliance: UK Medical Device Regulations 2002 Part II (UKCA Class I)		
		US Compliance		ASTM D6319
Personal Protective Equipment		EU Compliance: PPE Regulation EU 2016/425 (PPE Cat.III)		EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018 Type B, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016 & ISO 16604:2004
		UK Compliance: Regulation 2016/425 on personal protective equipment, as amended to apply in GB		
US FDA		510K: K161422 MDL: D278303		
Glove Marking		Medical Device: CE Class I PPE: CE 2797 & UKCA 0086		
Food Contact		EU ResAP (2004) 4		
Others		ASTM D6978 – Tested for use with Chemotherapy Drugs Health Canada Compliance		
Quality Assurance & Environment Management System				
• MDSAP ISO 13485:2016 Quality Management System • ISO 9001:2015 Quality Management System • EN ISO 13485:2016 Quality Management System – Regulatory Purpose • ISO 14001:2015 Environmental Management System				

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