SPECIFICATION SHEET

Product Name			Dermagrip Ultra LS Nitrile Powder Free Exam Glove		
Reorder Number			D11xx-25		
Product Part Number			142xx.110111068		
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		
Surface Treatment			Chlorination on donning side		
Product Quality Requirement					
Dimension	Size	Target weight (g/pc)	Palm Width (mm)	Length (mm)	
	XS	2.5 ± 0.3	≤ 80	Min. 240	
	S	3.0 ± 0.3	80 ± 10	Min. 240	
	M	3.5 ± 0.3	95 ± 10	Min. 240	
	L	4.0 ± 0.3	110 ± 10	Min. 240	
	XL	4.5 ± 0.3	≥ 110	Min. 240	
		**Non-release criteria*			
Single-wall Thickness (mm) **All sizes*	Finger	Min. 0.05			
	Palm	Min. 0.05			
	Cuff	Min. 0.05			
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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