

**SPECIFICATION SHEET**

Product Name		Dermagrip Classic Powder Free Latex Exam Gloves		
Product Part Number		142xx.10471031		
Reorder Number		D15xx-10		
<b>Product Description</b>				
Design and Feature		Ambidextrous, fingers textured surface and beaded cuff		
Type		Powder free, non-sterile examination gloves		
Material		Natural rubber latex		
Colour		Natural		
Surface Treatment		Chlorination (1L-SM)		
<b>Product Quality Requirement</b>				
Dimension	Size	Target Weight (g/pc)	Palm Width (mm)	Length (mm)
	XS	7.0 ± 0.5	≤ 80	Min. 240
	S	7.7 ± 0.5	80 ± 10	Min. 240
	M	8.2 ± 0.5	95 ± 10	Min. 240
	L	9.2 ± 0.5	110 ± 10	Min. 240
	XL	9.9 ± 0.5	≥ 110	Min. 240
<i>*Non-release criteria</i>				
Single-wall Thickness (mm) <i>*All sizes</i>	Finger	0.21 (-0.04/+0.05)		
	Palm	0.16 (-0.02/+0.03)		
	Cuff	0.13 (-0.02/+0.03)		
Powder Residue (mg/glove)		≤ 2		
Protein Content (µg/dm <sup>2</sup> )		≤ 50		
Physical Properties	Standard	Parameters	Before Aging	After Aging
	EN 455 Part 2	Force at break (N)	≥ 6	≥ 6
	ASTM D3578	Tensile Strength (MPa)	Min. 18	Min. 14
		Ultimate Elongation (%) Stress at 500% (MPa)	Min. 650 Max. 5.5	Min. 500 N/A
Shelf Life (upon manufacturing date)		3 years		
Glove Cuff Printing		No marking		
Packing Configuration		100 gloves by weight and 10 dispenser per carton		
Pre-shipment Inspection <i>*Single-Normal Sampling Plan</i>	Standard/Parameters	EN 455 Part 1, 2, 3	ASTM D3578	
	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	
	Protein Content	N=8	N=3	
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		
<b>Product Conformance</b>				
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 FDA: 510(k): K953213 MDL: K036480		ASTM D3578	
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			
Glove Marking	Medical Device: CE Class I PPE: CE 2797 & UKCA 0086			
Others	Health Canada Compliance			
<b>Quality Assurance &amp; Environment Management System</b>				
<ul style="list-style-type: none"> <li>• MDSAP ISO 13485:2016 Quality Management System</li> <li>• ISO 9001:2015 Quality Management System</li> <li>• EN ISO 13485:2016 Quality Management System – Regulatory Purpose</li> <li>• ISO 14001:2015 Environmental Management System</li> </ul>				

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