SPECIFICATION SHEET

Product Name		Profeel Double Gloving Powder Free Latex Surgical Gloves		
Reorder Number		P33xx-61		
Product Part Number		402xx.110921021		
Product Description				
Design and Feature		Hand specific, micro roughened surface, and beaded cuff One pouch contains one pair of overgloves as per size printed on the packaging and one pair of undergloves half a size larger		
Type		Powder free, polymer coated, Damp-Hand-Donnable (DHD™) and Gamma-sterilized surgical gloves		
Material		Natural Rubber Latex		
Colour		Overglove : Natural Underglove : Dark Green (PMS 3275)		
Surface Treatment		Polymer coating on inner surface to ease donning		
Product Quality Requirement				
Dimension	Size	Palm Width (mm)	Length (mm)	
	5.5	72 ± 4	Min. 278	
	6.0	77 ± 5	Min. 280	
	6.5	83 ± 5	Min. 280	
	7.0	89 ± 5	Min. 283	
	7.5	95 ± 5	Min. 287	
	8.0	102 ± 6	Min. 288	
	8.5	108 ± 6	Min. 290	
	9.0	114 ± 6	Min. 290	
Single-wall Thickness (mm) **All sizes*		Overglove	Underglove	
	Finger	0.21 ± 0.03	0.20 ± 0.03	
	Palm	0.19 ± 0.03	0.18 ± 0.03	
	Cuff	0.15 ± 0.03	0.16 ± 0.03	
Powder Residue (mg/glove)		≤ 2		
Protein Content (µg/dm²)		≤ 50		
Physical Properties	Standard	Parameters	Before Aging	After Aging
	EN 455	Force at break (N)	≥ 9	≥ 9
	ASTM	Tensile Strength (MPa)	Min. 24	Min. 18
		Ultimate Elongation (%)	Min. 750	Min. 560
		Stress at 500% (MPa)	Max. 5.5	N/A
Shelf life (upon manufacturing date)		3 years		
Glove Cuff Printing		The cuff of each glove is marked with 'PROFEEL', Hand and Size.		
Packing configuration		1 pair of gloves per inner wrapper (Overglove), 1 pair of gloves per inner wrapper (Underglove), 2 inner wrapper per pouch, 25 pouches per dispenser, 4 dispensers per carton (Long Pack)		
Pre - shipment Inspection **Single-Normal Sampling Plan*	Standard/Parameters	EN 455	ASTM	
	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 0.65	G-I, AQL 0.65	
	Powder Residue	N=6	N=5	
	Protein Content	N=8	N=3	
	Visual Inspection (Major Defects)	G-I, AQL 1.5	G-I, AQL 1.5	
	Visual Inspection (Minor Defects)	G-I, AQL 2.5	G-I, AQL 2.5	
Product Conformance				
Medical Device		EU Compliance: MDR (EU) 2017/745 (CE Class IIa)	EN 455 Part 1,2,3,4	
		US Compliance	ASTM D3577	
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 2797 PPE: CE 2797 & UKCA 0086		
Others		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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Name : Rosnaini Binti Rashidin
Title : Product Management Manager