SPECIFICATION SHEET

Product Name			Profeel Double Gloving Powder Free Non-Latex Surgical Gloves	
Reorder Number			P33xx-62	
Product Part Number			402xx.104121025	
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			Polyisoprene (Not Made with 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	0.22 ± 0.03	0.20 ± 0.02
		Palm	0.18 ± 0.03	Min. 0.15
		Cuff	0.14 ± 0.03	Min. 0.13
Powder Residue (mg/glove)			≤ 2	
Physical Properties	Standard	Parameters	Before Aging	After Aging
	EN 455 Part 2	Force at break (N)	≥ 9	≥ 9
	ASTM D3577	Tensile Strength (MPa)	Min. 17	Min. 12
		Ultimate Elongation (%)	Min. 650	Min. 490
		Stress at 500% (MPa)	Max. 7.0	N/A
Shelf life (upon manufacturing date)			5 years	
Glove Cuff Printing			The cuff of each glove is marked with 'PROFEEL NON-LATEX', Hand and Size.	
Packing configuration			1 pair of gloves per inner wrapper (Overglove), 1 pair of gloves per inner wrapper (Underglove), 2 inner wrappers per pouch, 25 pouches per dispenser, 4 dispensers per carton (Long Pack)	
Pre - shipment Inspection **Single-Normal Sampling Plan*	Standard/Parameters		EN 455 Part 1,2,3	ASTM D3577
	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
	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
			UK Compliance: UK Medical Device Regulations 2002 Part II (UKCA Class IIa)	
			US FDA	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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WRP Asia Pacific Sdn. Bhd. (147817-V) Selangor

Name : Rosnaini Binti Rashidin
Title : Product Management Manager