

SPECIFICATION SHEET

Product Name		Profeel DHD Sensitive Powder Free Latex Surgical Gloves	
Reorder Number		P33xx-55	
Product Part Number		402xx.110822047	
Product Description			
Design and Feature		Hand specific, micro roughened surface, and beaded cuff	
Type		Powder free, polymer coated, Damp-Hand-Donnable (DHD™) and Gamma-sterilized surgical gloves	
Material		Natural Rubber Latex	
Colour		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	Finger	0.20 ± 0.03	
	Palm	0.18 ± 0.03	
	Cuff	0.16 ± 0.03	
Powder Residue (mg/glove)		≤ 2	
Protein Content (µg/dm ²)		≤ 50	
Physical Properties	Standard	Parameters	Before Aging
	EN 455	Force at break (N)	≥ 9
	ASTM	Tensile Strength (MPa)	Min. 24
		Ultimate Elongation (%)	Min. 750
Stress at 500% (MPa)		Max. 5.5	After Aging
			≥ 9
			Min. 18
			Min. 560
			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, 1 inner wrapper per pouch, 50 pouches per dispenser, 4 dispensers per carton (Short 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		
US FDA	510K: K022442 MDL: D036514		
Glove Marking	Medical Device: CE 2797 PPE: CE 2797 & UKCA 0086		
Others	Health Canada Compliance		
Quality Assurance & Environment Management System			
<ul style="list-style-type: none"> 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 			

WRP ASIA PACIFIC SDN BHD.



Name : Rosnaini Binti Rashidi
Title : Product Management Manager