

SPECIFICATION SHEET

Product Name	Profeel DHD Extra Protection Powder Free Latex Surgical Gloves			
Reorder Number	P33xx-35			
Product Part Number	362xx.108021060			
Product Description				
Design and Feature	Hand specific, micro roughened surface, and beaded cuff			
Type	Extra thick, powder free, polymer coated, Damp-Hand-Donnable (DHD™) and Gamma-sterilized surgical gloves			
Material	Natural Rubber Latex			
Colour	Brown			
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)	Finger	0.34 ± 0.03		
	Palm	0.29 ± 0.03		
	Cuff	0.21 ± 0.03		
*All sizes				
Powder Residue (mg/glove)	≤ 2			
Protein Content (µg/dm ²)	≤ 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, 1 inner wrapper per pouch, 40 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			
US FDA	510K: K021784 MDL: D036513			
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.




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