

SPECIFICATION SHEET

Product Name		Profeel DHD Polyisoprene Powder Free Surgical Gloves	
Reorder Number		P33xx-56	
Product Part Number		402xx.111122041	
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		Polyisoprene (Not made with Natural Rubber Latex)	
Colour		Cream	
Surface Treatment		Polymer coating (DHD-PI)	
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
Single-wall Thickness (mm) *All sizes	Finger	0.22 ± 0.03	
	Palm	0.18 ± 0.03	
	Cuff	0.14 ± 0.03	
Powder Residue (mg/glove)		≤ 2	
Physical Properties	Standard	Parameters	Before Aging
	EN 455 Part 2	Force at break (N)	≥ 9
	ASTM D3577	Tensile Strength (MPa)	Min. 17
		Ultimate Elongation (%)	Min. 650
		Stress at 500% (MPa)	Max. 7.0
Shelf life (upon manufacturing date)		5 years	
Glove Cuff Printing		The cuff of each glove is marked with 'PROFEEL NON-LATEX', Hand & 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 Part 1,2,3
	Dimension		N=13, Median
	Physical Properties		N=13, Median
	1000ml Water Leak		G-I, AQL 0.65
	Powder Residue		N=6
	Visual Inspection (Major Defects)		G-I, AQL 1.5
Visual Inspection (Minor Defects)		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: 510(k): K222058 MDL: D483139		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	
Other		ASTM D6978 – Tested for use with Chemotherapy Drugs & Fentanyl 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			

WRP ASIA PACIFIC SDN. BHD.



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