SPECIFICATION SHEET

PROFEEL DHD Synthetic Powder Free

NON-LATEX POWDER FREE SURGICAL GLOVES, STERILE

Size	Reorder#	Dimension		
		Target weight (g/pcs)	Palm Width (mm)	Length (mm)
5.5	P3255-24	12.8 ± 0.5	72 ± 4	Min. 278
6.0	P3260-24	13.0 ± 0.5	77 ± 5	Min. 280
6.5	P3265-24	14.8 ± 0.5	83 ± 5	Min. 280
7.0	P3270-24	15.8 ± 0.5	89 ± 5	Min. 283
7.5	P3275-24	16.0 ± 0.5	95 ± 5	Min. 287
8.0	P3280-24	17.5 ± 0.5	102 ± 6	Min. 288
8.5	P3285-24	18.5 ± 0.5	108 ± 6	Min. 290
9.0	P3290-24	19.5 ± 0.5	114 ± 6	Min. 290
		*non-release criteria		

Product Part #		362xx.103922042
510K & MDL #		K003019 & D036530
Design and Feature		Hand specific, curved fingers, micro roughened surface and beaded cuff
Type		Powder free, polymer coated, damp-hand-donnable (DHD™) and Gamma-sterilized surgical gloves
Material		Polychloroprene (latex-free)
Colour		Brown
Surface Treatment		Polymer coating on inner surface to ease donning (1L-DHD)
Powder Residue (mg/glove)		≤ 2
Single-wall Thickness (mm) *All sizes*		Specification
	Finger	0.20 ± 0.03
	Palm	Min. 0.15
	Cuff	Min. 0.13

Physical Properties		Unaged	Aged
	Tensile Strength (MPa)	Min. 17	Min. 12
	Ultimate Elongation (%)	Min. 650	Min. 490
	Stress at 500% (MPa)	Max. 7.0	N/A
	Force at break (N)	≥ 9	≥ 9

Packing Mode	Inner Wallet	1 Pair Gloves
	Pouch	1 Inner Wallet
	Dispenser	50 Pouches
	Carton	4 Dispensers
Glove Marking		The cuff of each glove is marked with 'WRP', 'Hand & Size'
Lot # Identification on Finished Goods		Lot Number Structure : YMMPPPPSS (9 Digits) Y = Year of packing (e.g. 3 for year 2023, 4 for year 2024, etc.) MM = Month of packing (e.g. 09 for Sept., 10 for Oct., etc.) PPPP = WRP's Packing Work Order# (PWO) SS = Size (55=5.5, 60=6.0, 65=6.5, 70=7.0, 75=7.5, 80=8.0, 85=8.5 and 90=9.0)
Recommended Shelf Life		5 years upon manufacturing date
Pre-shipment Inspection	Dimension	N=13 the Median; S-2, AQL 4.0
	Physical Properties	N=13 the Median; S-2, AQL 4.0
	1000ml Water Leak	G-I, AQL 0.65
	Powder Residue	N=6
	Major Visual Inspection	G-1, AQL 1.5
	Minor Visual Inspection	G-1, AQL 2.5
Product Conformance		• Medical Device: in compliance with 93/42/EEC, CE Class IIa • Personal Protective Equipment of Complex Design Category III, in compliance with European Regulation (EU) 2016/425, tested to EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018 Type A, EN ISO 374-2:2019, EN ISO 374-4:2019, EN ISO 374-5:2016, EN 16523-1:2015+A1:2018, CE2797 • EN455 Parts 1, 2, 3 and 4 • ASTM D3577 • ASTM D6978 (Chemotherapy testing) • Health Canada Compliance
Quality Assurance		• MDSAP ISO 13485:2016 Quality Management System • ISO 9001:2015 Quality Management System • EN ISO 13485:2016 • ISO 14001:2015, Environmental Management System

WRP ASIA PACIFIC SDN. BHD.

WRP Asia Pacific Sdn (1147817-V)

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