SPECIFICATION SHEET

Product Name			Profeel DHD Platinum Plus Powder Free Latex Surgical Gloves	
Reorder Number			P40xx-02	
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			Natural	
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	0.21 ± 0.03	
		Palm	0.19 ± 0.03	
		Cuff	0.16 ± 0.02	
Powder Residue (mg/glove)			≤ 2	
Protein Content (µg/dm²)			≤ 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, 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
US FDA			510K: K232079 MDL: D532669	
Glove Marking			Medical Device: CE 2797 PPE: CE 2797	
Others			ASTM D6978 – Tested for Use with Chemotherapy Drugs and Fentanyl	
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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