

**SPECIFICATION SHEET**

Product Name		Comfit Powder Free Latex Surgical Gloves		
Reorder Number		C40xx-93		
Product Part Number		402xx.111222046		
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	
Single-wall Thickness (mm) *All sizes	Finger	0.18 ± 0.03		
	Palm	0.16 ± 0.03		
	Cuff	0.14 ± 0.03		
Powder Residue (mg/glove)		≤ 2		
Protein Content (µg/dm²)		≤ 50		
Physical Properties	Standard	Parameters	Before Aging	After Aging
	EN 455 Part 2	Force at break (N)	≥ 9	≥ 9
	ASTM D3577	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		No marking		
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	ASTM D3577
	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	
	UK Compliance: UK Medical Device Regulations 2002 Part II (UKCA Class IIa)			
	US FDA: 510(k): K232079 MDL: D532669		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		
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				

WRP ASIA PACIFIC SDN. BHD.



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