



SPECIFICATION SHEET



Product Name		Comfit Premium Powder Free Latex Surgical Gloves Sterile		
Product Part Number		362xx.110122035		
Reorder Number		C36xx-96		
Product Description				
Design and Feature		Hand specific, curved fingers, micro roughened surface and beaded cuff		
Type		Powder free, polymer coated and Gamma-sterilized surgical gloves		
Material		Natural Rubber Latex		
Colour		Natural		
Surface Treatment		Polymer coated on inner surface to ease donning		
Product Quality Requirement				
Dimension	Size	Target Weight (g/pc)	Palm Width (mm)	Length (mm)
	5.5	9.6 ± 0.5	72 ± 4	Min. 278
	6.0	10.2 ± 0.5	77 ± 5	Min. 280
	6.5	10.8 ± 0.5	83 ± 5	Min. 280
	7.0	11.4 ± 0.5	89 ± 5	Min. 283
	7.5	12.0 ± 0.5	95 ± 5	Min. 287
	8.0	12.6 ± 0.5	102 ± 6	Min. 288
	8.5	13.2 ± 0.5	108 ± 6	Min. 290
	9.0	13.8 ± 0.5	114 ± 6	Min. 290
<i>*non-release criteria</i>				
Single-wall Thickness (mm)	Finger	0.21 ± 0.03		
	Palm	0.17 ± 0.03		
	Cuff	0.15 ± 0.02		
*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 'WRP', 'Hand' and 'Size'		
Packing Configuration		1 pair of gloves per inner wallet, 1 inner wallet per pouch, 50 pouches per dispenser, 4 dispensers per carton.		
Pre-shipment Inspection *Single-Normal Sampling Plan	Parameters/Standard		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=5	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
Packaging & Labelling (Major Defects)		G-I, AQL 1.5	G-I, AQL 1.5	
Packaging & Labelling (Minor Defects)		G-I, AQL 4.0	G-I, AQL 4.0	
Product Conformance				
Medical Device	EU Compliance: MDD 93/42/EEC (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	
US FDA	510K: K020019 MDL: D036512			
Glove Marking	Medical Device: CE 2797 PPE: CE 2797			
Quality Assurance				
<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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