

**SPECIFICATION SHEET**

Product Name		Comfit Powder Free Latex Surgical Gloves		
Reorder Number		C40xx-93		
Product Part Number		402xx.110522046		
<b>Product Description</b>				
Design and Feature		Hand specific, 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 coating on inner surface to ease donning		
<b>Product Quality Requirement</b>				
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	0.18 ± 0.03		
	Palm	0.16 ± 0.03		
	Cuff	0.14 ± 0.03		
Powder Residue (mg/glove)		≤ 2		
Protein Content (µg/dm <sup>2</sup> )		≤ 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		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	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	
<b>Product Conformance</b>				
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	
	UK Compliance: Regulation 2016/425 on personal protective equipment, as amended to apply in GB			
US FDA	510K: K020019 MDL: D036512			
Glove Marking	Medical Device: CE 2797 PPE: CE 2797			
<b>Quality Assurance &amp; Environment Management System</b>				
<ul style="list-style-type: none"> <li>MDSAP ISO 13485:2016 Quality Management System</li> <li>ISO 9001:2015 Quality Management System</li> <li>EN ISO 13485:2016 Quality Management System – Regulatory Purpose</li> <li>ISO 14001:2015, Environmental Management System</li> </ul>				

WRP ASIA PACIFIC SDN. BHD.



Name : Rosnaini Binti Rashidin  
Title : Product Management Manager