

**SPECIFICATION SHEET**

Product Name		Comfit Powdered Latex Surgical Gloves	
Reorder Number		C33xx-10	
Product Part Number		401xx.110422044	
Product Description			
Design and Feature		Hand specific, micro roughened surface, and beaded cuff	
Type		Lightly powdered and Gamma-sterilized surgical gloves	
Material		Natural Rubber Latex	
Colour		Natural	
Surface Treatment		Powdered with USP absorbable cornstarch	
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 Content (mg/dm ²)		Max. 15	
Protein Content (µg/g)		Max. 200	
Physical Properties	Parameters	Before Aging	After Aging
	Force at break (N)	≥ 9	≥ 9
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	Dimension	N=13, Median	
	Physical Properties	N=13, Median	
	1000ml Water Leak	G-I, AQL 0.65	
	Powder Content	N=2	
	Protein Content	N=8	
Visual Inspection (Major Defects)	G-I, AQL 1.5		
	Visual Inspection (Minor Defects)		
Product Conformance			
Compliance		EN 455 Part 1,2,3,4	
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		PPE: CE 2797	
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			

*Notes: Powdered Surgical Gloves are available for regions where CE MDR and Health Canada certification are not required. The product remains certified under CE PPE Category III, UKCA and MDA.

WRP ASIA PACIFIC SDN. BHD.




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