

SPECIFICATION SHEET

Product Name		Epic MT Powder Free Latex Surgical Gloves		
Reorder Number		EP-12-xx		
Product Part Number		362xx.106222043		
Product Description				
Design and Feature		Hand specific, micro roughened surface, and beaded cuff		
Type		Powder free, polymer coated with light chlorination and Gamma-sterilized surgical gloves		
Material		Natural Rubber Latex		
Colour		White		
Surface Treatment		Chlorination (1L-PcP)		
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)	Finger	0.22 ± 0.03		
*All sizes	Palm	0.18 ± 0.03		
	Cuff	0.15 ± 0.02		
Powder Residue (mg/glove)		≤ 2		
Protein Content (µg/g)		≤ 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		The cuff of each glove is marked with 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 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): K020019 MDL: D036512		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		
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.


Name : Rosnaini Binti Rashidin
Title : Product Management Manager