

DATA SHEET

EPIC^{MT}

PCP NR LATEX POWDER FREE SURGICAL GLOVES, STERILE

Size	Reorder#	Dimension		
		Target weight (g/pcs)	Palm Width (mm)	Length (mm)
5.5	EP-12-55	9.2 ± 0.5	72 ± 4	min. 278
6.0	EP-12-60	9.8 ± 0.5	77 ± 5	min. 280
6.5	EP-12-65	10.3 ± 0.5	83 ± 5	min. 280
7.0	EP-12-70	10.9 ± 0.5	89 ± 5	min. 283
7.5	EP-12-75	11.5 ± 0.5	95 ± 5	min. 287
8.0	EP-12-80	12.1 ± 0.5	102 ± 6	min. 288
8.5	EP-12-85	12.7 ± 0.5	108 ± 6	min. 290
9.0	EP-12-90	13.2 ± 0.5	114 ± 6	min. 290
<i>*non-release criteria</i>				
510K & MDL #		K020019 & D036512		
Design and Feature		Hand specific, curved fingers, 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)		
Powder Residue (mg/glove)		≤ 2		
Protein Content (µg/ dm ²)		≤ 50		
Single-wall Thickness (mm)	Finger	Specification		
	Palm	0.22 ± 0.03		
<i>*All sizes</i>	Cuff	0.18 ± 0.03		
Physical Properties	Tensile Strength (MPa)	Unaged		Aged
	Ultimate Elongation (%)	Min. 24		Min. 18
	Stress at 500% (MPa)	Min. 750		Min. 560
	Force at break (N)	Max. 5.5		N/A
		≥ 9		≥ 9
Packing Mode		1 pairs of gloves per inner wrap 1 inner wrap per pouch 50 pouch per dispenser 4 dispenser per carton		
Glove Marking		The cuff of each glove is marked with 'Hand and Size'		
Lot # Identification on Finished Goods		Lot Number Structure : YMMPPPPSS (9 Digits) Y = Year of packing (e.g. 2 for year 2022, 3 for year 2023, etc.) MM = Month of packing (e.g. 09 for Sept., 10 for Oct., etc.) PPPP = WRP's Packing Work Order# (PWO) SS = Size (00=XS, 01=S, 02=M, 03=L, 04=XL and 05=XXL)		
Shelf Life Claim		3 years upon manufacturing date		
Pre-shipment Inspection	Dimension	N=13, Median; S-2, AQL 4.0		
<i>*Single-Normal Sampling Plan</i>	Physical Properties	N=13, Median; S-2, AQL 4.0		
	1000ml Water Leak	G-1, AQL 0.65		
	Protein Content	N=8		
	Powder Free Residue	N=3		
	Major Visual Inspection	G-1, AQL 2.5		
	Minor Visual Inspection	G-1, AQL 4.0		
Product Conformance		<ul style="list-style-type: none"> Medical Device: in compliance with 93/42/EEC EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018 Type B, EN ISO 374-2:2019, EN ISO 374-4:2019, EN ISO 374-5:2016, EN 16523-1:2015+A1:2018, CE2797 EN 455 Part 1/2/3/4 ASTM D3577 		
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 		

Note: The above information is a guideline of typical performance values and characteristic of the product.

WRP ASIA PACIFIC SDN. BHD.




Name : Rosnaini Binti Rusli

Title : Product Management Manager