



**SPECIFICATION SHEET**



Product Name		Radiaxon PI Radiation Attenuating Surgical Polyisoprene Powder Free Gloves		
Reorder Number		XR35xx-85		
<b>Product Description</b>				
Design and Feature		Hand Specific and curved fingers		
Type		Powder free and Gamma sterilized radiation protective gloves		
Material		Polyisoprene		
Colour		Black		
Surface Treatment		Light chlorination on the inner surface to ease donning		
<b>Product Quality Requirement</b>				
Dimension	Size	Target Weight (g/pc)	Palm Width (mm)	Length (mm)
	6.0	30 ± 5	77 ± 5	min. 280
	6.5	36 ± 5	83 ± 5	min. 280
	7.0	41 ± 5	89 ± 5	min. 283
	7.5	47 ± 5	95 ± 5	min. 287
	8.0	53 ± 5	102 ± 5	min. 288
	8.5	59 ± 5	108 ± 5	min. 290
	9.0	65 ± 5	114 ± 5	min. 290
<i>*non-release criteria</i>				
Single-wall Thickness (mm) *All sizes		Finger	0.33 ± 0.03	
		Palm	0.31 ± 0.03	
		Cuff	0.33 ± 0.03	
Powder Residue (mg/glove)		≤ 2		
Physical Properties	Standard	Parameters	Before Aging	After Aging
	ASTM	Tensile Strength (MPa) Ultimate Elongation (%)	Min. 9 Min. 500	Min. 9 Min. 500
Shelf Life (upon manufacturing date)		3 years		
Glove Cuff Printing		The cuff of each glove is marked with 'Hand' & 'Size'		
Packing Configuration		1 pair of gloves per inner wallet, 1 inner wallet per pouch, 5 pouches per dispenser, 4 dispensers per carton.		
Pre - shipment Inspection *Single-Normal Sampling Plan	Parameters/Standard		ASTM	
	Dimension		S-2, AQL 4.0	
	Physical Properties		S-2, AQL 4.0	
	1000ml Water Leak		G-I, AQL 0.65	
	Powder Residue		N=5	
	Visual Inspection (Major Defects)		G-I, AQL 1.5	
	Visual Inspection (Minor Defects)		G-I, AQL 4.0	
Packaging & Labelling (Major Defects)		G-I, AQL 1.5		
Packaging & Labelling (Minor Defects)		G-I, AQL 4.0		
<b>Product Conformance</b>				
Medical Device		US Compliance	ASTM D3577 ASTM D7866-14a (Primary Radiation) ASTM F3094-14 (Scattered Radiation)	
<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