

**SPECIFICATION SHEET**

Note: This spec. sheet is not applicable for USA Markets

Product Name		Radiaxon PI Radiation Attenuating Surgical Polyisoprene Powder Free Gloves	
Product Part Number		302xx.104621001	
Reorder Number		R35xx-85	
Product Description			
Design and Feature		Hand specific	
Type		Powder free and Gamma sterilized radiation protective gloves	
Material		Polyisoprene	
Colour		Black	
Surface Treatment		Light chlorination on the inner surface to ease donning	
Product Quality Requirement			
Dimension	Size	Palm Width (mm)	Length (mm)
	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	0.33 ± 0.03	
	Palm	0.33 ± 0.03	
	Cuff	0.33 ± 0.03	
Powder Residue (mg/glove)		≤ 2	
Physical Properties	Parameters	Before Aging	After Aging
	Force at break (N)	≥ 9	≥ 9
Shelf Life (upon manufacturing date)		Product shall conform to the WRP internal specification for a period of three (3) years from the date of manufacture	
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 (Long 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 Residue	N=6	
	Visual Inspection (Major Defects)	G-I, AQL 1.5	
Visual Inspection (Minor Defects)		G-I, AQL 4.0	
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)	
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, EN 61331-3:2014, EN 421:2010
		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			

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