



**SPECIFICATION SHEET**

Product Name		Radiaxon Radiation Attenuating Surgical NR Latex Powder Free Gloves	
Product Part Number		302xx.10852726	
Reorder Number		R32xx-28	
<b>Product Description</b>			
Design and Feature		Hand Specific and beaded cuff	
Type		Powder free and Gamma sterilized radiation protective gloves	
Material		Natural rubber latex	
Colour		Brown	
Surface Treatment		Light chlorination on the inner surface to ease donning	
<b>Product Quality Requirement</b>			
Dimension	Size	Palm Width (mm)	Length (mm)
	6.0	77 ± 5	min. 275
	6.5	83 ± 5	min. 275
	7.0	89 ± 5	min. 280
	7.5	95 ± 5	min. 285
	8.0	102 ± 6	min. 285
	8.5	108 ± 6	min. 285
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	
Protein Content (µg/dm <sup>2</sup> )		≤ 50	
Physical Properties	Standard	Parameters	Before Aging
	EN 455	Force at break (N)	≥ 9
	ASTM	Tensile Strength (MPa)	Min. 12
		Ultimate Elongation (%)	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 (Long Pack).	
Pre - shipment Inspection *Single-Normal Sampling Plan	Parameters/Standard		ASTM
	EN 455		
	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 4.0	G-I, AQL 4.0	
<b>Product Conformance</b>			
Medical Device	EU Compliance: MDR (EU) 2017/745 (CE Class IIa)		EN 455 Part 1,2,3,4 EN 61267:2006 EN 61331-1:2014 EN 421:2010
	US Compliance		ASTM D3577 ASTM D7866-14a (Primary Radiation) ASTM F3094-14 (Scattered Radiation)
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
	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		
<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>			

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