



RFB LATEX LIMITED

Specification of *Surgical Gloves for X-Ray Radiation Resistance*

* Manufacturing Product Name	RFB RADIOGRAPHIC PROTECTION GLOVES						
* Trade Name	RFB X-L, RFB X-1, RFB X-2						
* Intended Use	<i>These devices are intended to protect the operator, patient or other person from unnecessary exposure to radiation during radiological procedures by providing an attenuating barrier to radiation. Some Specific uses are Cardiology, Angiographies, Neuroradiology, and other such similar uses</i>						
* Material	Dry Natural Rubber, Lead Oxide, Vulcanizing Chemicals, Antioxidant						
* Donning Lubricant	Chlorinated (Internal and External surface)						
* Powder Content Per Gloves	Powder Free Gloves- <2 mg/glove (Tested as per ASTM D 6124)						
* Size	6.0	6.5	7.0	7.5	8.0	8.5	9.0
* Width (mm)	76±10	83±10	89±10	95±10	102±10	108±10	114±10
* Length	280 mm (Minimum)						
* Thickness (Minimum)	RFB X-L (mm)		RFB X-1 (mm)		RFB X-2 (mm)		
Cuff	0.20		0.28		0.35		
Palm	0.22		0.30		0.38		
Finger	0.20		0.28		0.35		

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* Physical Requirements	Before Ageing	After Ageing	
* Minimum force at Break	7.5 Newtons	5.5 Newtons	
* Ageing	100 ± 2°C for 22 ± 0.3 Hrs. or 70 ± 2°C for 166 ± 2 Hrs.		
* Orientation	Anatomically shaped with thumb positioned towards the Palmer surface.		
* Beading	As required		
* Sterilization	* Gamma irradiation * Ethylene Oxide Sterilization	*As required by the customer	
* Colour	Brownish Grey		
* Sterility Assurance Level (SAL)	10 ⁻⁶		
* Protein (Maximum)	<i>Action Limit</i>		<i>Method</i>
	100µg/gm		Lowry Assay
* ETO Residue(If sterilized by ETO)	25 ppm		ISO/DIS/10993
Direct Beam Energy Level	RFB X-L	RFB X-1	RFB X-2
60 KVP	42%	62%	68%
80 KVP	38%	58%	60%
100 KVP	31%	49%	54%
120 KVP	28%	43%	48%
* Packaging			
Inner Wrapper	Contains a pair of gloves		
Wallet	Pair of inner wrapped gloves are heat sealed in a wallet.		
Inner Box	Contains the wallets as per customer requirements.		
Master Carton	Contains the inner boxes as per customer requirements.		