

DATA SHEET



Lead Free & Powder Free Radiation Attenuating Latex Free Surgical Glove

Reorder#/Size		6 : R3560-85	8 : R3580-85
		6½ : R3565-85	8½ : R3585-85
		7 : R3570-85	9 : R3590-85
		7½ : R3575-85	
Design and Features		Hand specific, curved fingers and textured fingers & palm	
Type		Powder free and gamma-sterilized radiation protective glove	
Material		Polyisoprene	
Colour		Black	
Surface Treatment		Chlorination	
Powder Residues (mg/glove)		≤ 2 (powder free)	
Dimensions – Palm width (mm)		6 : 77 ± 5	8 : 102 ± 6
		6½ : 83 ± 5	8½ : 108 ± 6
		7 : 89 ± 5	9 : 114 ± 6
		7½ : 95 ± 5	
Dimensions - Length (mm)		6 : min. 280	8 : min. 288
		6½ : min. 280	8½ : min. 290
		7 : min. 283	9 : min. 290
		7½ : min. 287	
Single wall thickness (mm)	Finger	<u>Specification</u>	<u>Typical Value</u>
	Palm	min. 0.30	0.37
	Cuff	min. 0.29	0.34
		min. 0.30	0.33
Physical Properties	Tensile Strength (MPa)	Before aging : min. 9	After aging : min. 15
	Elongation (%)	: min. 500	: min. 500
	Force at break (N) - specification	: min. 9	: min. 9
	Typical Force at break (N)	: 14.0	: 13.0
Packing mode	Inner Wrapper	1 pair of gloves	
	Pouch	1 inner wrapper	
	Dispenser	5 pouches	
	Outer carton	4 dispensers	
Glove marking		The cuff of each glove is marked with the respective hand (L/R) & size	
Lot number		Lot number structure: YMMPPPPSS Y = year of packing P = internal reference no. MM = month of packing SS = size	
Shelf life		3 years from date of manufacture	
Pre-shipment Quality Inspection	Dimensions	N=13 (EN 455-2)	
	Physical Properties	N=13 (EN 455-2)	
	1000ml Water Leak	G-I, AQL 0.65 (EN 455-1)	
	Major Visual Inspection	G-I, AQL 1.5	
	Minor Visual Inspection	G-I, AQL 4.0	
	Powder Residues	N=3 pairs (EN 455-3)	
Product Conformance		- Medical Device in compliance with European Medical Device Regulation (EU) 2017/745 (CE Class IIa): EN 455 Parts 1, 2, 3 & 4 - Personal Protection Equipment in compliance with European Regulation (EU) 2016/425 (category III, type tested to EN ISO 21420:2020, EN ISO 374-1:2016 Type B, EN ISO 374-5:2016), CE 2797 - Regulation 2016/425 on personal protective equipment, as amended to apply in GB (in UK), UKCA 0086 - ASTM D3577	
Quality Assurance		- ISO 9001 - ISO 13485 Quality Management System - ISO 14001 Environmental Management System - US FDA Quality System Regulation (QSR)	

Note: The above information is a guideline of typical performance values and characteristics of the product and not to be used as actual product specifications.