

DATA SHEET

EPIC^{MT} SURGICAL GLOVES Powder Free Latex Surgical Glove

Reorder#/Size	5½ : EP-12-55 7½ : EP-12-75 6 : EP-12-60 8 : EP-12-80 6½ : EP-12-65 8½ : EP-12-85 7 : EP-12-70 9 : EP-12-90	
Design and Features	Hand specific, curved fingers, Bisque-Finish and beaded cuff	
Type	Powder free and gamma-sterilized surgical glove	
Material	Natural rubber latex	
Colour	Natural	
Surface Treatment	Chlorination and polymer coating	
Protein Content (µg/g)	≤ 50	
Powder Residues (mg/glove)	≤ 2 (powder free)	
Dimensions – Palm width (mm)	5½ : 72 ± 4 7½ : 95 ± 5 6 : 77 ± 5 8 : 102 ± 6 6½ : 83 ± 5 8½ : 108 ± 6 7 : 89 ± 5 9 : 114 ± 6	
Dimensions - Length (mm)	5½ : min. 278 7½ : min. 287 6 : min. 280 8 : min. 288 6½ : min. 280 8½ : min. 290 7 : min. 283 9 : min. 290	
Single wall thickness (mm)	Finger	Specification 0.20 ± 0.03
	Palm	Typical Value 0.21
	Cuff	0.17 ± 0.03 0.18
		0.15 ± 0.03 0.15
Physical Properties	Tensile Strength (MPa)	Before aging : min. 24 After aging : min. 18
	Elongation (%)	: min. 750 : min. 560
	Force at break (N) - specification	: min. 12 : min. 9
	Typical Force at break (N)	: 19.5 : 17.0
Packing mode	Inner Wrapper	1 pair of gloves
	Pouch	1 inner wrapper
	Dispenser	50 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
	Protein Content	N=8 (EN 455-3)
	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.