



PROFEEL® LIGHTLY POWDERED NR LATEX SURGICAL GLOVES, STERILE

Reorder #	Size: 5½ : P3055-20 Size: 7½ : P3075-20 6 : P3060-20 8 : P3080-20 6½ : P3065-20 8½ : P3085-20 7 : P3070-20 9 : P3090-20	
Product Part #	361xx.10992020	
510K & MDL #	K951662 & D036522	
Design and Feature	Hand specific, curved fingers SH3 and beaded cuff	
Type	Powdered and Gamma sterilized surgical gloves	
Material	Natural rubber latex	
Color	Natural	
Surface Treatment	Light powdering using FDA approved USP absorbable cornstarch	
Powder Content (mg/dm ²)	Maximum 15	
Protein Content (µg/dm ²)	<200	
Dimension - Palm Width (mm)	Size: 5½ : 72 ± 4 Size: 7½ : 95 ± 5 6 : 77 ± 5 8 : 102 ± 6 6½ : 83 ± 5 8½ : 108 ± 6 7 : 89 ± 5 9 : 114 ± 6	
Dimension - Length (mm)	Size: 5½ : min.278 Size: 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 Palm Cuff	0.22 ± 0.03 0.19 ± 0.02 0.16 ± 0.02
Physical Properties	Tensile Strength (MPa) Ultimate Elongation (%) Stress at 500% (MPa) Force at Break (N)	<u>Before Aging</u> : <u>After Aging</u> Min. 24 Min. 18 Min. 750 Min. 560 Max. 5.5 Not Applicable ≥ 9 ≥ 9
Packing Mode	Inner Wallet Pouch Dispenser Carton	1 Pair Gloves 1 Inner Wallet 50 Pouches 6 Dispensers
Glove Marking	The cuff of each glove is marked with 'WRP', 'Hand & Size'	
Lot # identification on Finished Goods	Lot Number Structure: YMMPPPPSS Y = Year of Packing P = WRP's PWO MM = Month of Packing SS = Size	
Product Shelf Life	5 years upon manufactured date.	
Pre-shipment Inspection	Dimension Physical Properties 1000ml Water Leak Protein Content Powder Content Major Visual Inspection Minor Visual Inspection	N=13 N=13 G-I, AQL 0.65 N=8 N=2 G-I, AQL 1.5 G-I, AQL 4.0
Product Conformance	<ul style="list-style-type: none"> Medical Device: In compliance with European MDR (EU) 2017/745 (CE CLASS IIa Sterile) EN455 Parts 1, 2, 3 and 4 Personal Protective Equipment of Complex Design Category III, in European Regulation (EU) 2016/425, tested to EN 420:2003+A1:2009, EN ISO 374-1:2016 Type B, EN 374-2:2014, EN 374-4:2013, EN ISO 374-5:2016 & EN 16523-1:2015, CE 2797 ASTM D3577 	
Quality Assurance	<ul style="list-style-type: none"> US FDA Quality System Regulation (QSR) ISO9001:2015 Quality Management Systems ISO13485:2016 and EN ISO13485:2016 Quality Management Systems 	

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