

NOVAPROTECT 12" CUFFS

510K CHEMOTHERAPY



STANDARDS

SPECIFICATIONS

Medical Device Directive	N/A	MDD 93/42/EEC	Weight (M Size)	6.0 grams	
Personal Protective Equipment	✓	PPE 89/686 EEC	Material	Nitrile	
	✓	EC#1935/2004	Color	Lavender	
Food Contact	N/A	ISO 22000 Food Safety Management	Inner Treatment	Polymer Coated	
EN 455	1-4		Outer Surface	Finger & Palm Textured	
EN 420	✓	EU Standard	Length	Minimum 270 mm	
EN 374	1-5		Sterile	Non-Sterile	
ASTM F1671	✓	US Standard	Thickness (Single Wall) mm	Middle Finger: Min 0.14 ± .02 Palm: Min 0.12 ± .02 Cuff: Min 0.09 ± .02	
ASTM D6319/D3578	✓	US Standard	AQL (up to)	1.5	
ASTM D6978	✓	US Standard	Protein Content	N/A	
FSC™ Option	N/A		Water Leak Test	Inspection Level GI AQL 1.5	
			Visual & Aesthetics	Inspection Level S4 AQL Major 2.5 AQL Minor 4.0	
			Physical Dimension	Inspection Level S2 AQL 4.0	
			Physical Properties	Inspection Level S2 AQL 4.0	
			Particulate Residue	≤2mg/glove	
			Tensile Strength	Minimum 14 MPa Minimum 14 MPa	Before Aging After Aging
			Elongation	Minimum 500% Minimum 400%	Before Aging After Aging
			Force at Break	Median 6N Median 6N	Before Aging After Aging

