

# SUPERNOVA 4 MIL 510K EXAM



Check out the Envelicus Supernova gloves in action.



## STANDARDS

<b>Medical Device Directive</b>	N/A	MDD 93/42/EEC
<b>Personal Protective Equipment</b>	✓	PPE 89/686 EEC
	✓	CE#1935/2004
<b>Food Contact</b>	N/A	ISO 22000 Food Safety Management
<b>EN 455</b>	1-4	EU Standard
<b>EN 420</b>	✓	EU Standard
<b>EN 374</b>	1-5	EU Standard
<b>ASTM F1671</b>	✓	US Standard
<b>ASTM D6319/D3578</b>	✓	US Standard
<b>FSC™ Option</b>	N/A	

## SPECIFICATIONS

<b>Weight (M Size)</b>	4.0 grams
<b>Material</b>	Nitrile
<b>Color</b>	Light Blue
<b>Inner Treatment</b>	Polymer Coated
<b>Outer Surface</b>	Finger & Palm Textured
<b>Length</b>	Minimum 240 mm
<b>Sterile</b>	Non-Sterile
<b>Thickness (Single Wall) mm</b>	Middle Finger Min 0.10 ± .02 Palm Min 0.08 ± .02 Cuff Min 0.07 ± .02
<b>AQL (up to)</b>	1.5
<b>Protein Content</b>	N/A

<b>Water Leak Test</b>	Inspection Level GI AQL 1.5
<b>Visual &amp; Aesthetics</b>	Inspection Level S4 AQL Major 2.5 AQL Minor 4.0
<b>Physical Dimension</b>	Inspection Level S2 AQL 4.0
<b>Physical Properties</b>	Inspection Level S2 AQL 4.0

<b>Particulate Residue</b>	≤2mg/glove
<b>Tensile Strength</b>	Minimum 14 MPa Minimum 14 MPa
<b>Elongation</b>	Minimum 500% Minimum 400%
<b>Force at Break</b>	Median 6N Median 6N



Before Aging  
After Aging  
Before Aging  
After Aging  
Before Aging  
After Aging