

SUBLIME DATA SHEET

NITRILE 3.5G, EXAMINATION GLOVES, POWDER FREE, NON-STERILE

Size:		XS, S, M, L, & XL	
510k / MDL #		K133168/D222519	
		K141982 & D236305 (with Chemo drug claim)	
Design and Feature		Ambidextrous, textured surface at fingers (E1) and beaded cuff	
Type		Powder free and non-sterile examination gloves	
Material		100% nitrile (Acrylonitrile-butadiene)	
Color		Blue (PMS2726/PMS292)	
Surface Treatment		Chlorination on donning side	
Powder Free Residue (mg/glove)		≤ 2	
Dimension (mm)	Size: XS	<u>Palm Width</u>	<u>Length</u>
	S	≤80	Min. 240
	M	80 ± 10	Min. 240
	L	95 ± 10	Min. 240
	L	110 ± 10	Min. 240
	≥110		Min. 240
Weight	Size: XS	2.5 ± 0.3	
	S	3.0 ± 0.3	
	M	3.5 ± 0.3	
	L	4.0 ± 0.3	
	XL	4.3 ± 0.3	
Single-wall Thickness (mm) *All sizes	Finger	<u>Spec</u> Min. 0.05	
	Palm	Min. 0.05	
	Cuff	Min. 0.05	
Physical Properties	Tensile Strength (MPa) Elongation (%) Force at Break (N)	<u>Before Aging</u>	<u>After Aging</u>
		Min 14	Min 14
		Min 500	Min 400
	≥ 6	≥ 6	
Packing Mode	100	Dispenser	100 gloves by weight (XS-XL)
		Carton	10 dispensers per carton
	200	Dispenser	200 gloves by weight (XS-L); 200/180 gloves by weight (XL)
		Carton	10 dispensers per carton
Recommended Shelf Life		5 years upon manufactured date.	
Pre-shipment Inspection *Single-Normal Sampling Plan	Dimension	N=13, Median; S-2, AQL 4.0	
	Physical Properties	N=13, Median, S-2 AQL 4.0	
	1000ml Water Leak	G-I, AQL 1.5	
	Powder Free Residue	N=5	
	Major Visual Inspection	G-I, AQL 2.5	
Minor Visual Inspection	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 I) • EN455 Parts 1, 2, 3 and 4 • Personal Protective Equipment of Complex Design Category III, in European Regulation (EU) 2016/425, type tested to EN420:2003+A1:2009, EN ISO 374-1:2016 Type B, EN 374-2:2014, EN 374 4:2013, EN 374-5:2016 & EN 16523-1:2015, CE 2797 • ASTM D6319, ASTM D6978 	
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.