



**PRODUCT INFORMATION\***  
**SC® Nitrile Ultra**

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Product Information:				
Trade Name	SC® Nitrile Ultra			
Type	Non-sterile Nitrile Examination Gloves, powder free			
Intended Use	To conduct medical examination, diagnostic and therapeutic procedures to protect patient and user from cross contamination or infection.			
Product Conformance	Medical Device Directive 93/42/EEC, CE Class 1, Tested to EN 420:2003, EN 374-2:2003, EN455 1:2000, EN 455-2:2009, EN 455-3:2006, EN 455-4:2009 ASTM D6319			
Material	Nitrile Butadiene Rubber (NBR)			
Cuff Finishing	Beaded			
Color	Purple			
PowderFree Residue (mg/glove)	Max 2 mg/glove			
Design	Ambidextrous			
Surface finish	Finger textured			
Surface treatment	Both inner and outer surface are polymer coated			
Product Specification Conform EN420:2003 (Dimension Test and pH), EN374-2 (Water-tight test), EN455-1:2000, EN 455-2:2009, EN 455-3:2006, EN 455-4:2009				
Reference codes	Size	Order code	Packing unit	Innerboxes
	X-Small	08845_	2000	10 x 200
	Small	08846_	2000	10 x 200
	Medium	08847_	2000	10 x 200
	Large	08848_	2000	10 x 200
	Extra Large	08849_	2000	10 x 200
Dimensions	Size	Palm Width (mm)	Length (mm)	
	X-Small	75 ± 5	Min 240	
	Small	85 ± 5	Min 240	
	Medium	95 ± 5	Min 240	
	Large	106 ± 5	Min 240	
	Extra Large	116 ± 5	Min 240	
Thickness	<u>Single wall thickness (mm) / Location</u>			
	Cuff (at 25mm ± 5 from bead)		0.04	
	Palm (at center of palm)		0.05	
	Finger (at 13mm ± 3 from the tip)		0.06	
Physical Properties	<u>Before Aging</u>	Specification		
	Force at Break (N)	min 6.0 N		
	Elongation (%)	min 500%		
	Tensile Strength	min 14 Mpa		
Physical Properties	<u>After Aging</u>	Specification		
	Force at Break (N)	min 6.0 N		
	Elongation (%)	min 400%		
	Tensile Strength	min 14 Mpa		
Shelf life	3 Years upon manufacturing date			
Quality Inspection (pre-shipment)	Dimension		N=13, Median	
	Physical properties		N=13, Median	
	Water Leak Test 1000ml		G1, AQL 1,5	
	Visual Inspection – Major		G1, AQL 2,5	
	Visual Inspection – Minor		G1, AQL 4,0	
	Powder Free Residue		N=5	
Medica Europe BV				
Quality assurance	Medica Europe operates with a quality management system which complies with the requirements of ISO13485: 2003			

\* The product information provided is a guideline of typical performance characteristics of the product and is not to be used as actual product specification.