MEDICA EUROPE

PRODUCT INFORMATION*
SC® Nitrile Ultra

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	MDD 93/42/EEC, CE Class 1,& PPE Regulation 2016/425 Category III" EN 420:2003+A1:2009, EN455-1:2000, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 374-1:2016, EN 374-2:2014, EN 16253-1:2015, EN 374-4:2013, EN 374-5:2016
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
Food compliance	Yes, see declaration
Dimensions of the innerboxes	240 x 128 x 80 mm
Dimensions of the outer carton	420 x 270 x 260 mm
Handling and Storage	Store in a cool and dry place. Opened boxes should be kept away from fluorescent and sunlight. Gloves are packed in dispenser which is suitable for transport. Keep the gloves in the box when not in use.

Product Specification Conform EN420:2003+A1:2009 (Dimension Test and pH), EN374-2:2014 (Water-tight test), EN455-1:2000, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009

Reference codes	Size	Order code	Packing unit	Innerboxes
	X-Small (5 - 6)	08845_	2000	10 x 200
	Small (6 - 7)	08846_	2000	10 x 200
	Medium (7 - 8)	08847_	2000	10 x 200
	Large (8 - 9)	08848_	2000	10 x 200
	Extra Large (9 - 10)	08849_	2000	10 x 200

Dimensions	Size	Palm Width (mm)	Length (mm)
	X-Small (5 - 6)	75 ± 5	Min 240
	Small (6 - 7)	85 ± 5	Min 240
	Medium (7 - 8)	95 ± 5	Min 240
	Large (8 - 9)	106 ± 5	Min 240
	Extra Large (9 - 10)	116 ± 5	Min 240

Thickness	Single wall thickness (mm) / Location	
	Cuff	≥0.04 mm
	Palm	≥0.05 mm
	Finger	≥0.06 mm

Physical Properties	Before Aging	Specification	After Aging	Specification
	Force at Break (N)	min 6.0 N	Force at Break (N)	min 6.0 N
	Elongation (%)	min 500%	Elongation (%)	min 400%
	Tensile Strength (MPa)	min 14 Mpa	Tensile Strength (MPa)	min 14 Mpa

Shelf life	3 Years upon manufacturing date				
Quality Inspection (pre-shipment)	Dimension		N=13, Median	Water Leak Test 1000ml	G1, AQL 1,5
	Physical properties		N=13, Median	Visual Inspection – Major	G1, AQL 2,5
			G1, AQL 1,5	Visual Inspection – Minor	G1, AQL 4,0

Product Specification Conform EN 374-1:2016, EN 374-2:2014, EN 16253-1:2015, EN 374-4:2013, EN 374-5:2016

Determination of resistance to penetration	Water Leak Test 1000ml according to EN374-2:2014	G1, AQL 1,5

EN ISO 374-1:2016 permeation levels are based on breakthrough times as follows:

Performance Level	1	2	3	4	5	6
Measured breakthrough time (mins)	> 10	> 30	> 60	> 120	> 240	> 480

Tested in accordance with EN 16523-1:2015 & EN 374-4:2013 and achieved the following levels/results

Chemicals	Performance Level	Mean Degradation / %	Chemicals	Performance Level	Mean Degradation / %
4% Chlorhexidine Digluconate	6	19,0	0.1% Phenol	6	33,8
40% Sodium Hydroxide (K)	6	-42,9	30% Hydrogen peroxide (P	2	22,8
10-13% Sodium Hypochlorite	6	14,7	1.5% Methanol in water	6	21,9
50% Sulphuric Acid	6	-20,5	70% Isopropanol	0	62,2
10% Acetic acid	4	66,7	35% Ethanol	0	38,8
5% Ethidium Bromide	6	3,4	99% Acetic acid (N)	0	93,9
37% Formaldehyde (T)	3	5,0	25% Ammonium Hydroxide	1	-52,0
65% Nitric Acid (M)	0	97,6	3% Povidone Iodine	6	33,7
50% Glutaraldehyde	6	27,4	10% Sodium Percarbonate	6	15,4

*The minimum observable permeation rate was 7ug/cm2/min.

This product has been tested in accordance with EN ISO 374-5:2016.

Protection against bacteria and fungi	Pass
Protection against viruses	Pass

Medica Europe BV

Quality assurance	Medica Europe operates with a quality management system which complies with the requirements of ISO13485: 2003 & ISO13485: 2012 and the environmental management system ISO 14001:2015

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