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	MDR 2017/745, CE Class 1,& PPE Regulation 2016/425 Category III" EN 420 / EN ISO 21420, EN455-1, EN 455-2, EN 455-3, EN 455-4, EN 374-1 (Type B) EN 374-2, EN 16253-1, EN 374-4, EN 374-5
Material	Nitrile Butadiene Rubber (NBR)
Cuff Finishing	Rolled Cuff
Color	Cobalt blue
PowderFree Residue (mg/glove)	≤ 2 mg (according to EN 455-3)
Design	Ambidextrous
Surface finish	Finger textured
Food compliance	Regulation (EC) 1935/2004 on Food Contact Materials
Dimensions of the innerboxes	L240 x W122 x H65mm
Dimensions of the outer carton	L340 x H252 x H250mm
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/ EN ISO 21420 (Dimension Test and pH), EN374-2 (Water-tight test), EN455-1, EN 455-2, EN 455-3, EN 455-4

Reference codes	Size	Order code	Packing unit	Innerboxes
	X-Small (5 - 6)	09300	2000	10 x 200
	Small (6 - 7)	09301	2000	10 x 200
	Medium (7 - 8)	09302	2000	10 x 200
	Large (8 - 9)	09303	2000	10 x 200
	Extra Large (9 - 10)	09304	1800	10 x 180
Dimensions	Size	Palm Width (mm)	Length (mm)	
	X-Small (5 - 6)	≤ 80	Min 240	
	Small (6 - 7)	80 ± 10	Min 240	
	Medium (7 - 8)	95 ± 10	Min 240	
	Large (8 - 9)	110 ± 10	Min 240	
	Extra Large (9 - 10)	≥ 110	Min 240	
Thickness	Minimum single wall thickness (mm) / Location			
	Cuff		0.04 mm	
	Palm		0.05 mm	
	Finger		0.05 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)	Freedom from holes		AQL ≤ 1,5	G1, AQL 1,5
	Dimensions and Physical properties		AQL 4.0	S2, AQL 4,0

EN ISO 374-1 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 & EN 374-4 and achieved the following levels/results

Chemicals	Performance Level	Mean Degradation / %
40% Sodium Hydroxide (K)	6	-9,5%
30% Hydrogen peroxide (P)	6	44,0%
37% Formaldehyde (T)	4	51,0%

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

Protection against bacteria and fungi	Pass
Protection against viruses	Pass

Tested in accordance with ASTM6978

Chemotherapy Drug	mg/ml	Breakthrough Detection Time (BDT) = Minutes (min)	Chemotherapy Drug	mg/ml	Breakthrough Detection Time (BDT) = Minutes (min)
5-Fluorouracil	50,0	>240	Etoposide	20,0	>240
Carmustine (BiCNU)	3,3	25	Ifosfamid	50,0	>240
Cisplatin	1,0	>240	Methotrexate	25,0	>240
Cyclophosphamide (Cytoxan)	20,0	>240	Mitomycin C	0,5	>240
Cytarabine	100,0	>240	Mitoxantrone HCl	2,0	>240
Dacarbazine (DTIC)	10,0	>240	Oxaliplatin	5,0	not available
Daunorubicin HCl	5,0	not available	Paclitaxel (Taxol)	6,0	>240
Doxorubicin HCl	2,0	>240	Thio-Tepa	10,0	37
Epirubicin	2,0	not available	Vincristine sulfate	1,0	>240

Caution: Damaged or swelling gloves shall be changed immediately!
For reason of precaution it is recommended to change gloves after 2 hours!

Medica Europe BV	
Quality assurance	Medica Europe operates with a quality management system which complies with the requirements of ISO13485:2016 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.