



**PRODUCT INFORMATION\***  
**SC® Nitrile Plus**

Doc 9 Revision:09  
Effective: 01/10/2022  
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**Product Information:**

Trade Name	SC® Nitrile Plus
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	Personal Protective Equipment Category III, in compliance with Regulation (EU) 2016/425, type tested to EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN 16523-1:2015 + A1:2018, EN ISO 374-4:2019 and EN ISO 374-5: 2016, CE 2777; Class I Medical Device, in compliance with MDR 2017/745, type tested to EN EN 455-1:2020+A1:2022, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009.
Material	Nitrile Butadiene Rubber (NBR)
Cuff Finishing	Beaded
Color	Blue
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 EN ISO 21420:2020 (Dimension Test and pH), EN ISO 374-2:2019 (Water-tight test), EN455-1:2020+A1:2022, EN 455-2:2015, EN 455-3:2015, EN 455-**

Reference codes	Size	Order code	Packing unit	Innerboxes
	X-Small (5 - 6)	08870	2000	10 x 200
	Small (6 - 7)	08871	2000	10 x 200
	Medium (7 - 8)	08872	2000	10 x 200
	Large (8 - 9)	08873	2000	10 x 200
	Extra Large (9 - 10)	08874	1800	10 x 180

  

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	spec	Typical
	Cuff (at 25mm ± 5 from bead)	0.04	0.05
	Palm (at center of palm)	0.05	0.07
	Finger (at 13mm ± 3 from the tip)	0.07	0.11

  

Physical Properties	Before Aging	Specification	Typical	After Aging	Specification	Typical
	Force at Break (N)	min 6.0 N	7.0 - 8.0	Force at Break (N)	min 6.0 N	7.0 - 8.0
	Elongation (%)	min 500%	520 - 560	Elongation (%)	min 400%	500 - 560
	Tensile Strength (MPa)	min 14 Mpa	29 - 33	Tensile Strength (MPa)	min 14 Mpa	30 - 34

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 ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN 16253-1:2015, EN ISO 374-4:2019, EN ISO 374-5:2016**

Determination of resistance to penetration	Water Leak Test 1000ml according to EN ISO 374-2:2019	G1, AQL 1,5
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**EN ISO 374-1:2016+A1:2018 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 + A1:2018 & EN ISO 374-4:2019 and achieved the following levels/results**

Chemicals	Performance Level	Mean Degradation / %	Chemicals	Performance Level	Mean Degradation / %
* 4% Chlorhexidine Diguconate	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	0	-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 7u/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

**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)
Carmustine (BCNU)	3,3	10,2	Fluorouracil	50,0	>240
Cisplatin	1,0	>240	Ifosfamide	50,0	>240
Cyclophosphamide (Cytoxan)	20,0	>240	Methotrexate	25,0	>240
Cytarabine	100,0	>240	Mitomycin C	0,5	>240
Dacarbazine (DTIC)	10,0	>240	Mitoxantrone	2,0	>240
Doxorubicin HCl	2,0	>240	Paclitaxel (Taxol)	6,0	>240
Etoposide	20,0	>240	Thiotepa	10,0	30,4
			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 1 hour!

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