

# Vasco® Nitril sky-blue

## NON STERILE EXAMINATION AND PROTECTIVE GLOVES | DATA SHEET



**B. Braun Avitum AG confirms that Vasco® Nitril sky-blue gloves comply with the following standards and regulations:**

### EC CERTIFICATES AND APPLIED STANDARDS

Medical Device Class I according to Medical Device Regulation (EU) 2017/745

EN 455 1-4

Personal Protective Equipment Category III according to Personal Protective Equipment Regulation (EU) 2016/425

EN ISO 21420, EN 374, EN 16523, ISO 16604

### QUALITY CERTIFICATES

ISO 9001, ISO 13485

### PERSONAL PROTECTIVE EQUIPMENT

Information and Declaration of Conformity according to PPER (EU) 2016/425:



[www.bbraun.com/gloves-declarations-of-conformity](http://www.bbraun.com/gloves-declarations-of-conformity)

<http://www.intcomedical.com/download.html>

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# Vasco<sup>®</sup> Nitril sky-blue

## NON STERILE EXAMINATION AND PROTECTIVE GLOVES | REGULATORY INFORMATION

### MEDICAL DEVICE INFORMATION

MDR (EU) 2017/745 (CLASS I), EN 455



### FOOD COMPLIANCE



Conformity for food contact according to 1935/2004/EEC

### PERSONAL PROTECTIVE EQUIPMENT INFORMATION



**2777** PPE Regulation (EU) 2016/425 (Cat. III); EN ISO 21240:2020

Tested in accordance with:

ISO 374-1/Type B



KPT

Code letter	Test chemical	EN 374-1:2016 Permeation level	EN 374-4:2013 Mean degradation
K	Sodium hydroxide 40%	Level 6	-68.1 %
P	Hydrogen peroxide 30%	Level 2	30.5 %
T	Formaldehyde 37%	Level 5	9.5 %

Tested acc. to EN 16523-1:2015

Performance levels acc. EN 374-1:2016 +A1:2018	1	2	3	4	5	6
Measured breakthrough times (mins)	> 10	> 30	> 60	> 120	> 240	> 480

Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical. NOTE: Where the test specimens gave an increased puncture force after chemical exposure, the result is reported as a negative degradation.

ISO 374-5:2016



VIRUS

AQL <1.5

Resistance to bacteria and fungi	pass
Resistance to virus	pass

This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals. The chemical and penetration resistance has been assessed under laboratory conditions from samples taken from the palm only and relates only to the chemical tested. It can be different if the chemical is used in a mixture. It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation. When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves. Before usage, inspect the gloves for any defect or imperfections.

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## NON STERILE EXAMINATION AND PROTECTIVE GLOVES | TECHNICAL DATA



SIZE	REF 200/180*pcs.	GLOVE DIMENSIONS (EN 455)	
		Width of palm	Total length
XS	9206902	≤ 80 mm	
S	9206910	85 ± 5 mm	
M	9206929	95 ± 5 mm	≥ 240 mm
L	9206937	110 ± 5 mm	
XL*	9206945	120 ± 5 mm	

### PHYSICAL PROPERTIES

		Min. specification	Typical value
Wall thickness	Finger	0.10+/-0.03 mm	0.08 mm
	Palm	0.08+/-0.03 mm	0.06 mm
	Cuff	0.07+/-0.03 mm	0.05 mm
Force at break	During shelf life	6 N	6 N after ageing
Elongation at break	Before ageing	500%	
	After ageing	400%	
Tensile strength	Before ageing	14 MPa	
	After ageing	14 MPa	

### GLOVE DESIGN

Colour	sky-blue
Shape	straight fingers, ambidextrous fitting
Cuff	rolled rim, regular cuff
Surface finish	fingertip textured
Inner glove surface	polymer coated, powder-free

### GLOVE MATERIAL

Nitrile butadiene rubber (NBR)	
Latex allergy risk	free of latex proteins

### ACCELERATORS

Zn-dibutyldithiocarbamate (ZDBC)	
Free of thiurames and mercaptobenzothiazoles MBT	

### LOGISTIC INFORMATION

Dispenser pack	200/ 180 pcs.	245 x 130 x 80 mm (L x W x H)
Transportation carton	10 dispenser packs	415 x 270 x 258 mm (L x W x H)
Shelf life	5 years	
Storage conditions	store at 5°C to 38°C, protect from dust, humidity, sun light and ozone	

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## NON STERILE EXAMINATION AND PROTECTIVE GLOVES | BARRIER PROPERTIES – CHEMICALS



Tested by ProQuares, NL, or SATRA, UK in accordance with

**EN 16523-1**: Determination of material resistance to permeation by chemicals.

CHEMICAL	CAS REGISTRY NO.	PERMEATION PERFORMANCE LEVEL	BREAKTHROUGH TIME
Formaldehyde 37 %	50-00-0	level 5	> 240 min
Hydrogen peroxide 30 %	7722-84-1	level 2	> 30 min
Sodium hydroxide 40 %	1310-73-2	level 6	> 480 min

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## NON STERILE EXAMINATION AND PROTECTIVE GLOVES | BARRIER PROPERTIES – CYTOSTATIC DRUGS



Tested by ARDL, USA, or Proquares, NL in accordance with

**ASTM D 6978:** Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs. Minimum detection rate 0,01 µg/cm<sup>2</sup>/min

CHEMOTHERAPY DRUG	MG/ML	CAS REGISTRY NO.	MIN BREAKTHROUGH DETECTION TIME
Bleomycin Sulfate	15.0	9041-93-4	> 240 min
Cyclophosphamide	20.0	50-18-0	> 240 min
Cytarabine HCL	100.0	69-74-9	> 240 min
Etoposide	20.0	33419-42-0	> 240 min
Fluorouracil	50.0	51-21-8	> 240 min
Idarubicin	1.0	58957-92-9	> 240 min
Mesna	100.0	19767-45-4	> 240 min
Mitomycin C	0.5	50-07-7	> 240 min
Paclitaxel (Taxol)	6.0	33069-62-4	> 240 min
Trisenox	1.0	85586-03-4	> 240 min
Vincristine Sulfate	1.0	2068-78-2	> 240 min

### CLASSIFICATION

- Not suitable
- Suitable if changed before permeation breakthrough
- Suitable for prolonged use