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 ISO 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.intcomedical.com/download.html

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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

CE 2777 PPE Regulation (EU) 2016/425 (Cat. III); EN ISO 21420:2020

Tested in accordance with:

EN ISO 374-1:2016 +A1:2018/Type B

KPT

Code letter	Test chemical	EN 374-1:2016+A1:2018 Permeation level	EN 374-4:2019 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+A1:2018

Performance levels acc. EN ISO 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.

EN 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 100 pcs.	REF 150/135*pcs.	GLOVE DIMENSIONS (EN 455) Width of palm	Total length
XS	9203902	9206502	≤ 80 mm	≥ 240 mm
S	9203910	9206510	85 ± 5 mm	
M	9203929	9206529	95 ± 5 mm	
L	9203937	9206537	110 ± 5 mm	
XL	9203945	9206545*	120 ± 5 mm	

			Min. specification	Typical value
PHYSICAL PROPERTIES	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	100 pcs.[1)]	203 x 110 x 60 mm (L x W x H)	
		150 / 135 pcs.[2)]	235 x 125 x 75 mm (L x W x H)	
	Transportation carton	10 dispenser packs	[1)] 310 x 225 x 210 mm (L x W x H)	
		10 dispenser packs	[2)] 395 x 260 x 250 mm (L x W x H)	
	Shelf life	5 years		
	Storage conditions	Store at 5 °C to 38 °C, keep dry, keep away from sunlight, protect from ozone, dust, humidity		

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NON STERILE EXAMINATION AND PROTECTIVE GLOVES | BARRIER PROPERTIES – CHEMICALS

Tested by ProQuares, NL, or SATRA Technology Europe Limited, Rep. of Ireland (NB2777)

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

CHEMICAL	CAS REGISTRATION NO.	PERMEATION PERFORMANCE LEVEL	BREAKTHROUGH TIME
Acrylamide 40 %	79-6-1	level 4	> 120 min
Benzalkonium Chloride 50 %	63449-41-2	level 6	> 480 min
Chlorhexidine gluconate 4 %	18472-51-0	level 6	> 480 min
Cidex OPA	643-79-8	level 3	> 60 min
Formaldehyde 37 %	50-00-0	level 5	> 240 min
Hydrochloric acid 37 %	7647-01-0	level 3	> 60 min
Hydrogen peroxid 30 %	7722-84-1	level 2	> 30 min
Isopropyl Alcohol, 99 %	67-63-0	level 1	> 10 min
Silver Nitrate 0.5 %	7761-88-8	level 6	> 480 min
Sodium hydroxide 40 %	1310-73-2	level 6	> 480 min
Sodium hypochlorite 13 %	7681-52-9	level 6	> 480 min

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

CLASSIFICATION

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

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/cm²/min

CHEMOTHERAPY DRUG	MG/ML	CAS REGISTRY NO.	MIN BREAKTHROUGH DETECTION TIME
Arsenic Trioxide	1.0	1327-53-3	> 240 min
Bendamustine	5.0	97832-05-8	> 240 min
Bleomycin sulfate	15.0	9041-93-4	> 240 min
Bortezomib (Velcade)	1.0	179324-69-7	> 240 min
Busulfan	6.0	55-98-1	> 240 min
Carboplatin	10.0	41575-944	> 240 min
Carfilzomib	2.0	868540-17-4	> 240 min
Carmustine	3.3	154-93-8	13 min
Cetuximab (Erbitux)	2.0	205923-56-4	> 240 min
Chloroquine	50.0	54-05-7	> 240 min
Cisplatin	1.0	15663-27-1	> 240 min
Cladribine	1.0	4291-63-8	> 240 min
Cyclophosphamide	20.0	6055-19-2	> 240 min
Cyclosporin A	100.0	79217-60-0	> 240 min
Cytarabine	100.0	69-74-9	> 240 min
Cytovene	10.0	82410-32-0	> 240 min
Dacarbazine	10.0	4342-03-4	> 240 min
Daunorubicin	5.0	23541-50-6	> 240 min
Decitabine	5.0	2353-33-5	> 240 min
Docetaxel	10.0	114977-28-5	> 240 min
Doxorubicin HCL	2.0	25316-40-9	> 240 min
Epirubicin HCL (Ellence)	2.0	56420-45-2	> 240 min
Etoposide	20.0	33419-42-0	> 240 min
Fentanyl	100.0	201415-26-1	> 240 min
Fludarabine	25.0	21679-14-1	> 240 min
Fluorouracil	50.0	51-21-8	> 240 min
Fulvestrant	50.0	129453-61-8	> 240 min
Gemcitabine	38.0	95058-81-4	> 240 min

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CHEMOTHERAPY DRUG	MG/ML	CAS REGISTRY NO.	MIN BREAKTHROUGH DETECTION TIME
Idarubicin	1.0	58957-92-9	> 240 min
Ifosfamide	50.0	3778-73-2	> 240 min
Irinotecan	20.0	100286-90-6	> 240 min
Mechlorethamine HCL	1.0	55-86-7	> 240 min
Melphalan	5.0	148-82-3	> 240 min
Mesna	50.0	19767-45-4	> 240 min
Methotrexate	25.0	59-05-2	> 240 min
Mitomycin C	0.5	50-07-7	> 240 min
Mitoxantrone	2.0	65271-80-9	> 240 min
Oxaliplatin	2.0	61825-94-3	> 240 min
Paclitaxel	6.0	33069-62-4	> 240 min
Paraplatin	10.0	41575-94-4	> 240 min
Pemetrexed	25.0	150399-23-8	> 240 min
Raltitrexed	0.5	112887-68-0	> 240 min
Retrovir	10.0	30516-87-1	> 240 min
Rituximab	10.0	174722-31-7	> 240 min
Temsirolimus	25.0	162635-04-3	> 240 min
Thio-Tepa	10.0	52-24-4	> 120 min
Topotecan	1.0	119413-54-6	> 240 min
Triclosan	2.0	3380-34-5	> 240 min
Trisenox	1.0	1327-53-3	> 240 min
Vinblastine	1.0	865-21-4	> 240 min
Vincristine Sulfate	1.0	2068-78-2	> 240 min
Vinorelbine	10.0	71486-22-1	> 240 min
Zoledronic Acid	0.8	118072-93-8	> 240 min