

Vasco® Nitril Soft blue

NON STERILE EXAMINATION AND PROTECTIVE GLOVES | DATA SHEET



B. Braun Melsungen AG confirms that Vasco® Nitril Soft 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, ISO 11193-1, ASTM D6319

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

EN 420, EN 374, EN 16523, ISO 16604, ASTM F1671, ASTM D6978

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

www.sempermed.com/userinformation/bbraun



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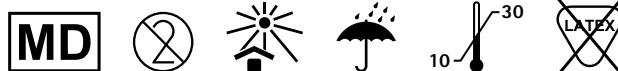

Dr. Hans-Ulrich Gaudin
Head of Global Regulatory Affairs OPM Germany

Vasco® Nitril Soft 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 420:2003+A1:2009

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	-9,5%
P	Hydrogen peroxide 30%	Level 6	44,0%
T	Formaldehyde 37%	Level 4	51,0%

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 1.0

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	9201107	≤ 80 mm	≥ 240 mm
S	9201115	80 ± 10 mm	
M	9201123	95 ± 10 mm	
L	9201131	110 ± 10 mm	
XL*	9201149	≥ 110 mm	

PHYSICAL PROPERTIES

		Min. specification	Typical value
Wall thickness	Finger	0.05 mm	0.09 mm
	Palm	0.05 mm	0.06 mm
	Cuff	0.04 mm	0.05 mm
Force at break	During shelf life	6 N	7 N after ageing
Elongation at break	Before ageing	500%	600%
	After ageing	400%	540%
Tensile strength	Before ageing	14 MPa	33 MPa
	After ageing	14 MPa	34 MPa

GLOVE DESIGN

Colour	violet blue
Shape	straight fingers, ambidextrous fitting
Cuff	rolled rim, regular cuff
Surface finish	fingertip textured
Inner glove surface	online chlorinated, powder-free

GLOVE MATERIAL

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

ACCELERATORS

Zn-dithiocarbamate	
Free of thiurames and mercaptobenzothiazoles MBT	

LOGISTIC INFORMATION

Dispenser pack	200/180 pcs.	245 x 125 x 74 mm (L x W x H)
Transportation carton	10 dispenser packs	380 x 258 x 255 mm (L x W x H)
Shelf life	3 years	
Storage conditions	store at room temperature, protect from dust, humidity, sun light and ozone	



Packaging is made from recycled material

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NON STERILE EXAMINATION AND PROTECTIVE GLOVES | BARRIER PROPERTIES – CHEMICALS



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

EN 374-3: Protective gloves against chemicals and micro-organisms – Determination of resistance to permeation by chemicals.

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

CHEMICAL	CAS REGISTRY NO.	PERMEATION PERFORMANCE LEVEL	BREAKTHROUGH TIME
Acetic acid 10 %	64-19-7	level 1	> 10 min
Acetone	67-64-1	not recommended	immediate
Acetonitrile	75-05-8	not recommended	immediate
Acrylamide 40 %	79-06-1	level 5	> 240 min
Ammonium hydroxide 25 %	1336-21-6	not recommended	1 – 10 min
Benzalconiumchloride liquid	63449-41-2	level 6	> 480 min
Chlorhexidine Digluconate 20 %	18472-51-0	level 6	> 480 min
Chloroform	67-66-3	not recommended	immediate
Dichlormethane	75-09-2	not recommended	immediate
Diethylamine	109-89-7	not recommended	immediate
Diethyl ether	60-29-7	not recommended	immediate
Dimethylsulfoxide	67-68-5	not recommended	immediate
Ethanol 20 %	64-17-5	level 6	> 480 min
Formaldehyde 37 %	50-00-0	level 4	> 120 min
Gasoline	8032-32-4	not recommended	immediate
Glutaraldehyde 5 %	111-30-8	level 5	> 240 min
Hydrochloric acid 10 %	7647-01-0	level 6	> 480 min
Hydrogen peroxide 30 %	7722-84-1	level 6	> 480 min
Isopropyl alcohol 40 %	67-63-0	level 6	> 480 min
Isopropyl alcohol 70 %	67-63-0	level 6	> 480 min
Nitric acid 10 %	7697-37-2	level 5	> 240 min
Phenol 10 %	108-95-2	not recommended	immediate
Povidone iodine 10 %	25655-41-8	level 6	> 480 min
Sodium hydroxide 40 %	1310-73-2	level 6	> 480 min
Sulfuric acid 96 %	7664-93-9	not recommended	1 – 10 min
Toluene	108-88-3	not recommended	immediate
Trichloroethane	71-55-6	not recommended	immediate
Xylene	95-47-6	not recommended	immediate

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



Tested by ARDL, USA 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

CLASSIFICATION

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

CHEMOTHERAPY DRUG	MG/ML	CAS REGISTRY NO.	MIN BREAKTHROUGH DETECTION TIME
Carmustine	3.3	154-93-8	■ 13 min
Cisplatin	1.0	15663-27-1	■ > 240 min
Cyclophosphamide	20.0	6055-19-2	■ > 240 min
Cytarabine	100.0	147-94-4	■ > 240 min
Dacarbazine	10.0	4342-03-4	■ > 240 min
Doxorubicin hydrochloride	2.0	25316-40-9	■ > 240 min
Etoposide	20.0	33419-42-0	■ > 240 min
Fluorouracil	50.0	51-21-8	■ > 240 min
Ifosfamid	50.0	3778-73-2	■ > 240 min
Methotrexate	25.0	59-05-2	■ > 240 min
Mitomycin C	0.5	50-07-7	■ > 240 min
Mitoxantrone	2.0	70476-82-3	■ > 240 min
Paclitaxel (Taxol)	6.0	33069-62-4	■ > 240 min
Thio-Tepa	10.0	52-24-4	■ 14 min
Vincristine sulfate	1.0	2068-78-2	■ > 240 min