Vasco® Nitril white

NON STERILE EXAMINATION AND PROTECTIVE GLOVES | DATA SHEET

B. Braun Melsungen AG confirms that
Vasco® Nitril white 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.hartalega.com.my

Hartalega NGC Sdn. Bhd., No.1, Persiaran Tanjung
Kawasan Perindustrian Tanjung, 43900 Sepang, Selangor Darul Ehsan
Malaysia

B. Braun Melsungen AG

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Vasco® Nitril white

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 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	-25,7 %
P	Hydrogen peroxide 30 %	Level 2	44,8 %
T	Formaldehyde 37 %	Level 5	-17,1 %

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

EN 421:2010

Protection against particulate radioactive contamination.

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.

B BRAUN
SHARING EXPERTISE

Vasco® Nitril white

NON STERILE EXAMINATION AND PROTECTIVE GLOVES | TECHNICAL DATA

SIZE	REF 100/90* pcs.	REF 150/135* pcs.	GLOVE DIMENSIONS (EN 455) Width of palm	Total length
XS	9207902	9208402	≤ 80 mm	
S	9207910	9208410	80 ± 10 mm	
M	9207929	9208429	95 ± 10 mm	≥ 240 mm
L	9207937	9208437	110 ± 10 mm	
XL*	9207945	9208445	≥ 110 mm	

			Min. specification	Typical value
PHYSICAL PROPERTIES	Wall thickness	Finger	0.08 mm	0.09 mm
		Palm	0.05 mm	0.06 mm
		Cuff	0.03 mm	0.06 mm
	Force at break	During shelf life	6 N	7 N after ageing
	Elongation at break	Before ageing	450 %	545 %
		After ageing	400 %	449 %
	Tensile strength	Before ageing	18 MPa	37 MPa
		After ageing	16 MPa	36 MPa
GLOVE DESIGN	Colour	white		
	Shape	straight fingers, ambidextrous fitting		
	Cuff	rolled rim, regular cuff		
	Surface finish	micro rough, textured fingers		
	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	100 / 90 pcs.[1)]	235 x 125 x 53 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)] 279 x 260 x 245 mm (L x W x H)	
			[2)] 395 x 260 x 250 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 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 3	> 60 min
Acetone	67-64-1	not recommended	immediate
Acrylamide 40 %	79-06-1	level 6	> 480 min
Ammonium hydroxide 25 %	1336-21-6	not recommended	immediate
Chlorhexidine gluconate 4 %	55-56-1	level 6	> 480 min
Ethanol 35 %	64-17-5	level 2	> 30 min
Ethanol 70 %	64-17-5	level 1	> 10 min
Ethidium bromide 1 %	1239-45-8	level 6	> 480 min
Formaldehyde 37 %	50-00-0	level 5	> 240 min
Formalin 10 %	50-00-0	level 6	> 480 min
Glutaraldehyde 1 %	111-30-8	level 6	> 480 min
Glutaraldehyde 4 %	111-30-8	level 6	> 480 min
Glutaraldehyde 5 %	111-30-8	level 6	> 480 min
Glutaraldehyde 50 %	111-30-8	level 6	> 480 min
Glycolic acid 2.5 %	79-14-1	level 6	> 480 min
Hexane-n	110-54-3	level 1	> 10 min
Hydrochloric acid 36 %	7647-01-0	level 2	> 30 min
Hydrogen peroxide 3 %	7722-84-1	level 6	> 480 min
Hydrogen peroxide 30 %	7722-84-1	level 2	> 30 min
Isopropanol 100 %	67-63-0	level 1	> 10 min
Isopropyl alcohol 70 %	67-63-0	level 1	> 10 min
Nitric acid 36 %	7697-37-2	level 1	> 10 min
Potassium hydroxide 30 %	1310-58-3	level 5	> 240 min
Sodium hydroxide 40 %	1310-73-2	level 6	> 480 min
Sodium percarbonate 15 %	15630-89-4	level 5	> 240 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 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
5-Azacytidine	25.0	320-67-2	> 240 min
Carboplatin	10.0	41575-94-4	> 240 min
Carmustine	3.3	154-93-8	11 min
Cisplatin	1.0	15663-27-1	> 240 min
Cyclophosphamide	20.0	6055-19-2	> 240 min
Dacarbazine	10.0	4342-03-4	> 240 min
Docetaxel	10.0	114977-28-5	> 240 min
Doxorubicin hydrochloride	2.0	25316-40-9	> 240 min
Epirubicin	2.0	56420-45-2	> 240 min
Etoposide	20.0	33419-42-0	> 240 min
Fluorouracil	50.0	51-21-8	> 240 min
Ifosfamide	50.0	3778-73-2	> 240 min
Irinotecan	20.0	100286-90-6	> 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
Oxaliplatin	5.0	61825-94-3	> 240 min
Paclitaxel (Taxol)	6.0	33069-62-4	> 240 min
Thio-Tepa	10.0	52-24-4	34 min
Vincristine sulfate	1.0	2068-78-2	> 240 min
Vinorelbine	10.0	125317-39-7	> 240 min