

# Vasco® Nitril Soft white Non sterile Examination and Protective Gloves

## DATA SHEET



AQL 1.0

**B. Braun Melsungen AG confirms that Vasco® Nitril Soft white gloves comply with the following standards and directives:**

### EC CERTIFICATES AND APPLIED STANDARDS

Medical device class I  
according to MDD 93/42/EEC  
EN 455 1-4, ISO 11993,  
ASTM D6319

Personal protective equipment category III CE 0321 (SATRA, UK)  
according to 89/686/EEC  
EN 420, EN 374 1-3, EN 388, ISO 16604,  
ASTM F1671, ASTM D6978

Conformity for food contact according to 1935/2004/EEC

### QUALITY CERTIFICATES

ISO 9001, ISO 13485

Certificates and complete list of applied standards are available on request.

B. Braun Melsungen AG

A handwritten signature in blue ink, appearing to read "H. Gaudin".

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

# Vasco<sup>®</sup> Nitril Soft white Non sterile Examination and Protective Gloves

## TECHNICAL DATA



SIZE	REF 200/180 pcs.	GLOVE DIMENSIONS (ACC. EN 455)		WALL THICKNESS Single wall ± 0.02 mm
		Width of palm	Total length median	
XS	9201100	≤ 80 mm	≥ 240 mm	
S	9201110	80 ± 10 mm	≥ 240 mm	finger 0.09 mm
M	9201120	95 ± 10 mm	≥ 240 mm	palm 0.07 mm
L	9201130	110 ± 10 mm	≥ 240 mm	cuff 0.05 mm
XL	9201140	≥ 110 mm	≥ 240 mm	

### GLOVE DESIGN

Colour	white
Shape	straight fingers, ambidextrous fitting
Cuff	rolled rim, regular cuff
Surface finish	finger 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	

### PHYSICAL PROPERTIES

Force at break (median)	≥ 6 N during shelf life		
Elongation at break (median)	before ageing	≥ 450 %	after ageing ≥ 400 %
Tensile strength (median)	before ageing	≥ 18 MPa	after ageing ≥ 16 MPa
Water-tightness	AQL 1.0		

### LOGISTIC INFORMATION

Dispenser pack dimensions	dispenser pack 200 / 180 pcs.	245 x 124 x 74 mm (L x W x H)
Transportation carton	10 dispenser packs	
Shelf life	3 years	
Storage conditions	store at room temperature, protect from dust, humidity, sun light and ozone	

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## 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.

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
Ammonium hydroxide 25 %	1336-21-6	not recommended	immediate
Chlorhexidine 4 %	55-56-1	level 6	> 480 min
Ethanol 35 %	64-17-5	level 1	> 10 min
Ethanol 70 %	64-17-5	level 1	> 10 min
Ethidium bromide 1 %	1239-45-8	level 6	> 480 min
Formaldehyde 35 %	50-00-0	level 3	> 60 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
Heptane-n	142-82-5	not recommended	immediate
Hexane-n	110-54-3	not recommended	immediate
Hydrochloric acid 36 %	7647-01-0	level 2	> 30 min
Hydrogen peroxide 3 %	7722-84-1	level 6	> 480 min
Isopropanol	67-63-0	not recommended	immediate
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

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## 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/cm<sup>2</sup>/min

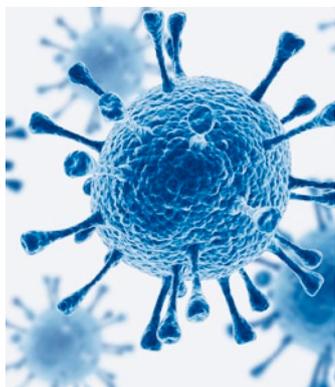
CHEMOTHERAPY DRUG	mg/ml	CAS registry no.	MIN BREAKTHROUGH DETECTION TIME
Carmustine	3.3	154-93-8	15 min
Cisplatin	1.0	15663-27-1	> 240 min
Cyclophosphamide	20.0	6055-19-2	> 240 min
Dacarbazine	10.0	4342-03-4	> 240 min
Doxorubicin hydrochloride	2.0	25316-40-9	> 240 min
Etoposide	20.0	33419-42-0	> 240 min
5-Fluorouracil	50.0	51-21-8	> 240 min
Methotrexate	25.0	59-05-2	> 240 min
Mitomycin C	0.5	50-07-7	> 240 min
Paclitaxel (Taxol)	6.0	33069-62-4	> 240 min
Thio-Tepa	10.0	52-24-4	15 min
Vincristine sulfate	1.0	2068-78-2	> 240 min

### CLASSIFICATION

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

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## BARRIER PROPERTIES – VIRAL PENETRATION



Tested by TÜV SÜD PSB Singapore in accordance with

**ASTM F 1671**: Standard Test Method for Resistance of Materials used in Protective Clothing to Penetration by Blood Borne Pathogens using Phi-X 174 Bacteriophage Penetration as a Test System.

Specimens that exhibit no detectable (< 1 PFU/mL) Phi-X174 in the assay titer pass the test.

TEST RESULT	ASSESSMENT		VALUE
Pass	No plaques	No virus penetration	< 1 PFU/mL (PFU: Plaque-forming unit)

### NOTE

All tests are conducted under laboratory conditions. The product properties are directly dependant upon the conditions of use. The gloves should be checked in advance for any holes or tears. Damaged or swelling gloves must be replaced immediately. In general, it is recommended to change gloves after 1-2 hours of working. In special cases, double gloving (colored underglove as indicator glove and white overglove) may be appropriate.

Tests and certificates can only be regarded as general information and do not reflect all actual working conditions. Glove selection shall be based on a risk assessment procedure. Hand hygiene by rubbing or washing is basic for hand decontamination before and after glove use.