

# Vasco® Nitril semilong white

NON STERILE EXAMINATION AND PROTECTIVE GLOVES | DATA SHEET



**B. Braun Melsungen AG confirms that Vasco® Nitril semilong 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](http://www.bbraun.com/gloves-declarations-of-conformity)

[www.hartalega.com.my](http://www.hartalega.com.my)



Hartalega Sdn. Bhd., C-G-9, Jalan Dataran SD1  
Dataran SD PJU9, Bandar Sri Damansara, 52200 Kuala Lumpur  
Malaysia

B. Braun Melsungen AG

A handwritten signature in blue ink, appearing to read 'Hans-Ulrich Gaudin'.

Dr. Hans-Ulrich Gaudin

Head of Global Regulatory Affairs OPM Germany

# Vasco® Nitril semilong 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



**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	3,2%
P	Hydrogen peroxide 30%	Level 2	26,9%
T	Formaldehyde 37%	Level 5	13,8%

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.

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## NON STERILE EXAMINATION AND PROTECTIVE GLOVES | TECHNICAL DATA



SIZE	REF 150/135* pcs.	GLOVE DIMENSIONS (EN 455)	
		Width of palm	Total length
XS	9205944	≤ 80 mm	
S	9205945	80 ± 10 mm	
M	9205946	95 ± 10 mm	≥ 265 mm
L	9205947	110 ± 10 mm	
XL*	9205948	≥ 110 mm	

### PHYSICAL PROPERTIES

		Min. specification	Typical value
Wall thickness	Finger	0.08 mm	0.11 mm
	Palm	0.05 mm	0.07 mm
	Cuff	0.03 mm	n/a
Force at break	During shelf life	6 N	7 N after ageing
Elongation at break	Before ageing	450%	552%
	After ageing	400%	478%
Tensile strength	Before ageing	18 MPa	34 MPa
	After ageing	16 MPa	33 MPa

### GLOVE DESIGN

Colour	white
Shape	straight fingers, ambidextrous fitting
Cuff	rolled rim, extended 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	

### LOGISTIC INFORMATION

Dispenser pack	150/135 pcs.	240 x 125 x 68 mm (L x W x H)
Transportation carton	10 dispenser packs	350 x 255 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
Chloroform 99 %	67-66-3	not recommended	immediate
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 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 10 %	111-30-8	level 6	> 480 min
Glycolic acid 2.5 %	79-14-1	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
Hydrogen peroxide 30 %	7722-84-1	level 2	> 30 min
Isopropanol 70 %	67-63-0	level 1	> 10 min
Isopropanol 100 %	67-63-0	not recommended	immediate
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 6	> 480 min

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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/cm<sup>2</sup>/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	<span style="color: orange;">■</span> 15 min
Cisplatin	1.0	15663-27-1	<span style="color: teal;">■</span> > 240 min
Cyclophosphamide	20.0	6055-19-2	<span style="color: teal;">■</span> > 240 min
Dacarbazine	10.0	4342-03-4	<span style="color: teal;">■</span> > 240 min
Doxorubicin hydrochloride	2.0	25316-40-9	<span style="color: teal;">■</span> > 240 min
Etoposide	20.0	33419-42-0	<span style="color: teal;">■</span> > 240 min
Fluorouracil	50.0	51-21-8	<span style="color: teal;">■</span> > 240 min
Methotrexate	25.0	59-05-2	<span style="color: teal;">■</span> > 240 min
Mitomycin C	0.5	50-07-7	<span style="color: teal;">■</span> > 240 min
Paclitaxel (Taxol)	6.0	33069-62-4	<span style="color: teal;">■</span> > 240 min
Thio-Tepa	10.0	52-24-4	<span style="color: orange;">■</span> 15 min
Vincristine sulfate	1.0	2068-78-2	<span style="color: teal;">■</span> > 240 min