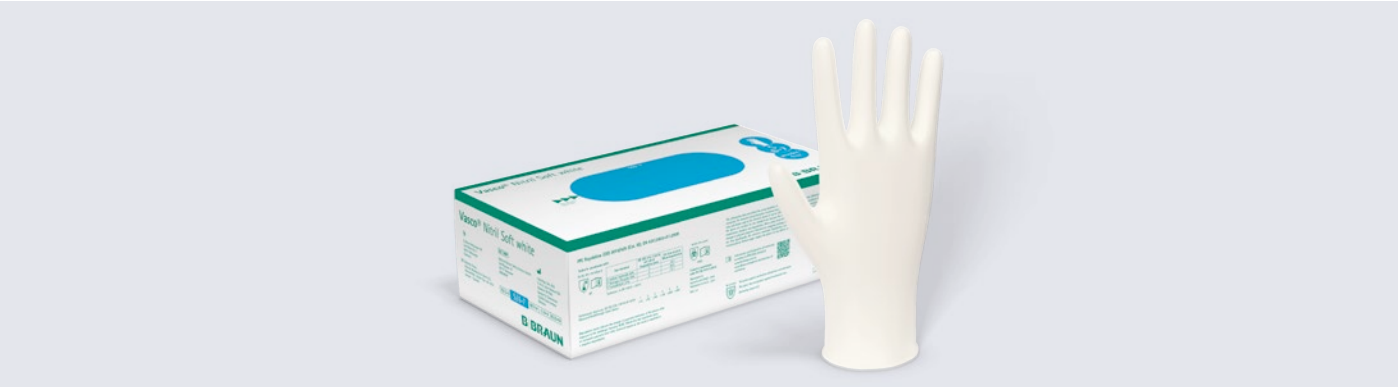
Vasco® Nitril Soft white

NON STERILE EXAMINATION AND PROTECTIVE GLOVES | DATA SHEET



B. Braun Melsungen AG confirms that
Vasco® Nitril Soft 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

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

Vasco® Nitril Soft 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

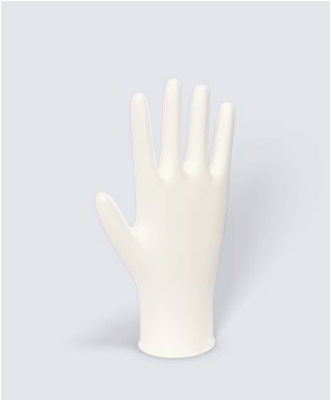
EN 421:2010

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.

Vasco® Nitril Soft white

NON STERILE EXAMINATION AND PROTECTIVE GLOVES | TECHNICAL DATA



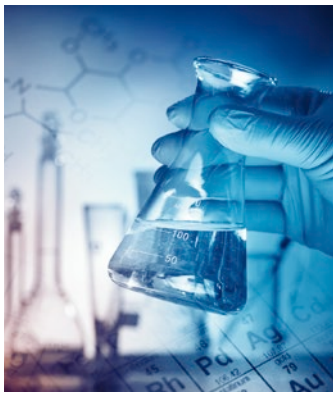
SIZE	REF 200/180* pcs.	GLOVE DIMENSIONS (EN 455) Width of palm	Total length
XS	9201100	≤ 80 mm	≥ 240 mm
S	9201110	80 ± 10 mm	
M	9201120	95 ± 10 mm	
L	9201130	110 ± 10 mm	
XL*	9201140	≥ 110 mm	

			Min. specification	Typical value
PHYSICAL PROPERTIES	Wall thickness	Finger	0.05 mm	0.08 mm
		Palm	0.05 mm	0.06 mm
		Cuff	0.035 mm	0.05 mm
	Force at break	During shelf life	6 N	7 N after ageing
	Elongation at break	Before ageing	450 %	570 %
		After ageing	400 %	469 %
	Tensile strength	Before ageing	18 MPa	39 MPa
		After ageing	16 MPa	42 MPa

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		
LOGISTIC INFORMATION	Dispenser pack	200 / 180 pcs.	245 x 124 x 74 mm (L x W x H)
	Transportation carton	10 dispenser packs	382 x 262 x 257 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	

Vasco® Nitril Soft white

NON STERILE EXAMINATION AND PROTECTIVE GLOVES | BARRIER PROPERTIES – CHEMICALS



Tested by SATRA, UK in accordance with

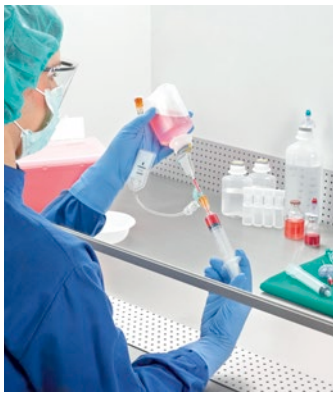
EN 374-3: Protective gloves against chemicals and micro-organisms – Determination of resistance to permeation by chemicals.

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

CHEMICAL	CAS REGISTRY NO.	PERMEATION PERFORMANCE LEVEL	BREAKTHROUGH TIME
Acetone	67-64-1	not recommended	immediate
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 1	> 10 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 50 %	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
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	not recommended	immediate
Sodium hydroxide 40 %	1310-73-2	level 6	> 480 min
Sodium percarbonate 15%	15630-89-4	level 6	> 480 min

Vasco® Nitril Soft white

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
Carmustine	3.3	154-93-8	14 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
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	24 min
Vincristine sulfate	1.0	2068-78-2	> 240 min