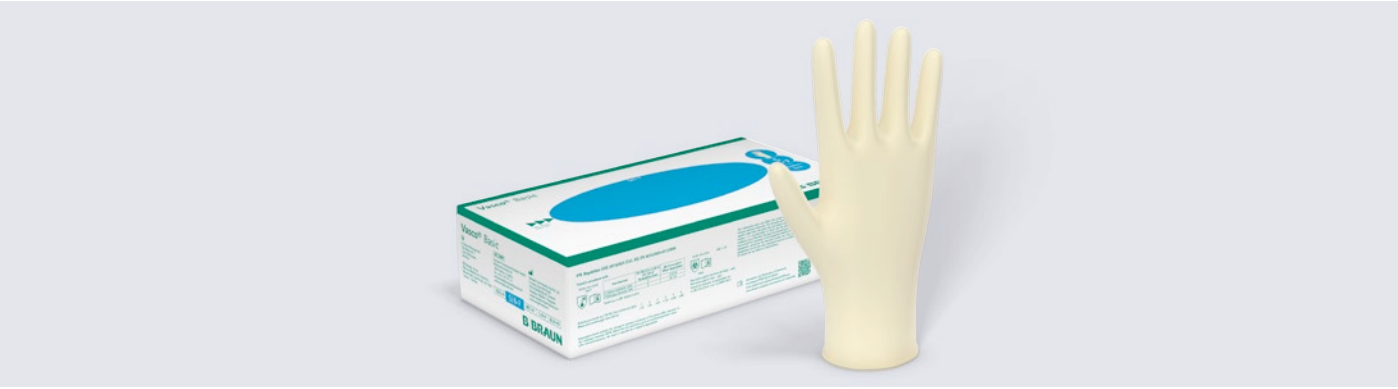
Vasco® Basic

NON STERILE EXAMINATION AND PROTECTIVE GLOVES | DATA SHEET



B. Braun Melsungen AG confirms that
Vasco® Basic 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 D3578

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

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

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

Semperit Investments Asia Pte Ltd, 8 Jurong Town Hall Road
#29-03/04/05/06 JTC Summit, Singapore 609434/Singapore
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B. Braun Melsungen AG

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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 0534 PPE Regulation (EU) 2016/425 (Cat. III); EN 420:2003+A1:2009

Tested in accordance with:

ISO 374-1/Type C

Code letter	Test chemical	EN 374-1:2016 Permeation level	EN 374-4:2013 Mean degradation
K	Sodium hydroxide 40 %	Level 5	-27,0 %
P	Hydrogen peroxide 30 %	Level 6	-9,1 %

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 < 1.5

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	GLOVE DIMENSIONS (EN 455)	
	100/90*pcs.	Width of palm	Total length
XS	6066608	≤ 80 mm	≥ 240 mm
S	6066616	80 ± 10 mm	
M	6066624	95 ± 10 mm	
L	6066632	110 ± 10 mm	
XL*	6066640	≥ 110 mm	

			Min. specification	Typical value
PHYSICAL PROPERTIES	Wall thickness	Finger	0.10 mm	0.12 mm
		Palm	0.08 mm	0.09 mm
		Cuff	0.06 mm	0.06 mm
	Force at break	During shelf life	6 N	7 N after ageing
	Elongation at break	Before ageing	650 %	800 %
		After ageing	500 %	760 %
	Tensile strength	Before ageing	18 MPa	23 MPa
		After ageing	14 MPa	24 MPa
GLOVE DESIGN	Colour	natural white		
	Shape	straight fingers, ambidextrous fitting		
	Cuff	rolled rim, regular cuff		
	Surface finish	textured fingers		
	Inner glove surface	polymer coated, powder-free		
GLOVE MATERIAL	Natural rubber latex (NRL)	Protein content ≤ 50 µg/g lower claims are not considered to be reliable given the expected process variation in manufacture and inter-laboratory testing (EN 455-3:2020)		
	Latex allergy risk	containing natural rubber latex which may cause allergic reactions including anaphylactic reactions		
ACCELERATORS	Zn-dithiocarbamate, Zn-mercaptobenzothiazolate			
	Free of thiurames			
LOGISTIC INFORMATION	Dispenser pack	100 / 90 pcs.	240 x 122 x 65 mm (L x W x H)	
	Transportation carton	10 dispenser packs	340 x 252 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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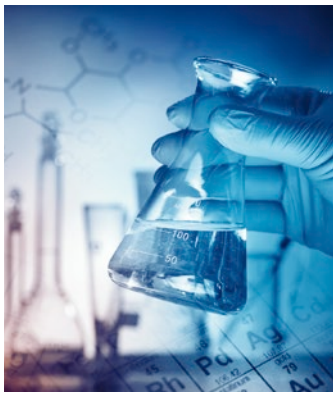
NON STERILE EXAMINATION AND PROTECTIVE GLOVES | BARRIER PROPERTIES – CHEMICALS



Tested by SATRA, UK 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
Acetone	67-64-1	not recommended	immediate
Acetonitrile	75-05-8	not recommended	immediate
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 DMSO	67-68-5	not recommended	immediate
Ethanol 70 %	64-17-5	not recommended	immediate
Ethyl acetate	141-78-6	not recommended	immediate
Formaldehyde 37 %	50-00-0	level 6	> 480 min
Gasoline	8032-32-4	not recommended	immediate
Heptane-n	142-82-5	not recommended	immediate
Hexane-n	110-54-3	not recommended	immediate
Hydrogen peroxide 30 %	7722-84-1	level 6	> 480 min
Methanol p.a.	67-56-1	not recommended	immediate
Sodium hydroxide 40 %	1310-73-2	level 5	> 240 min
Toluene	108-88-3	not recommended	immediate
Trichloroethane	71-55-6	not recommended	immediate
Xylene	95-47-6	not recommended	immediate