Vasco® Guard

NON STERILE EXAMINATION AND PROTECTIVE GLOVES | DATA SHEET

B. Braun Melsungen AG confirms that
Vasco® Guard 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.sempermed.com/userinformation/bbraun

Semperit Investments Asia Pte Ltd, 8 Jurong Town Hall Road
#29-03/04/05/06 JTC Summit, Singapore 609434/Singapore
sempermed@semperitgroup.com, www.sempermed.com

B. Braun Melsungen AG

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

Vasco® Guard

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	-38,0 %
P	Hydrogen peroxide 30 %	Level 6	9,7 %
T	Formaldehyde 37 %	Level 6	23,0 %

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	GLOVE DIMENSIONS (EN 455)	
	100/90* pcs.	Width of palm	Total length
XS	9209600	≤ 80 mm	≥ 240 mm
S	9209618	80 ± 10 mm	
M	9209626	95 ± 10 mm	
L	9209634	110 ± 10 mm	
XL*	9209642	≥ 110 mm	

			Min. specification	Typical value
PHYSICAL PROPERTIES	Wall thickness	Finger	0.10 mm	0.13 mm
		Palm	0.08 mm	0.08 mm
		Cuff	0.06 mm	0.07 mm
	Force at break	During shelf life	6 N	10 N after ageing
	Elongation at break	Before ageing	500 %	560 %
		After ageing	400 %	500 %
	Tensile strength	Before ageing	14 MPa	32 MPa
		After ageing	14 MPa	37 MPa

GLOVE DESIGN	Colour	ocean-blue	
	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.	220 x 110 x 68 mm (L x W x H)
	Transportation carton	10 dispenser packs	350 x 228 x 230 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
Acetic acid 10 %	64-19-7	level 5	> 240 min
Acetone	67-64-1	not recommended	immediate
Acetonitrile	75-05-8	not recommended	immediate
Acrylamide 40 %	79-06-1	level 6	> 480 min
Ammonium hydroxide 25 %	1336-21-6	level 1	> 10 min
Chloroform	67-66-3	not recommended	immediate
Dichloromethane	75-09-2	not recommended	immediate
Diethyl amine	109-89-7	not recommended	immediate
Diethyl ether	60-29-7	not recommended	immediate
Dimethylsulfoxide DMSO	67-68-5	not recommended	immediate
Ethanol 20 %	64-17-5	level 6	> 480 min
Ethanol 70 %	64-17-5	not recommended	1 - 10 min
Ethidium bromide 1 %	1239-45-8	level 6	> 480 min
Ethyl acetate	141-78-6	not recommended	immediate
Formaldehyde 37 %	50-00-0	level 6	> 480 min
Gasoline	8032-32-4	not recommended	immediate
Glutaraldehyde 5 %	111-30-8	level 6	> 480 min
Heptane-n	142-82-5	not recommended	immediate
Hexane-n	110-54-3	not recommended	1 - 10 min
Hydrofluoric acid 40 %	7664-39-3	not recommended	1 - 10 min
Hydrogen peroxide 30 %	7722-84-1	level 6	> 480 min
Isopropyl alcohol 70 %	67-63-0	level 3	> 60 min
Methanol 5 %	67-56-1	level 6	> 480 min
Methanol p.a.	67-56-1	not recommended	immediate
Nitric acid 10 %	7697-37-2	level 6	> 480 min
Nitric acid 36 %	7697-37-2	level 3	> 60 min
Phenol 10 %	108-95-2	not recommended	immediate
Povidone iodine 10 %	25655-41-8	level 6	> 480 min
Sodium hydroxide 40 %	1310-73-2	level 6	> 480 min
Sulfuric acid 96 %	7664-93-9	not recommended	1 - 10 min
Toluene	108-88-3	not recommended	immediate
Trichlorethane	71-55-6	not recommended	immediate
Xylene	95-47-6	not recommended	immediate

Vasco® Guard 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	46 min
Cisplatin	1.0	15663-27-1	> 240 min
Cyclophosphamide monohydrate	20.0	6055-19-2	> 240 min
Cytarabine HCl	100.0	69-74-9	> 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
Ifosfamid	50.0	3778-73-2	> 240 min
Methotrexate	25.0	59-05-2	> 240 min
Mitomycin C	0.5	50-07-7	> 240 min
Mitoxantrone	2.0	65271-80-9	> 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	38 min
Vincristine sulfate	1.0	2068-78-2	> 240 min