Vasco® Sensitive

NON STERILE EXAMINATION AND PROTECTIVE GLOVES | DATA SHEET

B. Braun Melsungen AG confirms that
Vasco® Sensitive 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, 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

https://www.sritranggloves.com/en/update/document

Sri Trang Gloves (Thailand), Public Company Limited
10 Soi 10, Phetkasem Road, Hat Yai, Songkhla 90110, Thailand
www.sritranggroup.com

B. Braun Melsungen AG

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

Vasco® Sensitive

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	-18,2 %
P	Hydrogen peroxide 30 %	Level 3	3,3 %
T	Formaldehyde 37 %	Level 5	-28,2 %

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.

Vasco® Sensitive

NON STERILE EXAMINATION AND PROTECTIVE GLOVES | TECHNICAL DATA

SIZE	REF	GLOVE DIMENSIONS (EN 455)	
	100/90* pcs.	Width of palm	Total length
XS	6067500	≤ 80 mm	≥ 240 mm
S	6067526	80 ± 10 mm	
M	6067549	95 ± 10 mm	
L	6067565	110 ± 10 mm	
XL*	6067590	≥ 110 mm	

			Min. specification	Typical value
PHYSICAL PROPERTIES	Wall thickness	Finger	0.08 mm	0.14 mm
		Palm	0.08 mm	0.12 mm
		Cuff		0.08 mm
	Force at break	During shelf life	6 N	8.1 N after ageing
	Elongation at break	Before ageing	650 %	816 %
		After ageing	500 %	916 %
	Tensile strength	Before ageing	18 MPa	28 MPa
		After ageing	14 MPa	25 MPa

GLOVE DESIGN	Colour	natural white
	Shape	straight fingers, ambidextrous fitting
	Cuff	rolled rim, regular cuff
	Surface finish	fingertip textured
	Inner glove surface	polymer coated, powder-free
	Outer glove surface	chlorinated
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	
	Free of thiurames and mercaptobenzothiazoles (MBT)	

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 249 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	

Vasco® Sensitive

NON STERILE EXAMINATION AND PROTECTIVE GLOVES | BARRIER PROPERTIES – CHEMICALS

ed by SATRA, UK in accordance with

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

MICAL	CAS REGISTRY NO.	PERMEATION PERFORMANCE LEVEL	BREAKTHROUGH TIME
ne	67-64-1	not recommended	immediate
nitrile	75-05-8	not recommended	immediate
oform	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 70 %	64-17-5	not recommended	immediate
Ethidium bromide 1 %	1239-45-8	level 6	> 480 min
Ethyl acetate	141-78-6	not recommended	immediate
Formaldehyde 37 %	50-00-0	level 5	> 240 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 3	> 60 min
Methanol p.a.	67-56-1	not recommended	immediate
Nitric acid 10 %	7697-37-2	level 1	> 10 min
Nitric acid 65 %	7697-37-2	level 1	> 10 min
Sodium hydroxide 40 %	1310-73-2	level 6	> 480 min
Sulphuric acid 47 %	7664-93-9	level 1	> 10 min
Sulphuric acid 96 %	7664-93-9	level 1	> 10 min
Toluene	108-88-3	not recommended	immediate
Trichlorethane	71-55-6	not recommended	immediate
Xylene	95-47-6	not recommended	immediate