

Vasco® Powdered

NON STERILE EXAMINATION AND PROTECTIVE GLOVES | DATA SHEET



B. Braun Melsungen AG confirms that

Vasco® Powdered 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

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

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B. Braun Melsungen AG

Director Global Regulatory Affairs WOC Consumables & PPE Avitum



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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

PERSONAL PROTECTIVE **EQUIPMENT INFORMATION**

Tested in accordance with: ISO 374-1/Type C







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

Conformity for food contact according to 1935/2004/EEC

Code letter	Test chemical	EN 374-1:2016 Permeation level	EN 374-4:2013 Mean degradation		
L	Sulphuric acid 96%	Level 1	99.4%		
М	Nitric acid 65%	Level 1	53.3%		
P	Hydrogen peroxide	Level 1	-92.5%		

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





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	6066502	≤ 80 mm		
S	6066526	80 ± 10 mm		
M	6066542	95 ± 10 mm	≥ 240 mm	
L	6066569	110 ± 10 mm		
XL*	6066581	≥ 110 mm		

PHYSICAL PROPERTIES			Min. specification	Typical value		
	Wall thickness	Finger	0.08 mm	0.12 mm		
		Palm	0.08 mm	0.09 mm		
		Cuff		0.07 mm		
	Force at break	During shelf life	6 N	6.8 N after ageing		
	Elongation at break	Before ageing	650%	778%		
		After ageing	500%	739%		
	Tensile strength	Before ageing	18 MPa	25.6 MPa		
	-	After ageing	14 MPa	25.2 MPa		
GLOVE DESIGN	Colour	natural white				
	Shape	straight fingers, ambidextrous fitting				
	Cuff	rolled rim, regular cuff				
	Surface finish	micro rough				
	Inner glove surface	powdered				
	Powder	corn starch powder				
GLOVE MATERIAL	Natural rubber latex (NRL)					
	Latex allergy risk	~	I rubber latex which maphylactic reactions	ay cause allergic reac-		
ACCELERATORS	Zn-dithiocarbamate		<u> </u>			
	Free of thiurames and mercaptobenzothiazoles MBT					
LOGISTIC INFORMATION	Dispenser pack	100 / 90 pcs.	200 x 1	200 x 110 x 60 mm (L x W x H)		
	Transportation carton	10 dispenser pack	s 310 x 2	310 x 225 x 210 mm (L x W x H)		
	Shelf life	5 years				
	Storage conditions	store at room temperature, protect from dust, humidity, sun light and ozone				
		Packaging is made from recycled material				