

Vasco® Vinyl Powder-free

NON STERILE EXAMINATION AND PROTECTIVE GLOVES | DATA SHEET



**B. Braun Melsungen AG confirms that
Vasco® Vinyl Powder-free 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 11193-2, ASTM D5250

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

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

QUALITY CERTIFICATES

ISO 13485


DECLARATION OF CONFORMITY

Information and Declaration of Conformity according to PPER (EU) 2016/425:



www.bbraun.com/gloves-declarations-of-conformity

www.meditrade.de/GVU662

 Meditrade GmbH, Medipark 1, 83088 Kiefersfelden, Germany

B. Braun Melsungen AG

A handwritten signature in blue ink, appearing to read 'H. Gaudin', positioned below the printed name 'Dr. Hans-Ulrich Gaudin'.

Dr. Hans-Ulrich Gaudin

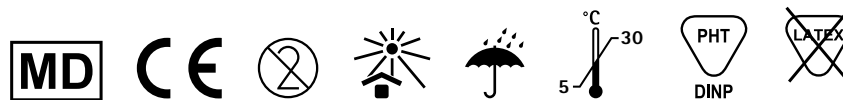
Director Global Regulatory Affairs WOC Consumables & PPE Avitum

Vasco® Vinyl Powder-free


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
(Do not use for fatty food)

PERSONAL PROTECTIVE EQUIPMENT INFORMATION

PPE Regulation (EU) 2016/425 (Cat. I); 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 6	13,7%

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.

ISO 374-5:2016



VIRUS

AQL 1,5

Resistance to bacteria and fungi pass

Resistance to virus pass

Reference viral penetration: ASTM F1671/F1671M-13

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 100 pcs.	GLOVE DIMENSIONS (EN 455)	
		Width of palm	Total length
XS	9209919	≤ 85 mm	
S	9209927	85 ± 5 mm	
M	9209939	95 ± 5 mm	
L	9209942	105 ± 5 mm	
XL	9209953	115 ± 5 mm	

PHYSICAL PROPERTIES

		Min. specification	Typical value
Wall thickness	Finger	0.07 ± 0.02 mm	0.085 mm
	Palm	0.07 ± 0.02 mm	0.073 mm
	Cuff	0.05 ± 0.02 mm	0.054 mm
Force at break	During shelf life	≥ 3.6 N	4 N before ageing
Elongation at break	Before ageing	300%	384 %
	After ageing	300%	
Tensile strength	Before ageing	11 MPa	14 MPa
	After ageing	11 MPa	

GLOVE DESIGN

Colour	white, clear
Shape	straight fingers, ambidextrous fitting
Cuff	rolled rim
Surface finish	smooth
Inner glove surface	polymer coated, powder-free

GLOVE MATERIAL

Polyvinyl chloride (PVC)	
Latex allergy risk	free of latex proteins

PLASTICIZER

DINP (diisononyl phthalate)	
Free of DOP/DEHP (dioctyl phthalate/diethylhexyl phthalate)	

ADDITIVES

Viscosity modifier, Ca-Zn stabilizer	
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LOGISTIC INFORMATION

Dispenser pack dimensions	dispenser pack 100 pcs.	240 x 125 x 60 mm (L x W x H)
Transportation carton	10 dispenser packs	
Shelf life	5 years	
Storage conditions	store at room temperature, protect from dust, humidity, sun light and ozone	



Packaging is made from recycled material