

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

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

EN 374, EN 16523

QUALITY CERTIFICATES

EN ISO 13485:2016

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

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Vasco® Vinyl Powder-free

NON STERILE EXAMINATION AND PROTECTIVE GLOVES | REGULATORY INFORMATION

MEDICAL DEVICE MDR (EU) 2017/745 (CLASS I), EN 455 **INFORMATION (** € ⊗ 🔆 🛣 🕺 30 **FOOD COMPLIANCE** Conformity for food contact according to 1935/2004/EEC (Do not use for fatty food) PERSONAL PROTECTIVE PPE Regulation (EU) 2016/425 (Cat. I) **EQUIPMENT INFORMATION** Tested in accordance with: Code Test chemical FN ISO 374-1:2016 FN ISO 374-4:2013 letter Permeation level Mean degradation ISO 374-1/Type C Κ Level 6 Sodium hydroxide 40% 13,7% Tested acc. to EN 16523-1:2015 Performance levels acc. EN 374-1:2016 +A1:2018 2 3 5 6 1 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

Resistance to virus

pass

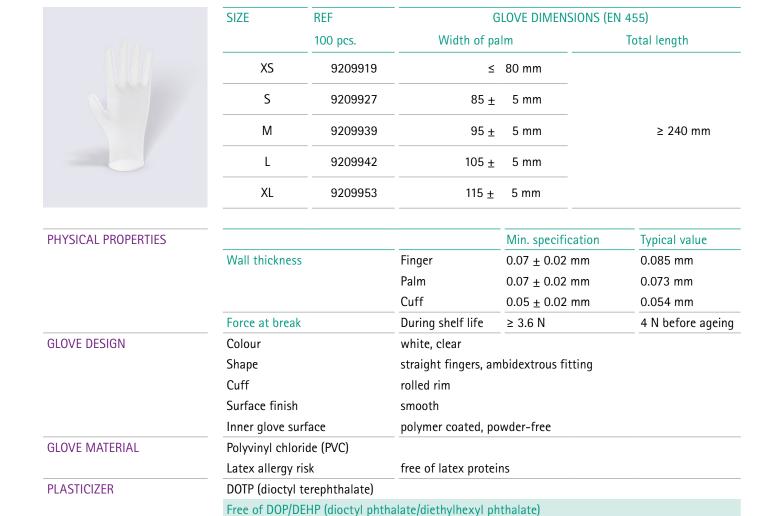
Reference viral penetration: ISO 16604

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



ADDITIVES

Viscosity modifier, Ca–Zn stabilizer

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