B BRAUN SHARING EXPERTISE

# 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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## 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

PPE Regulation (EU) 2016/425 (Cat. III); 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 |
|---|---|---|---|
| L | Sulphuric acid 96 % | Level 1 | 99.4 % |
| M | 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

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.

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

| | | | Min. specification | Typical value |
|---|---|---|---|---|
| PHYSICAL PROPERTIES | 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 | 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. | 200 x 110 x 60 mm (L x W x H) |
| | Transportation carton | 10 dispenser packs | 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 | |