

# Vasco® Nitril Soft white

## NON STERILE EXAMINATION AND PROTECTIVE GLOVES | DATA SHEET



**B. Braun Melsungen AG confirms that  
Vasco® Nitril Soft white 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 D6319

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

EN 420, EN 374, EN 16523, ISO 16604, ASTM F1671, ASTM D6978

### 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](http://www.bbraun.com/gloves-declarations-of-conformity)

[www.hartalega.com.my](http://www.hartalega.com.my)



Hartalega NGC Sdn. Bhd., No.1, Persiaran Tanjung  
Kawasan Perindustrian Tanjung, 43900 Sepang, Selangor Darul Ehsan  
Malaysia

B. Braun Melsungen AG

A handwritten signature in blue ink, which appears to read 'Dr. Hans-Ulrich Gaudin'.

Dr. Hans-Ulrich Gaudin

Head of Global Regulatory Affairs OPM Germany

# Vasco® Nitril Soft white

## 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

Tested in accordance with:

ISO 374-1/Type B



KPT

**CE 2777** PPE Regulation (EU) 2016/425 (Cat. III); EN 420:2003+A1:2009

| Code letter | Test chemical          | EN 374-1:2016 Permeation level | EN 374-4:2013 Mean degradation |
|-------------|------------------------|--------------------------------|--------------------------------|
| K           | Sodium hydroxide 40 %  | Level 6                        | -25,7 %                        |
| P           | Hydrogen peroxide 30 % | Level 2                        | 44,8 %                         |
| T           | Formaldehyde 37 %      | Level 5                        | -17,1 %                        |

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.

AQL 1.0

|                                  |      |
|----------------------------------|------|
| Resistance to bacteria and fungi | pass |
| Resistance to virus              | pass |

ISO 374-5:2016



VIRUS

EN 421:2010



Protection against particulate radioactive contamination.

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<br>200/180* pcs. | GLOVE DIMENSIONS (EN 455) |              |
|------|----------------------|---------------------------|--------------|
|      |                      | Width of palm             | Total length |
| XS   | 9201100              | ≤ 80 mm                   | ≥ 240 mm     |
| S    | 9201110              | 80 ± 10 mm                |              |
| M    | 9201120              | 95 ± 10 mm                |              |
| L    | 9201130              | 110 ± 10 mm               |              |
| XL*  | 9201140              | ≥ 110 mm                  |              |

### PHYSICAL PROPERTIES

|                     |                   | Min. specification | Typical value    |
|---------------------|-------------------|--------------------|------------------|
| Wall thickness      | Finger            | 0.05 mm            | 0.08 mm          |
|                     | Palm              | 0.05 mm            | 0.06 mm          |
|                     | Cuff              | 0.035 mm           | 0.05 mm          |
| Force at break      | During shelf life | 6 N                | 7 N after ageing |
| Elongation at break | Before ageing     | 450%               | 570%             |
|                     | After ageing      | 400%               | 469%             |
| Tensile strength    | Before ageing     | 18 MPa             | 39 MPa           |
|                     | After ageing      | 16 MPa             | 42 MPa           |

### GLOVE DESIGN

|                     |  |
|---------------------|--|
| Colour              | white                                  |
| Shape               | straight fingers, ambidextrous fitting |
| Cuff                | rolled rim, regular cuff               |
| Surface finish      | finger textured                        |
| Inner glove surface | online chlorinated, powder-free        |

### GLOVE MATERIAL

|                                |                        |
|--------------------------------|------------------------|
| Nitrile butadiene rubber (NBR) |                        |
| Latex allergy risk             | free of latex proteins |

### ACCELERATORS

|  |  |
|--|--|
| Zn-dithiocarbamate                               |  |
| Free of thiurames and mercaptobenzothiazoles MBT |  |

### LOGISTIC INFORMATION

|                       |  |                                |
|-----------------------|--|--------------------------------|
| Dispenser pack        | 200/180 pcs.   | 245 x 124 x 74 mm (L x W x H)  |
| Transportation carton | 10 dispenser packs   | 382 x 262 x 257 mm (L x W x H) |
| Shelf life            | 3 years  |                                |
| Storage conditions    | store at room temperature,<br>protect from dust, humidity, sun light and ozone |                                |



Packaging is made from recycled material

# Vasco® Nitril Soft white

## NON STERILE EXAMINATION AND PROTECTIVE GLOVES | BARRIER PROPERTIES – CHEMICALS



Tested by SATRA, UK in accordance with

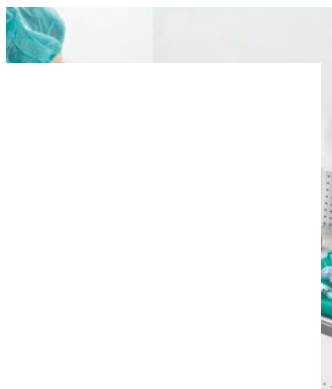
**EN 374-3**: Protective gloves against chemicals and micro-organisms – Determination of resistance to permeation by chemicals.

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

| CHEMICAL                    | CAS REGISTRY NO. | PERMEATION PERFORMANCE LEVEL | BREAKTHROUGH TIME |
|-----------------------------|------------------|------------------------------|-------------------|
| Acetone                     | 67-64-1          | not recommended              | immediate         |
| Ammonium hydroxide 25 %     | 1336-21-6        | not recommended              | immediate         |
| Chlorhexidine gluconate 4 % | 55-56-1          | level 6                      | > 480 min         |
| Ethanol 35 %                | 64-17-5          | level 1                      | > 10 min          |
| Formaldehyde 37 %           | 50-00-0          | level 5                      | > 240 min         |
| Formalin 10 %               | 50-00-0          | level 6                      | > 480 min         |
| Glutaraldehyde 1 %          | 111-30-8         | level 6                      | > 480 min         |
| Glutaraldehyde 50 %         | 111-30-8         | level 6                      | > 480 min         |
| Glycolic acid 2.5 %         | 79-14-1          | level 6                      | > 480 min         |
| Heptane-n                   | 142-82-5         | not recommended              | immediate         |
| Hexane-n                    | 110-54-3         | not recommended              | immediate         |
| Hydrogen peroxide 3 %       | 7722-84-1        | level 6                      | > 480 min         |
| Hydrogen peroxide 30 %      | 7722-84-1        | level 2                      | > 30 min          |
| Isopropanol 100 %           | 67-63-0          | not recommended              | immediate         |
| Sodium hydroxide 40 %       | 1310-73-2        | level 6                      | > 480 min         |
| Sodium percarbonate 15%     | 15630-89-4       | level 6                      | > 480 min         |

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## NON STERILE EXAMINATION AND PROTECTIVE GLOVES | BARRIER PROPERTIES – CYTOSTATIC DRUGS



Tested by ARDL, USA in accordance with

**ASTM D 6978:** Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs. Minimum detection rate 0,01 µg/cm²/min

- Not suitable
- Suitable if changed before permeation breakthrough
- Suitable for prolonged use

| CHEMOTHERAPY DRUG         | MG/ML | CAS REGISTRY NO. | MIN BREAKTHROUGH<br>DETECTION TIME |
|---------------------------|-------|------------------|------------------------------------|
| Carmustine                | 3.3   | 154-93-8         | 14 min                             |
| Cisplatin                 | 1.0   | 15663-27-1       | > 240 min                          |
| Cyclophosphamide          | 20.0  | 6055-19-2        | > 240 min                          |
| Dacarbazine               | 10.0  | 4342-03-4        | > 240 min                          |
| Doxorubicin hydrochloride | 2.0   | 25316-40-9       | > 240 min                          |
| Etoposide                 | 20.0  | 33419-42-0       | > 240 min                          |
| Fluorouracil              | 50.0  | 51-21-8          | > 240 min                          |
| Methotrexate              | 25.0  | 59-05-2          | > 240 min                          |
| Mitomycin C               | 0.5   | 50-07-7          | > 240 min                          |
| Paclitaxel (Taxol)        | 6.0   | 33069-62-4       | > 240 min                          |
| Thio-Tepa                 | 10.0  | 52-24-4          | 24 min                             |
| Vincristine sulfate       | 1.0   | 2068-78-2        | > 240 min                          |