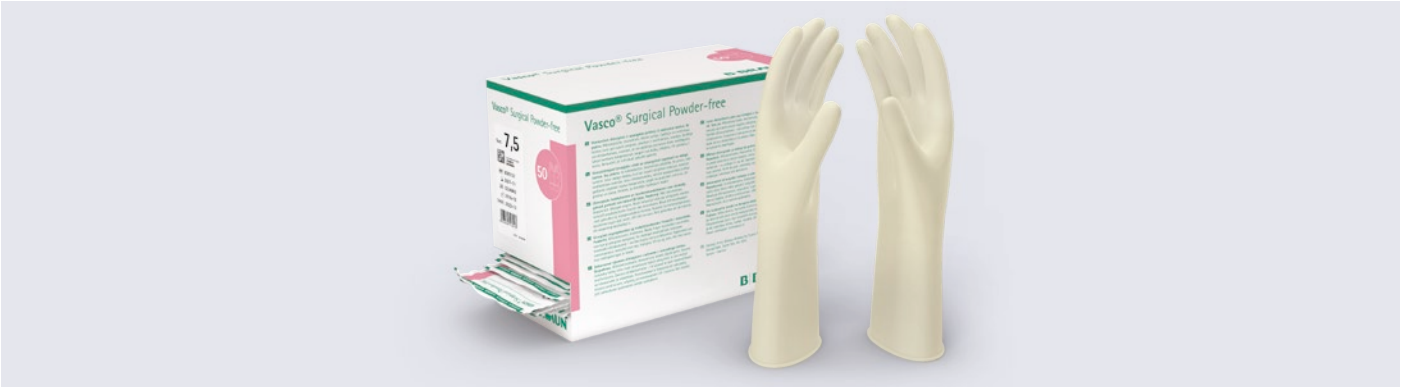
# Vasco® Surgical Powder-free

## STERILE SURGICAL AND PROTECTIVE GLOVES | DATA SHEET




**B. Braun Melsungen AG confirms that**
**Vasco® Surgical Powder-free gloves comply with the following standards, directives and regulations:**

EC CERTIFICATES AND APPLIED STANDARDS

Medical Device Class IIa CE 0123 (TÜV Süd, DE), according to MDD 93/42/EEC

EN 455 1-4, ISO 10282, ISO 10993, ISO 11137

ASTM D3577, ASTM D5712, ASTM D6978

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

EN 421, EN 420, EN 374, ISO 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

B. Braun Melsungen AG

Dr. Hans-Ulrich Gaudin
Head of Global Regulatory Affairs OPM Germany

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## STERILE SURGICAL AND PROTECTIVE GLOVES | REGULATORY INFORMATION

### MEDICAL DEVICE INFORMATION

MDD 93/42/EEC (CLASS IIa), EN 455

CE 0123

### PERSONAL PROTECTIVE EQUIPMENT INFORMATION

CE 2777

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

Tested in accordance with:

ISO 374-1:2016/Type B

KPT

| Code letter | Test chemical | EN 374-1:2016 Permeation level | EN 374-4:2013 Mean degradation |
|---|---|---|---|
| K | Sodium hydroxide 40 % | Level 6 | -11,0 % |
| P | Hydrogen peroxide 30 % | Level 6 | 10,1 % |
| T | Formaldehyde 37 % | Level 6 | 2,6 % |

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 0.65

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

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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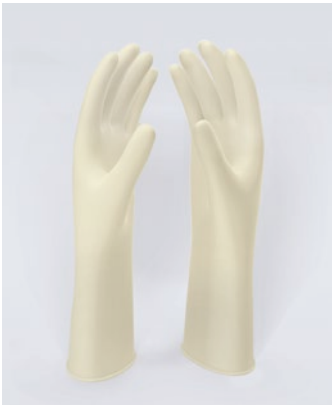
## STERILE SURGICAL AND PROTECTIVE GLOVES | TECHNICAL DATA



| SIZE | REF | GLOVE DIMENSIONS (EN 455) Width of palm | Total length |
|---|---|---|---|
| 5.5 | 6081100 | 70 ± 4 mm | ≥ 290 mm |
| 6 | 6081101 | 77 ± 5 mm | |
| 6.5 | 6081111 | 83 ± 5 mm | |
| 7 | 6081121 | 89 ± 5 mm | |
| 7.5 | 6081131 | 95 ± 5 mm | |
| 8 | 6081141 | 102 ± 6 mm | |
| 8.5 | 6081151 | 108 ± 6 mm | |
| 9 | 6081161 | 114 ± 6 mm | |

| | | | Min. specification | Typical value |
|---|---|---|---|---|
| PHYSICAL PROPERTIES | Wall thickness | Palm | 0.21 mm | 0.21 mm |
| | | Cuff | 0.17 mm | 0.17 mm |
| | Force at break (acc. to EN 455) | During shelf life | 9 N | 15 N before ageing<br>13 N after ageing |
| | Elongation at break (acc. to ASTM D 3577) | Before ageing | 750 % | 891 % |
| | | After ageing | 560 % | 869 % |
| | Tensile strength (acc. to ASTM D 3577) | Before ageing | 24 MPa | 29 MPa |
| | | After ageing | 18 MPa | 26 MPa |
| GLOVE DESIGN | Colour | natural white | | |
| | Shape | fully anatomical shape with curved fingers | | |
| | Cuff | rolled rim | | |
| | Surface finish | textured palm and finger area, silicone treated | | |
| | Inner glove surface | polymer coated, powder-free | | |
| GLOVE MATERIAL | Natural rubber latex | protein content < 50 µg/g | | |
| | Latex allergy risk | containing natural rubber latex which may cause allergic reactions including anaphylactic reactions | | |
| ACCELERATORS | Zn-dithiocarbamate | | | |
| | Free of thiurames, thioureas and thiazoles - including mercaptobenzothiazole MBT | | | |
| STERILIZATION | Electron beam radiation | | | |
| LOGISTIC INFORMATION | Peel pouch | 1 pair | 270 x 140 mm (L x W) | |
| | Dispenser pack | 50 pairs | 270 x 140 x 215 mm (L x W X H) | |
| | Transportation carton | 4 dispenser packs | 548 x 147 x 439 mm (L x W X H) | |
| | Shelf life | 5 years | | |
| | Storage conditions | store at room temperature, protect from dust, humidity, sun light and ozone | | |

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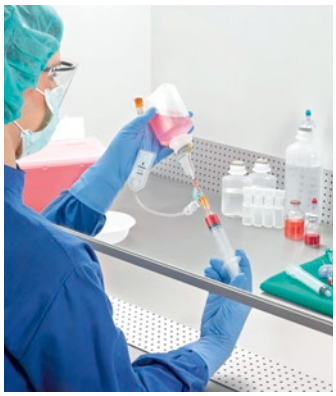
## STERILE SURGICAL AND PROTECTIVE GLOVES | BARRIER PROPERTIES – CYTOSTATIC DRUGS



CLASSIFICATION

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

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

| CHEMOTHERAPY DRUG | mg/ml | CAS registry no. | MIN BREAKTHROUGH DETECTION TIME |
|---|---|---|---|
| Carmustine | 3.3 | 154-93-8 | > 240 min |
| Cisplatin | 1.0 | 15663-27-1 | > 240 min |
| Cyclophosphamide monohydrate | 20.0 | 6055-19-2 | > 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 |
| Mitoxantrone | 2.0 | 65271-80-9 | > 240 min |
| Paclitaxel (Taxol) | 6.0 | 33069-62-4 | > 240 min |
| Thio-Tepa | 10.0 | 52-24-4 | > 240 min |