

Vasco® OP Underglove

STERILE SURGICAL AND PROTECTIVE GLOVES | DATA SHEET



B. Braun Melsungen AG confirms that Vasco® OP Underglove 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

ISO 9001, ISO 13485

QUALITY CERTIFICATES

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

A handwritten signature in blue ink, appearing to read 'H. Gaudin', is written over a faint blue line.

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

Vasco® OP Underglove

STERILE SURGICAL AND PROTECTIVE GLOVES | REGULATORY INFORMATION

MEDICAL DEVICE INFORMATION

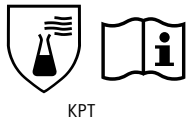
MDD 93/42/EEC (CLASS IIa), EN 455



PERSONAL PROTECTIVE EQUIPMENT INFORMATION

Tested in accordance with:

ISO 374-1:2016/Type B



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	-13,0%
P	Hydrogen peroxide 30%	Level 6	-9,1%
T	Formaldehyde 37%	Level 6	-0,2%

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



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	6081199	73 ± 3 mm	≥ 270 mm
6	6081200	79 ± 3 mm	≥ 270 mm
6.5	6081218	85 ± 3 mm	≥ 270 mm
7	6081226	91 ± 3 mm	≥ 280 mm
7.5	6081234	97 ± 3 mm	≥ 280 mm
8	6081242	105 ± 3 mm	≥ 280 mm
8.5	6081259	111 ± 3 mm	≥ 285 mm
9	6081267	112 ± 3 mm	≥ 285 mm

PHYSICAL PROPERTIES

		Min. specification	Typical value
Wall thickness	Palm	0.17 mm	0.20 mm
	Cuff	0.145 mm	0.165 mm
Force at break (acc. to EN 455)	During shelf life	9 N	15 N before ageing 11 N after ageing
Elongation at break (acc. to ASTM D 3577)	Before ageing	750%	823%
	After ageing	560%	855%
Tensile strength (acc. to ASTM D 3577)	Before ageing	24 MPa	28 MPa
	After ageing	18 MPa	21 MPa

GLOVE DESIGN

Colour	green
Shape	fully anatomical shape with curved fingers
Cuff	rolled rim
Surface finish	micro rough, silicone treated
Inner glove surface	polymer coated, powder-free
Natural rubber latex	Protein content ≤ 50 µg/g, lower claims are not considered to be reliable given the expected process variation in manufacture and inter-laboratory testing (EN 455-3)
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
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STERILIZATION

Gamma irradiation	
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LOGISTIC INFORMATION

Peel pouch	1 pair	270 x 150 mm (L x W)
Dispenser pack	40 pairs	270 x 150 x 205 mm (L x W x H)
Transportation carton	10 dispenser packs	785 x 283 x 417 mm (L x W x H)
Shelf life	3 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 – 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
Acetic acid 10%	64-19-7	level 6	> 480 min
Acetone	67-64-1	not recommended	immediate
Acetonitrile	75-05-8	not recommended	1 - 10 min
Acryl amide 40%	79-06-1	level 6	> 480 min
Ammonium hydroxide 25 %	1336-21-6	not recommended	1 - 10 min
Chlorhexidine digluconate 0.5 %	18472-51-0	level 6	> 480 min
Chloroform	67-66-3	not recommended	immediate
Dichloromethane	75-09-2	not recommended	immediate
Diethylamine	109-89-7	not recommended	immediate
Diethyl ether	60-29-7	not recommended	immediate
Ethanol 10%	64-17-5	not recommended	1 - 10 min
Ethanol 20%	64-17-5	not recommended	1 - 10 min
Ethanol 70%	64-17-5	not recommended	immediate
Ethidium bromide 1 %	1239-45-8	level 6	> 480 min
Ethyl acetate	141-78-6	not recommended	immediate
Formaldehyde 37 %	50-00-0	level 6	> 480 min
Glutaraldehyde 5 %	111-30-8	level 6	> 480 min
Heptane-n	142-82-5	not recommended	immediate
Hexane-n	110-54-3	not recommended	immediate
Hydrochloric acid 10 %	7647-01-0	level 6	> 480 min
Hydrochloric acid 36%	7647-01-0	level 3	> 60 min
Hydrogen peroxide 30 %	7722-84-1	level 6	> 480 min
Isopropyl alcohol 70 %	67-63-0	not recommended	1 - 10 min
Methanol p.a.	67-56-1	not recommended	immediate
Methyl methacrylate	80-62-6	not recommended	immediate
Ninhydrin 0,2 %	485-47-2	level 6	> 480 min
Nitric acid 10 %	7697-37-2	level 6	> 480 min
Phosphoric acid 85 %	7664-38-2	level 6	> 480 min
Potassium hydroxide 50 %	1310-58-3	level 6	> 480 min
Povidone-iodine 10 %	25655-41-8	level 6	> 480 min
Sodium hydroxide 40 %	1310-73-2	level 6	> 480 min
Sodium hypochlorite 10 %	7681-52-9	level 6	> 480 min
Sulfuric acid 30 %	7664-93-9	level 6	> 480 min
Sulfuric acid 96 %	7664-93-9	level 1	> 10 min
Toluene	108-88-3	not recommended	immediate
Trichloroethane	71-55-6	not recommended	immediate
Xylene	95-47-6	not recommended	immediate

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STERILE SURGICAL 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

CLASSIFICATION

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

CHEMOTHERAPY DRUG	mg/ml	CAS registry no.	MIN BREAKTHROUGH DETECTION TIME
Bleomycin sulphate	15	9041-93-4	■ > 240 min
Carboplatin	10	41575-94-4	■ > 240 min
Carmustine	3.3	154-93-8	■ 13 min
Cisplatin	1	15663-27-1	■ > 240 min
Cyclophosphamide	20	50-18-0	■ > 240 min
Cytarabine	100	147-94-4	■ > 240 min
Dacarbazine	10	4342-03-4	■ > 240 min
Daunorubicin HCl	5	23541-50-6	■ > 240 min
Docetaxel	10	114977-28-5	■ > 240 min
Doxorubicin hydrochloride	2	25316-40-9	■ > 240 min
Etoposide	20	33419-42-0	■ > 240 min
Fluorouracil	50	51-21-8	■ > 240 min
Gemcitabine HCl	38	122111-03-9	■ > 240 min
Idarubicin HCl	1	57852-57-0	■ > 240 min
Irinotecan HCl	20	100286-90-6	■ > 240 min
Ifosfamide	50	3778-73-2	■ > 240 min
Methotrexate	25	59-05-2	■ > 240 min
Mitomycin C	0.5	50-07-7	■ > 240 min
Mitoxantrone HCl	2	70476-82-3	■ > 240 min
Oxaliplatin	5	61825-94-3	■ > 240 min
Paclitaxel (Taxol)	6	33069-62-4	■ > 240 min
Thio-Tepa	10	52-24-4	■ 11 min
Topotecan HCl	1	119413-54-6	■ > 240 min
Vinblastin sulfate	1	143-67-9	■ > 240 min
Vincristine sulfate	1	2068-78-2	■ > 240 min
Vinorelbine ditartrate	0.1	125317-39-7	■ > 240 min