

Vasco® OP Powdered

STERILE SURGICAL AND PROTECTIVE GLOVES | DATA SHEET



**B. Braun Melsungen AG confirms that
Vasco® OP Powdered 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

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', positioned above the printed name of the signatory.

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



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	2,1%
P	Hydrogen peroxide 30%	Level 6	19,0%
T	Formaldehyde 37%	Level 6	-26,0%

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
6	6031510	79 ± 3 mm	≥ 270 mm
6.5	6031525	85 ± 3 mm	≥ 270 mm
7	6031532	91 ± 3 mm	≥ 280 mm
7.5	6031546	97 ± 3 mm	≥ 280 mm
8	6031553	104 ± 3 mm	≥ 280 mm
8.5	6031564	111 ± 3 mm	≥ 285 mm

PHYSICAL PROPERTIES

		Min. specification	Typical value
Wall thickness	Palm	0.195 mm	0.21 mm
	Cuff	0.17 mm	0.175 mm
Force at break (acc. to EN 455)	During shelf life	9 N	18 N before ageing 16 N after ageing
Elongation at break (acc. to ASTM D 3577)	Before ageing	750%	810%
	After ageing	560%	837%
Tensile strength (acc. to ASTM D 3577)	Before ageing	24 MPa	31 MPa
	After ageing	18 MPa	30 MPa

GLOVE DESIGN

Colour	natural white
Shape	fully anatomical shape with curved fingers
Cuff	rolled rim
Surface finish	micro rough, silicone treated
Inner glove surface	polymer coated
Powder	corn starch powder

GLOVE MATERIAL

Natural rubber latex	Protein content < 53.6 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

Gamma irradiation	
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LOGISTIC INFORMATION

Peel pouch	1 pair	270 x 150 mm (L x W)
Dispenser pack	50 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	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 – 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
Benzalconiumchloride liquid (Quats)	63449-41-2	not recommended	immediate
Chlorhexidine digluconate 0.5 %	18472-51-0	level 6	> 480 min
Ethanol 10 %	64-17-5	not recommended	1 - 10 min
Ethanol 20 %	64-17-5	not recommended	immediate
Ethidium bromide 1 %	1239-45-8	level 6	> 480 min
Formaldehyde 37 %	50-00-0	level 6	> 480 min
Glutaraldehyde 5 %	111-30-8	level 6	> 480 min
Hydrochloric acid 10 %	7647-01-0	level 6	> 480 min
Hydrogen peroxide 30 %	7722-84-1	level 6	> 480 min
Isopropyl alcohol 70 %	67-63-0	not recommended	immediate
Methanol p.a.	67-56-1	not recommended	immediate
Povidone-iodine 10 %	25655-41-8	level 5	> 240 min
Sodium hydroxide 40 %	1310-73-2	level 5	> 240 min
Sodium hypochlorite 10 %	7681-52-9	level 6	> 480 min
Sulfuric acid 96 %	7664-93-9	level 1	> 10 min