

Vasco® Surgical Powdered

STERILE SURGICAL AND PROTECTIVE GLOVES | DATA SHEET



B. Braun Melsungen AG confirms that Vasco® Surgical 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'.

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

Tested in accordance with:

ISO 374-1:2016/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	-17,0%
P	Hydrogen peroxide 30%	Level 6	-0,9%
T	Formaldehyde 37%	Level 6	-1,4%

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	6035567	70 ± 4 mm	≥ 280 mm
6	6035500	77 ± 5 mm	
6.5	6035518	83 ± 5 mm	
7	6035526	89 ± 5 mm	
7.5	6035534	95 ± 5 mm	
8	6035542	102 ± 6 mm	
8.5	6035559	108 ± 6 mm	
9	6035575	114 ± 6 mm	

PHYSICAL PROPERTIES

		Min. specification	Typical value
Wall thickness	Palm	0.18 mm	0.19 mm
	Cuff	0.16 mm	0.17 mm
Force at break (acc. to EN 455)	During shelf life	9 N	14 N before ageing 12 N after ageing
Elongation at break (acc. to ASTM D 3577)	Before ageing	750%	872%
	After ageing	560%	856%
Tensile strength (acc. to ASTM D 3577)	Before ageing	24 MPa	27 MPa
	After ageing	18 MPa	25 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	powdered
Powder	corn starch powder

GLOVE MATERIAL

Natural rubber latex	protein content < 60 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	