

Vasco® Surgical Micro

STERILE SURGICAL AND PROTECTIVE GLOVES | DATA SHEET



**B. Braun Melsungen AG confirms that
Vasco® Surgical Micro 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, which appears to read 'H. Gaudin'.

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

Vasco® Surgical Micro

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	-19,7 %
P	Hydrogen peroxide 30 %	Level 6	-10,5 %
T	Formaldehyde 37 %	Level 6	-45,0 %

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.

AQL 0.65

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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STERILE SURGICAL AND PROTECTIVE GLOVES | TECHNICAL DATA



SIZE	REF	GLOVE DIMENSIONS (EN 455)	
		Width of palm	Total length
5.5	6035800	72 ± 4 mm	≥ 290 mm
6	6035812	77 ± 5 mm	
6.5	6035824	83 ± 5 mm	
7	6035836	89 ± 5 mm	
7.5	6035848	95 ± 5 mm	
8	6035851	102 ± 6 mm	
8.5	6035863	108 ± 6 mm	
9	6035875	114 ± 6 mm	

PHYSICAL PROPERTIES

		Min. specification	Typical value
Wall thickness	Finger	0.18 mm	0.20 mm
	Palm	0.17 mm	0.19 mm
	Cuff	0.16 mm	0.16 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 %	873 %
	After ageing	600 %	839 %
Tensile strength (acc. to ASTM D 3577)	Before ageing	24 MPa	28 MPa
	After ageing	18 MPa	26 MPa

GLOVE DESIGN

Colour	tan
Shape	fully anatomical shape with curved fingers
Cuff	rolled rim
Surface finish	micro rough, 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 250 mm (L x W X H)
Transportation carton	4 dispenser packs	548 x 147 x 508 mm (L x W X H)
Shelf life	5 years	
Storage conditions	store at room temperature, protect from dust, humidity, sun light and ozone	