

Vasco[®] OP Protect Sterile Surgical and Protective Gloves

DATA SHEET



STERILE R



AQL 0.65

B. Braun Melsungen AG confirms that Vasco[®] OP Protect gloves comply with the following standards and directives:

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 CE 0321 (SATRA, UK)
according to 89/686/EEC
EN 420, EN 374 1-3, EN 16523, EN 388,
ASTM F1671

QUALITY CERTIFICATES

ISO 9001, ISO 13485

Certificates and complete list of applied standards are available on request.

B. Braun Melsungen AG

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

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TECHNICAL DATA



REF	SIZE	GLOVE DIMENSIONS (ACC. EN 455)		WALL THICKNESS Single wall
		Width of palm	Total length	
6035000	6	79 ± 3 mm	≥ 270 mm	
6035019	6.5	85 ± 3 mm	≥ 270 mm	finger ≥ 0.175 mm
6035027	7	91 ± 3 mm	≥ 280 mm	
6035035	7.5	97 ± 3 mm	≥ 280 mm	palm ≥ 0.195 mm
6035043	8	105 ± 3 mm	≥ 280 mm	cuff ≥ 0.17 mm
6035051	8.5	111 ± 3 mm	≥ 285 mm	

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 < 74,6 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	

PHYSICAL PROPERTIES

Force at break (median)	≥ 9 N during shelf life		
Elongation at break (median)	before ageing	≥ 850 %	after ageing ≥ 840 %
Tensile strength (median)	before ageing	≥ 30 MPa	after ageing ≥ 28 MPa
Water-tightness	AQL 0.65		

STERILIZATION

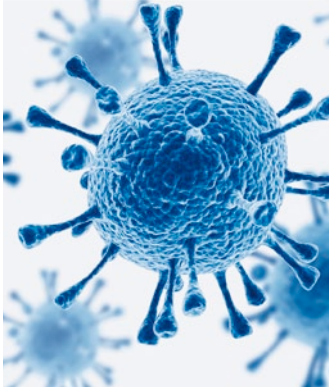
Gamma irradiation

LOGISTIC INFORMATION

Peel pouch	sterile film peel packs with 1 pair of gloves left/right with folded cuffs in paper cover		
Packaging dimensions	peel pouch	270 x 150 mm	
	dispenser box	270 x 150 x 205 mm (L x W x H)	
Packaging levels	50 pairs/box	10 boxes/carton (500 pairs)	
Shelf life	5 years		
Storage conditions	store at room temperature, protect from dust, humidity, sun light and ozone		

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BARRIER PROPERTIES – VIRAL PENETRATION



Tested by NELSON, USA in accordance with

ASTM F 1671: Standard Test Method for Resistance of Materials used in Protective Clothing to Penetration by Blood Borne Pathogens using Phi-X 174 Bacteriophage Penetration as a Test System.

Specimens that exhibit no detectable (< 1 PFU/mL) Phi-X174 in the assay titer pass the test.

TEST RESULT	ASSESSMENT		VALUE
Pass	No plaques	No virus penetration	< 1 PFU/mL (PFU: Plaque-forming unit)

NOTE

All tests are conducted under laboratory conditions. The product properties are directly dependant upon the conditions of use. The gloves should be checked in advance for any holes or tears. Damaged or swelling gloves must be replaced immediately. In general, it is recommended to change gloves after 1-2 hours of working. In special cases, double gloving (colored underglove as indicator glove and white overglove) may be appropriate.

Tests and certificates can only be regarded as general information and do not reflect all actual working conditions. Glove selection shall be based on a risk assessment procedure. Hand hygiene by rubbing or washing is basic for hand decontamination before and after glove use.