



# Vasco® OP | Technical Data Sheet

## Surgical Gloves (sterile)

Device variants	Size	Vasco® OP Free	Vasco® OP Underglove	Vasco® OP Sensitive	Vasco® OP Protect
	5.5	REF 9208291	REF 6081199	REF 6080990	
	6	REF 9208305	REF 6081200	REF 6081002	REF 6035000
	6.5	REF 9208313	REF 6081218	REF 6081010	REF 6035019
	7	REF 9208321	REF 6081226	REF 6081029	REF 6035027
	7.5	REF 9208330	REF 6081234	REF 6081037	REF 6035035
	8	REF 9208348	REF 6081242	REF 6081045	REF 6035043
	8.5	REF 9208356	REF 6081259	REF 6081053	REF 6035051
	9	REF 9208364	REF 6081267	REF 6081060	
<b>Logistic information:</b>					
Peel pouch		sterile film peel packs with 1 pair of gloves left/right with folded cuffs in paper cover			
Packaging dimensions	peel pouch	285 x 150 mm			
	dispenser box	270 x 150 x 205 mm (L x W x H)			
Packaging levels	pairs/box	40	40	40	50
	boxes/carton	10 (400 pairs)	10 (400 pairs)	10 (400 pairs)	10 (500 pairs)
Storage	shelf life	3 years	3 years	3 years	5 years
	conditions	store at room temperature, protect from dust, humidity and sun light			
Sterilization		gamma irradiation			
<b>Glove dimensions:</b>					
Width of palm (median)	5.5	73 ± 3 mm	73 ± 3 mm	73 ± 3 mm	
	6	79 ± 3 mm	79 ± 3 mm	79 ± 3 mm	79 ± 3 mm
	6.5	85 ± 3 mm	85 ± 3 mm	85 ± 3 mm	85 ± 3 mm
	7	91 ± 3 mm	91 ± 3 mm	91 ± 3 mm	91 ± 3 mm
	7.5	97 ± 3 mm	97 ± 3 mm	97 ± 3 mm	97 ± 3 mm
	8	105 ± 3 mm	105 ± 3 mm	105 ± 3 mm	105 ± 3 mm
	8.5	111 ± 3 mm	111 ± 3 mm	111 ± 3 mm	111 ± 3 mm
	9	112 ± 3 mm	112 ± 3 mm	112 ± 3 mm	
Total length (median)	5.5 – 6.5	≥ 270 mm	≥ 270 mm	≥ 270 mm	≥ 270 mm
	7 - 8	≥ 280 mm	≥ 280 mm	≥ 280 mm	≥ 280 mm
	8.5 - 9	≥ 285 mm	≥ 285 mm	≥ 285 mm	≥ 285 mm
Wall thickness (single wall)	finger	≥ 0.185 mm	≥ 0.165 mm	≥ 0.175 mm	≥ 0.175 mm
	palm	≥ 0.19 mm	≥ 0.17 mm	≥ 0.195 mm	≥ 0.195 mm
	cuff	≥ 0.175 mm	≥ 0.145 mm	≥ 0.16 mm	≥ 0.17 mm



	Vasco® OP Free	Vasco® OP Underglove	Vasco® OP Sensitive	Vasco® OP Protect	
<b>Glove design:</b>					
Colour	cream-coloured	green	natural white	natural white	
Shape	fully anatomical shape with curved fingers				
Cuff	rolled rim				
Surface finish	micro rough, silicone treated				
Inner glove surface	polymer coated				
Glove material	polyisoprene	natural rubber latex	natural rubber latex	natural rubber latex	
Latex allergy risk		containing natural rubber latex which may cause allergic reactions including anaphylactic reactions			
Protein content	free of latex	≤ 30 µg/g	≤ 30 µg/g	*	
Powder	powder-free	powder-free	powder-free	corn starch powder **	
<b>Additives:</b>					
Accelerators	Zn-dithiocarbamate, xanthogenate	Zn-dithiocarbamate	Zn-dithiocarbamate	Zn-dithiocarbamate	
<b>Free of</b>	<b>thiazoles – including mercaptobenzothiazole MBT, thiurames, thioureas</b>				
Vulcanization agent	sulphur				
Activator	zinc oxide				
Ageing protector	sterically modified phenols				
<b>Physical properties:</b>					
Force at break (median)	≥ 9 N during shelf life				
Elongation at break (median)	before ageing	≥ 880 %	≥ 840 %	≥ 830 %	≥ 850 %
	after ageing	≥ 800 %	≥ 830 %	≥ 820 %	≥ 840 %
Tensile strength (median)	before ageing	≥ 26 MPa	≥ 27 MPa	≥ 30 MPa	≥ 30 MPa
	after ageing	≥ 25 MPa	≥ 20 MPa	≥ 26 MPa	≥ 28 MPa
Water-tightness	AQL 1.0				
Applied standards	ISO 10282, EN 455 1-4, EN 374-3 ***, ISO 16604, ISO 11137, ASTM D3577, ASTM F1671, ASTM D5712 / ASTM D6978 ***				
EC certificate	Medical device class IIa CE 0123, according to MDD 93/42/EEC				
Quality certificates	ISO 9001, ISO 13485				

\* only indicated for powder-free latex gloves \*\* quantity adequate for easy donning, conform to United States Pharmacopoeia \*\*\* not applicable for Vasco® OP Protect