

# Biogel® Tech

Sterile natural rubber latex critical environment glove



Biogel® Tech is a durable all-purpose critical environment glove. It offers excellent barrier protection<sup>1,2</sup> as well as fit, feel and comfort<sup>3</sup>. It has been tested and cleared for use with chemotherapy agents.



## Biogel® key features and benefits:

- AQL\* result of 0.65, determined post packaging<sup>4</sup>
- Every glove (100%) is air-inflation tested for holes typically not detected in a visual inspection<sup>5</sup>
- PPE Category III, certified to Type C chemical permeation testing
- Low endotoxin level (<20 EU/pair)<sup>4</sup>
- Total Liquid Particle Count ( $\geq 0.5\mu\text{m}$ ): < 35200 counts/cm<sup>2</sup> <sup>6</sup>

## Material information

- Natural rubber latex
- Biogel hydrogel polymer coating
- Straight finger and textured surface
- Beaded cuff
- Powder-free

## Recommended use

The Biogel Tech is recommended to be used in any critical environment or controlled environment when a high quality sterile glove is required for protection from cross contamination, and when natural rubber latex allergy is not a concern.

## Biogel quality

Biogel gloves are designed to be comfortable with maintained tactile sensitivity even when double gloving<sup>3,7</sup>. They are manufactured using rigorous quality checks, numerous washing cycles<sup>4</sup> and air-inflation testing of every single glove<sup>5</sup>.

## Ordering information REF 44961

REF	Size	Pairs
4496155	5½	25x2/polybag
4496160	6	25x2/polybag
4496165	6½	25x2/polybag
4496170	7	25x2/polybag
4496175	7½	25x2/polybag
4496180	8	25x2/polybag
4496185	8½	25x2/polybag
4496190	9	20x2/polybag

4 polybags per case

\*AQL=Acceptable Quality Level refers to the maximum number of defective products that could be considered acceptable during the random sampling of an inspection, in this case freedom from holes in gloves. The lower the number, the fewer the holes and the higher the glove quality.

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## Biogel® Tech REF 44961 – Product specifications

REF	Size	Length, mm (Tolerance ±15mm)	Lay flat palm width, mm (±3 mm) 5.5- (+2,-4)
4496155	5½	280	74
4496160	6	280	79
4496165	6½	280	85
4496170	7	285	90
4496175	7½	285	96
4496180	8	295	101
4496185	8½	295	106
4496190	9	302	114

### Typical thickness profile – single wall

Cuff	8.1 mils	0.21 mm
Palm	10.0 mils	0.26 mm
Finger	11.0 mils	0.28 mm

### Biogel Tech are tested and manufactured to the following standards

PPE Regulation	(EU) 2016/425 Category III
Particle count	IEST-RP-CC005.4: Total Liquid Particle Count (0.5µm): < 35200 counts/cm²
Quality/Environment	ISO 13485, ISO 14001
Product	EN 455-1, EN 455-2, EN 455-3, EN 455-4, ASTM D3577, ISO 10282, EN ISO 374-1, EN ISO 374-2, EN ISO 374-4, EN 16523-1, EN ISO 374-5
Sterilisation	ISO 11137, Gamma Irradiation, SAL 10 <sup>-6</sup> (at ≥ 25 kGy dose)
Viral penetration	Bacteriophage Test, ISO 16604
Allergenicity	ISO 10993 (Part 5 and 10)
Pyrogenicity	ASTM D7102
Labelling/ Packaging	EN 556-1, EN ISO 15223-1, EN ISO 21420

## General information

**Contra-indications:** This product contains natural rubber latex, which may cause allergic reactions including anaphylactic responses.

**Allergenicity:** Biogel gloves are produced to have low levels of aqueous extractable protein.

**Pyrogenicity:** Each batch of Biogel gloves is tested to have a low endotoxin level (<20 EU/pair).

**Registering authority:** In Europe the gloves are CE-marked (notified body BSI, number 2797) and UKCA marked in the UK (authorised body BSI 0086) indicating compliance with PPE Regulation (EU) 2016/425.

**Storage:** Store in a dry place at a temperature of 5-25°C, away from sources of heat or direct sunlight.

**References:** 1. Aldyami, Ehab; Kulkarni, Ashwin; et al. Latex-free gloves Safer for Whom?; The Journal of Arthroplasty; 2010; Vol. 25 No. 1 pp. 27-30. 2. Naver, Lars P.S.; Gotttrup, Finn; Incidence of glove perforations in gastrointestinal surgery and the protective effect of double gloves: A prospective, Randomized controlled study; Eur J. Surg 2000; Vol 166 pp. 293-295. 3. Carter S, Choong S, Marino A, Sellu D. Can surgical gloves be made thinner without increasing their liability to puncture? Ann R Coll Surg Engl. 1996 May;78(3 [Pt 1]):186-7. 4. Summary of Technical Documents. Mölnlycke Health Care. Data on File. 5. Internal SOP. Automatic Glove Inspection by QMAX. Mölnlycke Health Care. Data on File. 6. Liquid Particle Count for Biogel Gloves. Mölnlycke Health Care, 2016. Data on File. 7. Fry D E et al. Influence of double-gloving on manual dexterity and tactile sensation of surgeons. J Am Coll Surg. 2010; 210(3):325-30.

Find out more at [www.molnlycke.com](http://www.molnlycke.com)

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Physical glove properties	Standard requirement	Biogel Tech Typical value
<b>Force at break (N)</b>		
Initial	≥9	17
Aged	≥ 9	16
<b>Tensile strength (MPa)</b>		
Initial	≥ 24	28
Aged	≥ 18	26
<b>Modulus stress @500% elongation (MPa)</b>		
Initial	5.5 max	3.0
Aged	n/a	2.6
<b>Elongation at break (%)</b>		
Initial	≥ 750	910
Aged	≥ 560	960
<b>Typical accelerator analysis (% w/w)</b>		
Dithiocarbamate (DTC)	n/a	<0.02
Diphenyl thiourea (DPTU)	n/a	none
Diphenylguanidine (DPG)	n/a	none
Zinc mercaptobenzothiazole (ZMBT)	n/a	none
Thiurams	n/a	none
<b>Typical extractable protein (µg/g)</b> (using Modified Lowry EN455-3/ASTM D5712)		
	<50	<50
<b>AQL freedom from holes (1000ml water leak test)</b>		
ASTM D3577	1.5	0.65**
EN 455-1	0.65	
<b>Process average (%)</b> (Total water leak holes detected over total water leak test conducted for a year)		
	n/a	<0.20
<b>Grip</b> (Measure of the surface grip. Scale of 1-5, the higher the value, the greater the level of drag)		
	n/a	1.5

\*\*post packaging

**Packaging:** One pair per pack, in a high quality inner wrap, packed into a film pack (constructed of a laminate of polyester and low-density polyethylene). 25 pairs per inner LDPE polybag for sizes 5.5 – 8.5; 20 pairs for size 9.0; 2 inner LDPE polybags are packed in an outer LDPE polybag. Four outer polybags per transit case, total of 200 pairs for sizes 5.5 – 8.5; 160 pairs for size 9.0.

**Disposal:** Gloves, outer wrap and polybags may be disposed of as clinical waste. Paper inner wrap and transit case can be recycled as paper or disposed of as clinical waste.

**Shelf life:** Three (3) years from date of manufacture.

**Manufacturer:** Made and packed in Malaysia by Mölnlycke Health Care Sdn Bhd.

**Country of origin:** Malaysia

**E-mail address:** [biogel@molnlycke.com](mailto:biogel@molnlycke.com)



Tested for use with chemotherapy agents

EN ISO 374-1:2016 Type C



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EN ISO 374-5:2016



VIRUS

Please refer to separate permeation sheet and instructions for use for breakthrough time for chemicals and chemotherapy agents.

  
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