

# Latex

## ● Biogel® Surgeons

Brosch Direct code: GS87



The Biogel® Surgeons is a sterile, latex surgical glove with excellent barrier protection. The unique Biogel® coating provides great fit, feel and comfort and makes the glove easy to don, even with damp hands.



### Biogel® key features and benefits

- 9/10 surgeons prefer Biogel for fit, feel and comfort<sup>1</sup>
- Reduced chance of a hole with an industry-leading AQL\* result of 0.65<sup>1</sup>
- Every glove (100%) is air inflation tested and visually inspected for quality and safety<sup>1</sup>
- Improved efficiency as less gloves are wasted<sup>2</sup>
- Non-pyrogenic, potentially reducing the risk of post-operative complications<sup>3</sup>

ACTUAL COLOUR REF 961

### Recommended use

Recommended for all surgical procedures.

### Material information

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

### Biogel quality

Biogel has an industry leading freedom from holes AQL\* of 0.65. The industry standard requirement for AQL\* is 1.5. The lower the number, the fewer the holes and the higher the quality of glove. Biogel is proven to have the lowest glove failure rate among major competitors. Non-Biogel gloves are at least 3.5 times as likely to fail than Biogel gloves<sup>2</sup>.

### Re-order REF 961

REF	Size	Pairs
96155	5½	50/Box
96160	6	50/Box
96165	6½	50/Box
96170	7	50/Box
96175	7½	50/Box
96180	8	50/Box
96185	8½	50/Box
96190	9	40/Box

4 boxes per case

## Product specifications Biogel® Surgeons gloves REF 961

REF	Size	Length, mm (Tolerance ±15 mm)	Lay flat palm width, mm (±3 mm) 5.5 - (+2 -4)
96155	5.5	280	74
96160	6.0	280	79
96165	6.5	280	85
96170	7.0	285	90
96175	7.5	295	96
96180	8.0	295	101
96185	8.5	295	106
96190	9.0	302	114

Pairs per box: 50/40 for size 9

### Typical thickness profile – single wall

Cuff	0.21 mm
Palm	0.26 mm
Finger	0.28 mm

Physical glove properties	Standard requirement	Biogel
<b>Force at break (N) (EN455)</b>		
Initial	≥9	17
Aged	≥9	16
<b>Typical accelerator analysis % w/w</b>		
Dithiocarbamate (DTC)	n/a	←0.02
Diphenyl thiourea (DPTU)	n/a	none
Diphenyl guanidine (DPG)	n/a	none
Zinc mercaptobenzothiazole (ZMBT)	n/a	none
Thiurams	n/a	none
<b>Typical extractable protein (using Modified Lowry EN455/ ASTM D5712)</b>	←50µg/g	←20µg/g
<b>AQL* freedom from holes (1000 ml water leak test) Post packing and irradiation Process average typically</b>	1.5	0.65 ←0.20%
<b>Grip (Measure of the surface grip. Scale of 1-5, the higher the value, the greater the level of drag)</b>	n/a	1.5

## 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 and have been shown to have a low potential for inducing allergic contact dermatitis or 'Type IV allergy'.

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

**Product standards:** Biogel gloves are tested and manufactured to the following standards:

- **Quality/Environmental:** ISO 9001, ISO 13485, ISO 14001
- **Product:** ASTM D3577, EN455-1, EN455-2, EN455-3, EN455-4
- **Sterilisation:** Gamma irradiation
- **Viral Penetration:** Bacteriophage test, ASTM F1671
- **Allergenicity/Pyrogenicity:** ISO 10993 (PART 5 and 10)

**Registering authority:** In Europe the gloves are CE marked (notified body BSi, number 0086) indicating compliance with Council Directive 93/42/EEC. In US the gloves are FDA registered. Biogel Surgical gloves are a Class IIa Product.

**Storage:** Store in a cool, dry place away from sources of heat or direct sunlight.

**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). 50 pairs per collation case for sizes 5.5–8.5; 40 pairs for size 9.0; 200 pairs per transit case for sizes 5.5–8.5; 160 pairs for size 9.0.

**Disposal:** Gloves & outer wrap dispose of as clinical waste. Paper inner wrap, collation case & transit case can be recycled as paper or disposed of as clinical waste.

**Shelf life:** Five (5) 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

**Date of issue:** May 2012.

References: 1. Why Choose Biogel. MKT004. 2009. Data on file. 2. In Use Surgical Glove Failure Rate Comparison. Study G009-005. 2009. Data on file. 3. Biogel Endotoxin Report, Non-Pyrogenic Surgical Gloves. REPRHJV004. 2010. Data on file.

\*AQL=Acceptable Quality Level refers to the maximum number of defective products that could be considered acceptable during the