

# Latex Biogel® Surgeons



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.



ACTUAL COLOUR REF 822

## 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>

## Recommended use

Recommended for all surgical procedures.

## Material information

- Natural rubber latex
- Micro-roughened 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 822

REF	Size	Pairs
82255	5 ½	50/Box
82260	6	50/Box
82265	6 ½	50/Box
82270	7	50/Box
82275	7 ½	50/Box
82280	8	50/Box
82285	8 ½	50/Box
82290	9	40/Box

4 boxes per case

## Product specifications Biogel® Surgeons gloves REF 822

REF	Size	Length, mm (Tolerance +20 mm; -10 mm)	Lay flat palm width, mm (±3 mm)
82255	5.5	283	71
82260	6.0	285	77
82265	6.5	285	85
82270	7.0	288	91
82275	7.5	298	96
82280	8.0	299	103
82285	8.5	301	109
82290	9.0	301	115

Pairs per box: 50/40 for size 9

Typical thickness profile – single wall		
Cuff	8.1 mils	0.21 mm
Palm	10.0 mils	0.26 mm
Finger	10.6 mils	0.27 mm

Physical glove properties	Standard requirement	Biogel
<b>Force at break (N) (EN455)</b>		
Initial	≥9	19
Aged	≥9	17
<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
<b>Grip</b> (Measure of the surface grip. Scale of 1-5, the higher the value, the greater the level of drag)	n/a	1.0

## 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 random sampling of an inspection, in this case freedom from holes in gloves.

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

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