

# Synthetic Biogel® PI Micro



A synthetic, powder-free and sterile surgical glove with the fit, feel and comfort of natural rubber latex. Typically 20% thinner than Biogel® PI UltraTouch®, it is designed for improved tactile sensitivity.



ACTUAL COLOR

## Biogel® key features and benefits:

- Industry-leading freedom from holes AQL\* result of 0.65<sup>1</sup>
- Every glove is air inflation tested for quality<sup>1</sup>
- Improved efficiency as fewer gloves are wasted<sup>2</sup>

## Recommended use

Recommended for all surgical procedures, especially where extra tactile sensitivity is needed or when latex allergies are a concern for patients or clinicians. It can be used alone or as an overglove with Biogel® PI Micro Indicator Underglove or Biogel® PI Indicator® Underglove.

## Material information:

- Synthetic polyisoprene
- Micro-roughened surface
- Anti-slip, beaded cuff
- Powder-free
- Non-pyrogenic

## Biogel quality

An industry-leading AQL\* of 0.65 is achieved through air inflation inspection of every single surgical glove. The industry standard requirement for AQL\* is 1.5, whereas the actual process average for Biogel is <0.20%. The lower the number, the fewer the holes and the higher the quality of glove. A study showed that non-Biogel gloves are at least 3.5 times as likely to have an in-use failure vs Biogel gloves<sup>2</sup>.

## Re-order REF 485

REF	Size	Pairs
48555	5.5	50/Box
48560	6.0	50/Box
48565	6.5	50/Box
48570	7.0	50/Box
48575	7.5	50/Box
48580	8.0	50/Box
48585	8.5	50/Box
48590	9.0	40/Box

4 boxes per case

## Product specifications Biogel® PI Micro REF 485

REF	Size	Length, mm (Tolerance +20 mm; -10 mm)	Lay flat palm width, mm (±3 mm)
48555	5.5	283	71
48560	6.0	285	77
48565	6.5	285	85
48570	7.0	288	91
48575	7.5	298	96
48580	8.0	299	103
48585	8.5	301	109
48590	9.0	301	115

Pairs per box: 50/40 for size 9

Typical thickness profile – single wall		
Cuff	6.3mils	0.16 mm
Palm	7.7mils	0.20 mm
Finger	8.3mils	0.21 mm

Physical glove properties	Standard requirement	Biogel
<b>Force at break (N)</b>		
Initial	≥9	15.0
Aged	≥9	12.0
<b>Typical accelerator analysis % w/w</b>		
Dithiocarbamate (DTC)	n/a	<0.10
Diphenyl thiourea (DPTU)	n/a	<0.03
Diphenyl guanidine (DPG)	n/a	<0.25
Zinc mercaptobenzothiazole (ZMBT)	n/a	<0.50
Thiurams	n/a	none
<b>AQL* freedom from holes, post packing</b> (1000 ml water leak test) Process average typically	1.5	0.65 <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

## General information

**Pyrogenicity:** Each batch of Biogel gloves is certified to be either non-pyrogenic or 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
- **Sterilization:** Gamma irradiation
- **Viral penetration:** Bacteriophage test, ASTM F1671
- **Allergenicity/pyrogenicity:** ISO 10993 (PART 5 and 10) /US Pharmacopoeia USP: (151 & 85)

**Registering authority:** In Europe the gloves are CE marked (notified body BSI, number 0086) indicating compliance with Council Directive 93/42/EEC, Annex VII and Annex V, section 3.2. Biogel surgical gloves are a Class IIa Product in Europe. Biogel PI Micro has 510(k) clearance in the USA.

**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 and outer wrap disposed of as clinical waste. Paper inner wrap, collation case and transit case can be recycled as paper or disposed of as clinical waste according to local regulations.

**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

**Date of issue:** September 2015

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.

\*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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