

# Latex Biogel<sup>®</sup> M

Powder-free surgical gloves with Biogel<sup>®</sup> coating  
Formulated for improved grip



Sterile, powder-free natural rubber latex gloves with a specially treated surface for extra grip and control.

Recommended for micro-vascular, cardiothoracic, ENT, plastic, neurosurgical, gynecological and general surgical procedures.

## Benefits

- Unique Biogel coating on the inner surface
  - Makes gloves easy to don even with damp hands
  - Soothes the skin to help prevent moisture loss<sup>1</sup>
- Beaded cuff for added security
- Every glove is air inflation tested and visually inspected for quality and user confidence
- Industry leading AQL freedom from holes of 0.65
- Powder-free to eliminate starch powder-related complications
- Powder-free to minimize the risk of allergic reactions to aerosolized natural rubber latex proteins
- Typically contains 50 µg/g or less of water-extractable proteins<sup>2</sup>
- Low dermatitis potential - this product demonstrated reduced potential for sensitizing users to chemical additives
- Non-pyrogenic

## Features

- Straight finger design
- Textured surface
- Unique shape for hard-to-fit hands
- Straw colored

## Material Information

- Natural rubber latex
- Biogel polymer coating



ACTUAL COLOR

## RE-ORDER # 305

#	SIZE	PAIRS	#	SIZE	PAIRS
30555	5 ½	50/Box	30575	7 ½	50/Box
30560	6	50/Box	30580	8	50/Box
30565	6 ½	50/Box	30585	8 ½	50/Box
30570	7	50/Box	30590	9	40/Box

4 BOXES PER CASE

## Essential Information

Responsible company: Mölnlycke Health Care AB, Gamlestadsvägen 3C, SE-402 52 Gothenburg, Sweden

For Inquiries: USA: Norcross GA USA 30092 1-800-843-8497

E-mail address: biogel@molnlycke.com

Website address: www.molnlycke.com

Manufacturer: Made and packed in Malaysia by Regent Hospital Products. Regent Hospital Products is a member of the Mölnlycke Health Care Group.

<sup>1</sup> Source: Testing conducted at PRAC and overseen by a board-certified dermatologist, 2004. Report 04-007  
<sup>2</sup> Using Modified Lowry (EN455) / ASTM D5712.

**PRODUCT SPECIFICATIONS**

SIZE	MIN LENGTH (mm)	AVERAGE PALM WIDTH (mm)
5 ½	280 (+15/-15)	75 (±3)
6	280 (+15/-15)	80 (±3)
6 ½	280 (+15/-15)	85 (±3)
7	285 (+15/-15)	90 (±3)
7 ½	285 (+15/-15)	96 (±3)
8	295 (+15/-15)	101 (±3)
8 ½	295 (+15/-15)	106 (±3)
9	302 (+15/-15)	114 (±3)

**TYPICAL THICKNESS PROFILE SINGLE WALL**

Cuff	8.1 mils	0.205 mm
Palm	10.0 mils	0.255 mm
Finger	11.0 mils	0.280 mm

**PHYSICAL GLOVE PROPERTIES**

	STANDARD REQUIREMENT	BIOGEL
<b>Force at Break (N):</b> Initial Aged	≥12 ≥9	Typically 19 Typically 18
<b>Typical Accelerator Analysis % w/w:</b> Dithiocarbamate (DTC)	n/a	<0.02
<b>Typical Extractable Protein</b> (using Modified Lowry EN455 / ASTM D5712)	<50µg/g	<20µg/g
<b>AQL Freedom from Holes</b> (1000ml water leak test. Post packing and irradiation) - Process Average Typically	1.5	0.65 <0.20%

**General Information**

**Contraindications:** This product contains natural rubber latex which may cause allergic reactions including anaphylactic responses. Do not use this product if you have a known allergy to natural rubber protein or chemical additives.

**Allergenicity:** Biogel gloves are produced to have low levels of water 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 certified to be either non-pyrogenic or to have a low endotoxin level (<0.5 EU/ml).

**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 (25kGy (2.5 Mrad)), EN552, EN556  
**Viral Penetration-** Bacrtiophage test, ASTM F1671  
**Allergenicity / Pyrogenicity-** ISO 10993, (PART 5 and 10) / US Pharmacopoeia USP: (151 & 85)

**Distributed by:** Mölnlycke Health Care, LLC, 5550 Peachtree Parkway, Suite 500, Norcross, GA 30092, 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 & Outer Wrap dispose of as for clinical waste. Paper Inner Wrap, Collation Case & Transit Case can be recycled as paper or disposed of as for clinical waste.

**Country of Origin:** Malaysia

**Date of issue:** October 2010

For further information on any of the above, please contact your local dealer or Mölnlycke Health Care representative directly.

