

Biogel® Dental Sterile

Natural rubber latex dental surgical glove



Biogel® Dental Sterile is a powder-free, sterile natural rubber latex glove for dental surgery. It offers excellent barrier protection^{1,2} as well as fit, feel and comfort³. This dental surgical glove is made with a textured surface for improved wet grip. Each sterile pack contains ergonomically-shaped right- and left hand gloves.



Biogel® key features and benefits:

- AQL* of 0.65, determined post packaging⁴
- Every glove (100%) is air inflation tested for holes typically not detected in a visual inspection⁵
- A study showed that Biogel gloves have the lowest failure rate among major competitors⁶
- Low endotoxin level (<20 EU/pair) which may reduce the risk of post-operative complications^{4,7}

Material information

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

Recommended use

Recommended for all dental surgical and oral surgical procedures, when latex allergy is not a concern for patients or clinicians.

Biogel quality

Biogel gloves are designed to be comfortable with maintained tactile sensitivity when double gloving^{3,8}. They are manufactured using rigorous quality checks, numerous washing cycles⁴ and air-inflation testing of every single glove⁵. Biogel is proven to have the lowest glove failure rate among major competitors. A study showed that non-Biogel gloves are at least 3.5 times as likely to fail compared to Biogel gloves⁶.

Ordering information REF 990

REF	Size	Pairs
9999055	5½	10/Box
9999060	6	10/Box
9999065	6½	10/Box
9999070	7	10/Box
9999075	7½	10/Box
9999080	8	10/Box
9999085	8½	10/Box
9999090	9	10/Box

10 boxes 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.



Biogel® Dental Sterile REF 990 – Product specifications

REF	Size	Length, mm (Tolerance ±15 mm)	Lay flat palm width, mm (±3mm) 5.5 - (+2, -4)
9999055	5½	280	74
9999060	6	280	79
9999065	6½	280	85
9999070	7	285	90
9999075	7½	285	96
9999080	8	295	101
9999085	8½	295	106
9999090	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 Dental are tested and manufactured to the following standards	
Quality/Environment	ISO 13485, ISO 14001
Product	ASTM D3578, EN455-1, EN455-2, EN455-3, EN455-4, ISO 10282
Sterilisation	ISO 11137, Gamma Irradiation, SAL 10-6
Viral penetration	Bacteriophage Test, ISO 16604
Allergenicity	ISO 10993 (Part 5 and 10)
Pyrogenicity	ASTM D7102
Labelling	EN 1041, EN 556-1, EN 15223-1
Packaging	EN ISO 11607

Physical glove properties	Standard requirement	Biogel Dental Sterile Typical value
Force at break (N)		
Initial	≥ 9	17
Aged	≥ 9	16
Tensile strength (MPa)		
Initial	≥ 24	28
Aged	≥ 18	26
Modulus Stress @500% elongation (MPa)		
Initial	5.5 max	3.0
Aged	n/a	2.6
Elongation at break (%)		
Initial	≥ 750	910
Aged	≥ 560	660
Typical accelerator analysis (% w/w)		
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
Typical extractable protein (µg/g) (using Modified Lowry EN 455-3/ ASTM D5712)		
	<50	<50
AQL freedom from holes (1000 ml water leak test)		
ASTM D3577	1.5	0.65**
EN 455-1	0.65	
Process average (%) (Total water leak holes detected over total water leak test conducted for a year)	n/a	<0.20
Grip (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

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) indicating compliance with Council Directive 93/42/EEC, section 3.2. They are a Class Is product according to the medical device directive.

Storage: Store in a dry place at a temperature of 5–25°C, 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). 10 pairs per collation case, 100 pairs per transit case.

Disposal: Gloves and outer wrap may be disposed of as clinical waste. Paper inner wrap, collation case 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

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References: 1. Aldiyami, 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.; Gottrup, 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. In Use Surgical Glove Failure Rate Comparison. Mölnlycke Health Care, 2009. Data on file. 7. Asplund Peiro S et al. Quantitative determination of endotoxins on surgical gloves. Journal of Hospital Infection 1990; 16:167-172. 8. 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.

