Biogel® NeoTech

Sterile synthetic critical environment glove

Biogel® NeoTech is a synthetic critical environment glove made from polychloroprene. It can be used alone or in combination with the Biogel® NeoTech Indicator® Underglove for improved protection of the goods handled as well as of the operator. It has been tested and cleared for use with chemotherapy agents.

Biogel® key features and benefits:

- AQL* of 0.65, determined post packaging[1]
- Every glove (100%) is air inflation tested for holes typically not detected in a visual inspection[2]
- PPE Category III, certified to Type A chemical permeation testing
- Low endotoxin level (<20 EU/pair)[1]
- Total Liquid Particle Count (≥0.5µm): ≤ 2500 counts/cm²[3]
- Suitable for use in aseptic and Class 100 (ISO 5) / EU GMP Grade A environments

Material information

- Synthetic polychloroprene
- Biogel hydrogel polymer coating
- Curved finger and smooth surface
- Beaded cuff
- Powder-free

Recommended use

The Biogel NeoTech is recommended to be used in any critical environment or controlled environment when a high quality sterile glove is required for protection from cross contamination, preferably in combination with the Biogel NeoTech Indicator Underglove.

Biogel quality

Biogel gloves are designed to be comfortable with maintained tactile sensitivity even when double gloving[4,5]. They are manufactured using rigorous quality checks, numerous washing cycles[1] and air-inflation testing of every single glove[2].

Ordering information REF 44509

REF	Size	Pairs
4450955	5½	25 x2 /polybag
4450960	6	25 x2 /polybag
4450965	6½	25 x2 /polybag
4450970	7	25 x2 /polybag
4450975	7½	25 x2 /polybag
4450980	8	25 x2 /polybag
4450985	8½	25 x2 /polybag
4450990	9	20 x2 /polybag

4 polybags 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® NeoTech REF 44509 – Product specifications

REF	Size	Length, mm (Tolerance ±15mm)	Lay flat palm width mm (+ 3 mm) 5.5- (+2, -4)
4450955	5½	283	71
4450960	6	285	77
4450965	6½	285	85
4450970	7	288	91
4450975	7½	298	96
4450980	8	299	103
4450985	8½	301	109
4450990	9	301	115

Typical thickness profile – single wall		
Cuff	6.7 mils	0.17 mm
Palm	7.5 mils	0.19 mm
Finger	8.3 mils	0.21 mm

Biogel NeoTech are tested and manufactured to the following standards	
PPE Regulation	(EU) 2016/425 Category III
Particle count	IEST-RP-CC005.4: Total Liquid Particle Count (≥0.5µm): ≤ 2500 counts/cm²
Quality/ Environment	ISO 13485, ISO 14001
Product	EN 455-1, EN 455-2, EN 455-3, EN 455-4, ASTM D3577, ISO 10282 , EN ISO 374-1, EN 374-2, EN 374-4, EN 16523-1, EN ISO 374-5
Sterilisation	ISO 11137, Gamma Irradiation, SAL 10^{-6} (at ≥ 25 kGy dose)
Viral penetration	Bacteriophage Test, ISO 16604, ASTM F1671
Allergenicity	ISO 10993 (Part 5 and 10)
Pyrogenicity	ASTM D7102
Labelling/ Packaging	EN 556-1, EN ISO 15223-1, EN ISO 21420

Physical glove properties	Standard requirement	Biogel NeoTech Typical value
Force at break (N)		
Initial	≥ 9	12
Aged	≥ 9	14
Tensile strength (MPa)		
Initial	≥ 17	21
Aged	≥ 12	28
Modulus Stress @500% elongation (MPa)		
Initial	7.0 max	2.0
Aged	n/a	2.7
Elongation at break (%)		
Initial	≥ 650	1040
Aged	≥ 490	890
Typical accelerator analysis (% w/w)		
Dithiocarbamate (DTC)	n/a	Below detection limit
Diphenyl thiourea (DPTU)	n/a	<0.25
Diphenyl guanidine (DPG)	n/a	none
Zinc mercaptobenzothiazole (ZMBT)	n/a	none
Thiurams	n/a	none
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

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) and UKCA marked in the UK (authorised body BSI 0086) indicating compliance with PPE Regulation (EU) 2016/425.

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 polyethylene inner wrap, packed into a film pack (constructed of a laminate of polyester and low-density polyethylene). 25 pairs per inner LDPE polybag for sizes 5.5 – 8.5; 20 pairs for size 9.0; 2 inner LDPE polybags are packed in an outer LDPE polybag. Four outer polybags per transit case, total of 200 pairs for sizes 5.5 – 8.5; 160 pairs for size 9.0.

Disposal: Gloves, outer wrap, inner wrap and polybags may be disposed of as clinical waste. 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. Summary of Technical Documents. Mölnlycke Health Care. Data on File. 2. SOP LR2200. Automatic Glove Inspection by QMAX. Mölnlycke Health Care. Data on file. 3. Liquid particle count test report AR-21-SV-011884-01 Eurofins, 2021. 4. Gottrup F, Müller K, Bergmark S, Nørregaard S. Powder-free, non sterile gloves assessed in a wound healing centre. Eur J Surg. 2001 Aug;167(8):625-7. 5. 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.

Please refer to separate permeation sheet and instructions for use for breakthrough time for chemicals and chemotherapy agents.

Find out more at www.molnlycke.com

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