

About

Anatomically shaped and designed to be double-donnable, BioClean Advance™ Sterile Latex Cleanroom Gloves provide exceptional flexibility and wearer comfort. The natural-coloured 300mm (12") long, hand specific latex gloves feature a textured surface for enhanced grip and a beaded cuff for stability on the arm.

Specifications

COMPATIBILITY:

ISO Class 4 & EU GMP Grade A

LENGTH:

300mm (12")

MATERIAL:

Latex

PROTEIN LEVEL:

Less than 50 μ g/gram

SURFACE:

Textured

SHAPE:

Hand specific

COLOUR:

Natural

STERILIZATION:

Gamma irradiation

Features

- **Exceptional flexibility and comfort**
- Powder-free
- Beaded cuff
- EasyOn[™] proprietary technology allows for easy double-donning
- Non-particulating EasyTear[™] packaging







BIOCLEAN ADVANCE[™] Sterile Latex Gloves

TEXTURED FOR IMPROVED GRIP

ANATOMICALLY SHAPED

EXCEPTIONAL FLEXIBILITY & COMFORT

DOUBLE-DONNABLE







Quality Standards

- Manufactured in a facility holding ISO 9001: 2008 and 89/686/EEC
 Article 11b certifications
- Conforms to Category 3 Complex Design Personal Protective Equipment PPE Directive 89/686/EEC
- Processed in an NEBB certified ISO Class 4 environment
- Complies with the requirements of Glove Standard EN420:2003 and EN374-1, 2 & 3:2003
- Physical properties comply with European Medical Glove Standard EN455-2:2009
- Sterilized in accordance with ISO 11137-1:2006

Sterilization

Method: Gamma irradiation Minimum Dose: 25kGy Sterility Assurance Level: 10⁻⁶

Shelf Life & Storage

Five (5) years from date of manufacture. Store in a dry, cool place (<40°C) away from direct sunlight and fluorescent light.

Physical Properties

| CHARACTERISTICS | VALUE | TEST METHOD |
|---|--|---------------|
| Freedom From Holes | 0.65 AQL Performance Level 3 | EN 374-2:2003 |
| Minimum Length (mm/inches) | 290/11.4 | EN 420:2003 |
| Single Wall Thickness Minimum (mils) | Cuff: 4.33 Palm: 6.69 Finger Tip: 7.87 | EN 455-2:2009 |
| Force At Break During Shelf Life | ≥12 N | EN 455-2:2009 |

| PALM WIDTHS (mm) ± 5mm | | | | | | | | |
|------------------------|-----|-----|--------------|-----|-----|-----|-----|------|
| SIZE | 6.0 | 6.5 | 7.0 | 7.5 | 8.0 | 8.5 | 9.0 | 10.0 |
| mm | 77 | 83 | 89 | 95 | 102 | 108 | 114 | 121 |
| TEST METHOD | | | EN455-2:2009 | | | | | |

Glove Cleanliness Characteristics

| PARTICLES | | | | TYPICAL PARTICLE COUNT | | | TEST METHOD | |
|------------------------------------|----------|----------|----------|------------------------|-------------|-----------------|-------------|-----------------|
| ≥ 0.5µm(counts/cm²) | | | <2000 | | | IEST-RP-CC005.3 | | |
| TYPICAL EXTRACTABLE IONS | | | | | TEST METHOD | | | |
| ANIONS | Fluoride | Chloride | Nitrite | Bromide | Nitrate | Phosphate | Sulphate | IEST-RP-CC005.3 |
| (µg/cm²) | ND | 1.581 | ND | ND | 0.614 | ND | 0.260 | |
| CATIONS | Lithium | Sodium | Ammonium | Potassium | Calcium | Magnesium | Zinc | |
| (µg/cm²) | ND | 0.018 | 0.268 | 0.084 | 0.458 | 0.030 | 0.262 | |
| ND = Not Detected, NT = Not Tested | | | | | | | | |





TO ORDER

| Re-order code | Size |
|---------------|------|
| BASL6.0 | 6.0 |
| BASL6.5 | 6.5 |
| BASL7.0 | 7.0 |
| BASL7.5 | 7.5 |
| BASL8.0 | 8.0 |
| BASL8.5 | 8.5 |
| BASL9.0 | 9.0 |
| BASL10.0 | 10.0 |

Packing

One pair per inner PE wallet; one wallet per sealed EasyTear™ PE pouch; 10 pouches per sealed outer PE bag; 20 outer bags per lined carton (200 pairs).

CONTACT

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BioClean™ is a brand of Nitritex Ltd.
For more information, please visit <u>www.bioclean.com</u>

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