

#### **About**

At 400mm (16") BioClean Extra Sterile Latex Gloves provide elbow length protection and flexibility and comfort for prolonged use. This natural-coloured glove features a textured surface and a beaded cuff for strength.

#### **Specifications**

**COMPATIBILITY:** 

ISO Class 4 & EU GMP Grade A

LENGTH:

400mm (16")

MATERIAL:

Latex

PROTEIN LEVEL:

Less than  $50\mu g/gram$ 

SURFACE:

Textured

SHAPE:

**Ambidextrous** 

COLOUR:

Natural

STERILIZATION:

Gamma irradiation

#### **Features**

- Flexible & comfortable
- · Elbow length protection
- Powder-free
- Beaded cuff
- Easy double-donning
- Non-particulating EasyTear packaging









# BIOCLEAN EXTRA Sterile Latex Gloves BI AS





### **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
- Suitable for contact with dry, alcoholic and acidic foodstuffs.

#### **Physical Properties**

CHARACTERISTICS	VALUE	TEST METHOD
Freedom From Holes	1.5 AQL	EN 374-2:2003
	Performance Level 2	
Glove Length	400/16	EN 420:2003
+/-10mm (mm/inches)		
Single Wall Thickness	Cuff: 4.72/0.12	EN 455-2:2009
Minimum (mils/mm)	Palm: 6.69/0.17	
	Finger Tip: 8.27/0.21	
Force At Break	≥12 N	EN 455-2:2009
During Shelf Life		

#### Sterilization

Method: Gamma irradiation Minimum Dose: 25kGy Sterility Assurance Level: 10<sup>-6</sup>

#### 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.

PALM WIDTHS (mm) ± 5mm						
SIZE	Small	Medium	Large	XLarge		
mm	85	95	106	115		
TEST METHOD EN 420:2003						

## Glove Cleanliness Characteristics

	PART	ICLES			TYPICA	AL PARTICLE	COUNT	TEST METHOD
≥ 0.5µm(counts/cm <sup>2</sup> )			<2400		IEST-RP-CC005.4			
TYPICAL EXTRACTABLE IONS					TEST METHOD			
ANIONS	Fluoride	Chloride	Nitrite	Bromide	Nitrate	Phosphate	Sulphate	IEST-RP-CC005.4
(μg/cm <sup>2</sup> )	ND	4.412	ND	0.053	0.528	0.014	0.267	
CATIONS	Lithium	Sodium	Ammonium	Potassium	Calcium	Magnesium	Zinc	
(μg/cm <sup>2</sup> )	0.230	0.025	0.333	0.075	1.155	ND	ND	
ND = Not Detected, NT = Not Tested								







#### TO ORDER

Size		
Small		
Medium		
Large		
XLarge		

#### **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)

For additional information visit us at www.bioclean.com, or call us at +44 1638 663338

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BLAS/1806/PDS30

Caution: This product contains natural rubber latex (latex) which may cause allergic reactions in some users. Safe use of this glove by or on latex sensitized individuals has not been established.

Neither this document nor any other statement made herein by or on behalf of Ansell should be construed as a warranty of merchantability or that any Ansell product is fit for a particular purpose. Ansell assumes no responsibility for the suitability or adequacy of an end user's selection of gloves for a specific application.

\*Warning: No glove provides complete protection against all chemicals. Users must test the gloves against the particular chemicals and environment in which they will be used.

\*\*Please see product validation pack or contact Ansell customer service for specific data on use of gloves with cytotoxic drugs. Gloves used for protection against such drugs must be selected specifically for the type of chemicals used.

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