

#### **USP 797 & 800 Compliance Specialists**

Everything you need to achieve and maintain a compliant cleanroom environment

# **BioClean N-Plus Sterile Nitrile Gloves**

BIOCLEAN N-PLUS Sterile Nitrile Gloves **BNPS** 

#### **About**

BioClean N-Plus™ is a sterile, hand specific, white, powder-free and latex-free nitrile glove, with excellent antistatic properties. It is resistant to a wide range of chemicals and has been tested against ASTM D6978-05, the most stringent testing method designed specifically for cytotoxics.

## **TEXTURED**

LATEX-FREE

**ANTISTATIC** 

**ELBOW LENGTH** 

**EXCELLENT CHEMICAL RESISTANCE** 

## **Specifications**

**COMPATIBILITY:** 

ISO Class 4 & EU GMP Grade A

LENGTH: 400mm (16")

MATERIAL: Nitrile

PROTEIN LEVEL:

Nitrile contains no natural latex proteins

SURFACE:

**Textured** 

SHAPE:

Hand specific

COLOUR:

White

STERILIZATION:

Gamma irradiation

# **Features**

- Resistant to a wide range of chemicals
- Elbow length protection
- Powder-free & latex-free
- Antistatic
- Beaded cuff
- Part of the BioClean-C™ Chemotherapy range
- Non-particulating EasyTear™ packaging







Carter-Health Disposables, LLC Phone: (407) 296.6689 Web: www.Carter-Health.com

## **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
- Tested against permeation standard ASTM D6978-05 for cytotoxic drugs
- Sterilized in accordance with ISO 11137-1:2006

## **Physical Properties**

CHARACTERISTICS	VALUE	TEST METHOD
Freedom From Holes	0.65 AQL Performance Level 3	EN 374-2:2003
Minimum Length (mm/inches)	390/15.3	EN 420:2003
Single Wall Thickness Minimum (mils)	Cuff: 3.54 Palm: 6.69 Finger Tip: 7.87	
Force At Break During Shelf Life	≥9 N	EN 455-2:2009

## **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	6.0	6.5	7.0	7.5	8.0	8.5	9.0	10.0
mm	75	82	89	95	102	107	115	121
TEST METHOD			EN455-2:2009					

## **Glove Cleanliness Characteristics**

PARTICLES					TYPICAL PARTICLE COUNT			TEST METHOD
≥ 0.5µm(counts/cm²)					<3300			IEST-RP-CC005.3
TYPICAL EXTRACTABLE IONS						TEST METHOD		
ANIONS	Fluoride	Chloride	Nitrite	Bromide	Nitrate	Phosphate	Sulphate	IEST-RP-CC005.3
(µg/cm²)	ND	0.619	ND	NT	6.362	ND	0.507	
CATIONS	Lithium	Sodium	Ammonium	Potassium	Calcium	Magnesium	Zinc	
(μg/cm²)	NT	0.554	0.139	0.593	1.854	0.035	0.153	
ND = Not Detected, NT = Not Tested								

## **Product Numbers**

BNPS60	6.0	1 pr/pk,	10 pks/mb, 20 mbs/cs
BNPS65	6.5	1 pr/pk,	10 pks/mb, 20 mbs/cs
BNPS70	7.0	1 pr/pk,	10 pks/mb, 20 mbs/cs
BNPS75	7.5	1 pr/pk,	10 pks/mb, 20 mbs/cs
BNPS80	8.0	1 pr/pk,	10 pks/mb, 20 mbs/cs
BNPS85	8.5	1 pr/pk,	10 pks/mb, 20 mbs/cs
BNPS90	9.0	1 pr/pk,	10 pks/mb, 20 mbs/cs



