



## Synthetische Handschuhe BioClean Fusion

pure<sup>11</sup>-Nr.: 05235, Hersteller: BioClean



### Zusammenfassung

- Neue pure11-Artikelnummer (ab 01.07.2023): 1105235
- Material: Polychloropren
- Beidhändig tragbar
- Puderfrei
- Latexfrei
- AQL-Wert (Acceptable Quality Level): 1.5
- Gammasterilisiert
- Texturiert
- Gut geeignet zum Double-Gloving

### Empfohlene Reinraumklassen

ISO  3  4  5  6  7  8  9

GMP   A/B  C  D

### Produktvarianten

**pure<sup>11</sup>-Nr.: 052355**

Farbe: Grün / Größe: 5,0-5,5 / Herst.-Nr.: S-BFAP-5055 / VE: 200 Paar

**pure<sup>11</sup>-Nr.: 052356**

Farbe: Grün / Größe: 6,0-6,5 / Herst.-Nr.: S-BFAP-6065 / VE: 200 Paar

**pure<sup>11</sup>-Nr.: 052357**

Farbe: Grün / Größe: 7,0-7,5 / Herst.-Nr.: S-BFAP-7075 / VE: 200 Paar

**pure<sup>11</sup>-Nr.: 052358**

Farbe: Grün / Größe: 8,0-8,5 / Herst.-Nr.: S-BFAP-8085 / VE: 200 Paar

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**pure<sup>11</sup>-Nr.: 052359**

Farbe: Grün / Größe: 9,0 / Herst.-Nr.: S-BFAP-9090 / VE: 200 Paar

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**pure<sup>11</sup>-Nr.: 0523510**

Farbe: Grün / Größe: 10,0 / Herst.-Nr.: S-BFAP-1010 / VE: 200 Paar

Quelle: <https://www.pure11.de/synthetische-handschuhe-bioclean-fusion>

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# BIOCLEAN FUSION

Sterile Polychloroprene Gloves  
**S-BFAP**

## About

BioClean Fusion Sterile Polychloroprene Cleanroom Gloves contain no natural latex proteins, are comfortable and thin to reduce wearer fatigue and increase tactility. The Fusion is double-donnable and features a beaded cuff for strength.

## Specifications

**COMPATIBILITY:**

ISO Class 4 & EU GMP Grade A

**LENGTH:**

290mm (11.4")

**MATERIAL:**

Polychloroprene

**PROTEIN LEVEL:**

Polychloroprene contains no natural latex proteins

**SURFACE:**

Finger-textured

**SHAPE:**

Ambidextrous

**COLOUR:**

Green

**STERILIZATION:**

Gamma irradiation

TACTILE

CHEMICAL RESISTANT\*

DOUBLE-DONNABLE

## Features

- Increased tactility
- Powder-free & latex-free
- Beaded cuff for strength
- Non-particulating EasyTear packaging

EN 421:2010 ISO 374-5:2016



EN ISO 374  
Type C



CE 0598

**Ansell**

## Quality Standards

- Manufactured in a facility holding ISO 9001:2015 and (EU)2016/425 Module D certifications
- Conforms to Category 3 - Complex Design Personal Protective Equipment PPE Regulation (EU)2016/425
- Processed in an NEBB certified ISO Class 4 environment
- Complies with the requirements of European Glove Standards EN420:2003 +A1:2009, EN374-1:2016, EN374-5:2016 and EN421:2010
- Physical properties comply with European Medical Glove Standard EN455-2:2015
- Sterilized in accordance with ISO 11137-1:2006
- Suitable for contact with all foodstuffs. Regulation (EC)1935/2004 and (EC) 2023/2006.
- Tested against permeation standard ASTM D6978-05 for cytotoxic drugs

## Physical Properties

CHARACTERISTICS	VALUE	TEST METHOD
Freedom From Holes	AQL 0.65 Performance Level 3	EN 374-2:2015
Glove Length +/-10mm (mm/inches)	290/11.4	EN 420:2003 + A1:2009
Single Wall Thickness Minimum (mils/mm)	Cuff: 2.76/0.07 Palm: 3.94/0.10 Finger Tip: 4.72/0.12	EN 455-2:2015
Force At Break During Shelf Life	≥9 N	EN 455-2:2015

PALM WIDTHS (mm) ± 5mm						
SIZE	5.0-5.5	6.0-6.5	7.0-7.5	8.0-8.5	9.0	10.0
mm	76	86	95	106	115	120
TEST METHOD				EN 420:2003 + A1:2009		

## 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.

## Glove Cleanliness Characteristics

PARTICLES				TYPICAL PARTICLE COUNT				TEST METHOD
$\geq 0.5\mu\text{m}(\text{counts}/\text{cm}^2)$				850				IEST-RP-CC005.4
TYPICAL EXTRACTABLE IONS								TEST METHOD
ANIONS	Fluoride	Chloride	Nitrite	Bromide	Nitrate	Phosphate	Sulphate	IEST-RP-CC005.4
( $\mu\text{g}/\text{cm}^2$ )	ND	0.194	ND	ND	0.884	ND	0.025	
CATIONS	Lithium	Sodium	Ammonium	Potassium	Calcium	Magnesium	Zinc	
( $\mu\text{g}/\text{cm}^2$ )	ND	0.099	0.003	0.315	0.652	0.007	ND	
ND = Not Detected, NT = Not Tested								

## TO ORDER

### Re-order code

S-BFAP-5055  
S-BFAP-6065  
S-BFAP-7075  
S-BFAP-8085  
S-BFAP-9090  
S-BFAP-1010

### Size

5.0-5.5  
6.0-6.5  
7.0-7.5  
8.0-8.5  
9.0  
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)

For additional information visit us at [www.bioclean.com](http://www.bioclean.com), or contact us at;

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S-BFAP/1904/PDS29



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\*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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