

## About

Manufactured in a cleanroom environment from ultra-clean low-density polythene. Because the material is free of additives, there is no contamination from particulates, surface leaching chemicals or out-gassing. For general-purpose use, ideal as waste bags, transportation bags or storage bags. BioClean Sterile Bags are suitable for use within the pharmaceutical, medical, semiconductor, aerospace and many other industries.

## Specifications

**MATERIAL:**

Polythene

**COMPATIBILITY:**

ISO Class 4 & EU GMP Grade A

**COLOUR:**

Clear

**STERILIZATION:**

Gamma irradiation

## Features

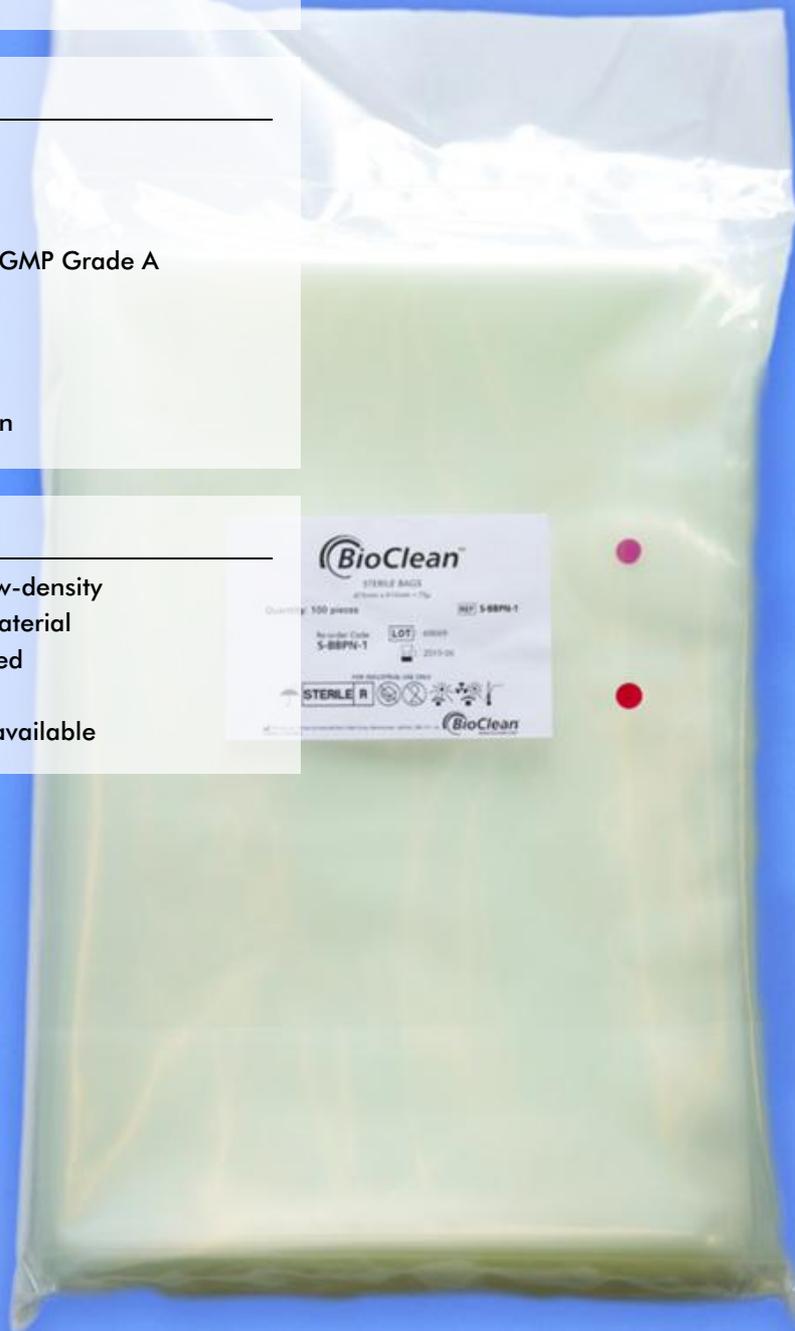
- Ultraclean & low-density
- Additive-free material
- Gamma sterilized
- Double bagged
- Range of sizes available

ULTRACLEAN

LOW-DENSITY

ADDITIVE-FREE

RANGE OF SIZES



## Quality Standards

- Manufactured in a facility holding ISO 9001:2015

## 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/General Properties

| Property Measured          | Method Used       | Units of Measurement                              | Typical Value             |
|----------------------------|-------------------|---|---------------------------|
| <b>Granule Properties</b>  |                   |   |                           |
| Melt Index                 | ASTM D 1238       | g/10min   | 0.75                      |
| Density                    | ASTM D 2839/D1505 | g/cm <sup>3</sup>                                 | 0.923                     |
| Crystallization Point      | ASTM D3418        | °C  | 96                        |
| Peak Melting Temperature   | ASTM D3418        | °C  | 109                       |
| Slip/Antiblock Additive    | None              |   |                           |
| Antistatic Additive        | None              |   |                           |
| <b>Film Properties</b>     |                   |   |                           |
| Film Thickness             | μm                |   | 60 – 200<br>(+/- 10% Avg) |
| Tensile Strength at Break* | ASTM D882         | MPa   | MD: 24, TD: 23            |
| Elongation at Break*       | ASTM D882         | %   | MD: 370, TD: 570          |
| Elmendorf Tear Strength*   | ASTM D1922        | g/μm  | MD: 4, TD: 4              |
| Puncture Resistance**      | FTMS 101C 2065-1  | N   | 43.4                      |
| 1% Secant Modulus*         | ASTM D882         | MPa   | MD: 220, TD: 260          |
| Haze                       | ASTM D1003        | %   | 7                         |
| Gloss, 60° angle           | ASTM D2457        | %   | 9                         |
| MVTR                       | DIN 54122-2-D     | g/m <sup>2</sup> /24 hrs / bar at 90% RH and 38°C | 2.77                      |
| OTR                        | DIN 53380-3       | cm <sup>3</sup> / m <sup>2</sup> /day/bar         | 1059                      |

## Physical/General Properties Continued...

| Cleanliness Properties  |  |                     |                         |                 |                 |                 |                 |
|---|--|---------------------|-------------------------|-----------------|-----------------|-----------------|-----------------|
| Particulates  | Liquid Particle Count                      | >0.30 $\mu\text{m}$ | <20.0 per $\text{cm}^2$ |                 |                 |                 |                 |
| Particulates  | Liquid Particle Count                      | >0.50 $\mu\text{m}$ | <10.0 per $\text{cm}^2$ |                 |                 |                 |                 |
| Particulates  | Liquid Particle Count                      | >1.00 $\mu\text{m}$ | <3.0 per $\text{cm}^2$  |                 |                 |                 |                 |
| Ion Chromatography  |  |                     |                         |                 |                 |                 |                 |
| Anions  | F  | Cl                  | Br                      | NO <sub>3</sub> | NO <sub>2</sub> | SO <sub>4</sub> | PO <sub>4</sub> |
| Found   | <0.020                                     | <0.017              | <0.057                  | <0.014          | <0.020          | <0.084          | <0.096          |
| LLD   | 0.020                                      | 0.017               | 0.057                   | 0.014           | 0.020           | 0.084           | 0.096           |
| Cations   | Li   | Na                  | NH <sub>4</sub>         | K               | Mg <sup>2</sup> | Ca <sup>2</sup> |                 |
| Found   | <0.014                                     | <0.015              | <0.121                  | <0.021          | <0.057          | <0.034          |                 |
| LLD   | 0.014                                      | 0.015               | 0.121                   | 0.021           | 0.057           | 0.034           |                 |
| Measures given in ng/cm LLD = Low Limit Detection   |  |                     |                         |                 |                 |                 |                 |
| VOC (Outgassing)  | Global contamination as toluene equivalent |                     |                         |                 |                 | $\mu\text{g/g}$ | <20             |
| Surface Cleanliness   | (Mil - STD 1246C) Level 25                 |                     |                         |                 |                 |                 |                 |
| <p>* Film properties measured on 50-micron film with a blow up ratio of 2.5</p> <p>** Film properties measured on 150-micron film with a blow up ratio of 2.5</p> <p>All cleanliness properties measured on 150-micron film with a blow up ratio of 2.5</p> |  |                     |                         |                 |                 |                 |                 |

## TO ORDER

| Re-order code | Size           |
|---------------|----------------|
| S-BBPN-1      | 475mm x 610mm  |
| S-BBPN-2      | 980mm x 1090mm |
| S-BBPN-3      | 700mm x 980mm  |
| S-BBPN-4      | 800 x 1000mm   |
| S-BBPN-5      | 600mm x 600mm  |
| S-BBPN-6      | 150mm x 200mm  |
| S-BBPN-10     | 864mm x 1067mm |
| S-BBPN-11     | 660mm x 711mm  |
| S-BBPN-11-25  | 660mm x 711mm  |
| S-BBPN-12     | 508mm x 762mm  |
| S-BBPN-12-50  | 508mm x 762mm  |
| S-BBPN-13     | 457mm x 762mm  |
| S-BBPN-13-100 | 457mm x 762mm  |
| S-BBPN-14     | 254mm x 457mm  |
| S-BBPN-15     | 600mm x 810mm  |
| S-BBPN-18-20  | 930mm x 864mm  |

### Packing

All BioClean Sterile Bags are double bagged.

S-BBPN-10, S-BBPN-11, S-BBPN-12, S-BBPN-13, S-BBPN-14 & S-BBPN-18-20 = 20 pcs per pack

S-BBPN-11-25 & S-BBPN-2 = 25 pcs per pack

S-BBPN-3, S-BBPN-4, S-BBPN-5, S-BBPN-15 & S-BBPN-12-50 = 50 pcs per pack

S-BBPN-1, S-BBPN-6 & S-BBPN-13-100 = 100 pcs per pack

#### THICKNESS;

50 $\mu$ m - S-BBPN-13, S-BBPN-13-100, S-BBPN-14

75 $\mu$ m - S-BBPN-1, S-BBPN-03, S-BBPN-04, S-BBPN-05, S-BBPN-06, S-BBPN-15

70 $\mu$ m - S-BBPN-02

125 $\mu$ m - S-BBPN-10, S-BBPN-11, S-BBPN-11-25, S-BBPN-12, S-BBPN-12-50

#### PLEASE NOTE:

This product is a non-stock item and all sizes are subject to a Minimum Order Quantity (MOQ) and delivery lead time. Please contact us for details.

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

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