

# Biosafe® 110 Bottle-shaped Bags

### Product Information

Our complete range of Biosafe® 110 bottle-shaped bags offers reliable and easy-to-use solutions for the secure transfer of components and materials while maintaining the integrity of the critical area in isolators, RABS and cleanrooms.

Used in conjunction with the Biosafe® 110 port, the Biosafe® 110 bottle-shaped bags are available in a variety of configurations designed to meet the specific needs of all applications.



### Features and Benefits

| Aseptic and contained single-use transfer technology | Enhanced sterility assurance and safety                            |
|--|--|
| Bag chamber overmolding to the connector             | Maximum robustness   |
| Automated bag manufacturing process                  | High cleanliness   |
| Bottle-shaped bag design                             | Material transfer efficiency                                       |
| Flexible portfolio with different confirgurations    | Highly adaptable for various process needs and sterilization types |

### **Applications**

Biosafe® 110 bottle-shaped bags allow the transfer of stoppers, plungers, seals, plastic bottles | components, and various other components between two environments with different air quality classifications. The Biosafe® 110 aseptic transfer bags are the single-use alternative to traditional stainless steel rigid transfer containers in a large variety of applications. This transfer is done thanks to the Biosafe® 110 port which is installed on the wall of the critical area.

#### Enhanced sterility assurance and safety

Single-use Biosafe® 110 bags improve process safety by reducing the risk of cross-contamination from batch to batch and product to product. The ports also eliminate the need for costly and time consuming cleaning and sterilization procedures that are required with traditional transfer containers.

### Maximum robustness for the bag and the connection

The overmolding of the bottle-shaped bag film directly onto the flange of the connector results in a high level of robustness of the attachment.

The bottle-shaped bags have been extensively qualified to ensure highest robustness of the container in comparison with the real conditions of use of the Biosafe® 110 bags when they are filled with components.

#### High cleanliness

The manufacturing process of the Biosafe® 110 bottle-shaped bags has been improved to bring automation to the most critical assembly steps, resulting in a high cleanliness level of the final product.

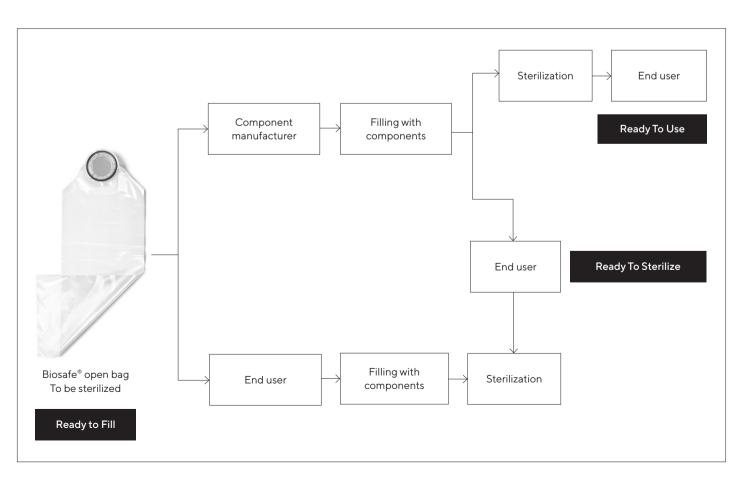
#### Improved material transfer efficiency

The bottle shape of the Biosafe® 110 bag allows for the efficient and simple transfer of components to the critical area.

# Highly adaptable for various applications and sterilization types

The Biosafe® 110 aseptic transfer bags can be manufactured with several optional add-ons to best fit your requirements. An inner flexible sleeve or rigid collar can be deployed in the critical area to guide the components during their passage through the Biosafe® 110 port. A protective cover over the Biosafe® 110 connector protects from particle contamination prior to docking the bag.

| Applications   | Biosafe® 110 bottle-shaped bag configuration(s)  |  |  |
|--|--|--|--|
| Closure component transfer:<br>for pre-fillable syringes | <ul> <li>Steam   gamma sterilizable bags</li> <li>Prefilled by component<br/>manufacturer;</li> <li>Filled by end user;</li> <li>Sterilized by component<br/>manufacturer or end user</li> </ul> |  |  |
| Closure component transfer:<br>for vials & cartridges    | <ul> <li>Steam   gamma sterilizable bags</li> <li>Prefilled by component<br/>manufacturer;</li> <li>Filled by end user;</li> <li>Sterilized by component<br/>manufacturer or end user</li> </ul> |  |  |
| Tools   Filling parts entry                              | <ul><li>Steam sterilizable bags</li><li>Filled by end user;</li><li>Steam sterilized by end user</li></ul>   |  |  |



## Technical Data

### **Specifications**

| Material of construction                |   |   |  |  |
|---|---|---|--|--|
| Type of bag                             | Steam sterilizable  | Gamma sterilizable  |  |  |
| Film                                    | DuPont™ Tyvek®   HDPE¹ 80 μm                                      | PE   PA   PE² 120 μm  |  |  |
| Connector                               | PC <sup>3</sup> port, HDPE over molding<br>110 mm useful diameter | PC <sup>3</sup> port, HDPE over molding<br>110 mm useful diameter |  |  |
| Options available                       |   |   |  |  |
| Rigig collar* for external opening port | PC  | PC  |  |  |
| Protective cover                        | DuPont™ Tyvek®  | DuPont™ Tyvek®  |  |  |

<sup>\*</sup>The rigid collar can also be used with the inside opening port

| Bag dimensions    | Sterilization   | Working volume  | Options   |   |
|-------------------|---|---|---|---|
|                   |   |   | Rigid<br>collar   | Protective cover  |
| team sterilizable |   |   |   |   |
| 850 × 350 mm      | One steam sterilization cycle at 121°C for 30 minutes   | 25 L  |   |   |
| 850 × 350 mm      | One steam sterilization cycle at 121°C for 30 minutes   | 25 L  |   |   |
| 850 × 350 mm      | One steam sterilization cycle at 121°C for 30 minutes   | 25 L  | •   |   |
| 850 × 350 mm      | One steam sterilization cycle at 121°C for 30 minutes   | 25 L  | •   | •   |
| amma sterilizable |   |   |   |   |
| 1000 × 350 mm     | To be gamma sterilized<br>25 - 45 kGy   | 31 L  |   |   |
| 1000 × 350 mm     | To be gamma sterilized<br>25 - 45 kGy   | 31 L  |   | •   |
| 1000 × 350 mm     | To be gamma sterilized<br>25 - 45 kGy   | 31 L  | •   |   |
| 1000 × 350 mm     | To be gamma sterilized<br>25 - 45 kGy   | 31 L  | •   | •   |
|                   | team sterilizable  850 × 350 mm  850 × 350 mm  850 × 350 mm  850 × 350 mm  1000 × 350 mm  1000 × 350 mm | team sterilizable  850 × 350 mm  One steam sterilization cycle at 121°C for 30 minutes  850 × 350 mm  One steam sterilization cycle at 121°C for 30 minutes  850 × 350 mm  One steam sterilization cycle at 121°C for 30 minutes  850 × 350 mm  One steam sterilization cycle at 121°C for 30 minutes  1000 × 350 mm  To be gamma sterilized 25 - 45 kGy  1000 × 350 mm  To be gamma sterilized 25 - 45 kGy  1000 × 350 mm  To be gamma sterilized 25 - 45 kGy  1000 × 350 mm  To be gamma sterilized 25 - 45 kGy | team sterilizable           850 × 350 mm         One steam sterilization cycle at 121°C for 30 minutes         25 L           850 × 350 mm         One steam sterilization cycle at 121°C for 30 minutes         25 L           850 × 350 mm         One steam sterilization cycle at 121°C for 30 minutes         25 L           850 × 350 mm         One steam sterilization cycle at 121°C for 30 minutes         25 L           amma sterilizable         31 L           1000 × 350 mm         To be gamma sterilized 25 - 45 kGy         31 L           1000 × 350 mm         To be gamma sterilized 25 - 45 kGy         31 L           1000 × 350 mm         To be gamma sterilized 31 L         31 L | Rigid collar           team sterilizable           850 × 350 mm         One steam sterilization cycle at 121°C for 30 minutes         25 L           850 × 350 mm         One steam sterilization cycle at 121°C for 30 minutes         25 L           850 × 350 mm         One steam sterilization cycle at 121°C for 30 minutes         25 L           850 × 350 mm         One steam sterilization cycle at 121°C for 30 minutes         25 L           amma sterilizable         31 L           1000 × 350 mm         To be gamma sterilized 25 - 45 kGy         31 L           1000 × 350 mm         To be gamma sterilized 25 - 45 kGy         31 L           1000 × 350 mm         To be gamma sterilized 25 - 45 kGy         31 L           1000 × 350 mm         To be gamma sterilized 25 - 45 kGy         31 L           1000 × 350 mm         To be gamma sterilized 31 L         ■ |

 $\mathsf{DuPont}^{\mathsf{TM}}\,\mathsf{and}\,\mathsf{Tyvek}^{\$}\,\mathsf{are}\,\mathsf{trademarks}\,\mathsf{or}\,\mathsf{registered}\,\mathsf{trademarks}\,\mathsf{of}\,\mathsf{E.I.}\,\mathsf{du}\,\mathsf{Pont}\,\mathsf{de}\,\mathsf{Nemours}\,\mathsf{and}\,\mathsf{Company}.$ 



<sup>&</sup>lt;sup>1</sup> HDPE : High Density Polyethylene <sup>2</sup> PE | PA | PE : Polyethylene | Polyamide | Polyethylene <sup>3</sup> PC : Polycarbonate

# Ordering Information

| Reference     | Description  | Pack size |
|---------------|--|-----------|
| BIO1502IR     | Biosafe® 110 bottle-shaped bag autoclavable  | 28        |
| BIO1502MMIR   | Biosafe® 110 bottle-shaped bag autoclavable with protective cover                                    | 28        |
| BIO1502TRIR   | Biosafe® 110 bottle-shaped bag autoclavable with rigid collar  | 20        |
| BIO1502TRMMIR | Biosafe® 110 bottle-shaped bag autoclavable with rigid collar and protective cover                   | 20        |
| BIO1002       | Biosafe® 110 bottle-shaped bag gamma sterilizable  | 28        |
| BIO1002MM     | Biosafe® 110 bottle-shaped bag gamma sterilizable with protective cover                              | 28        |
| BIO1002TR     | Biosafe® 110 bottle-shaped bag gamma sterilizable with rigid collar                                  | 20        |
| BIO1002TRMM   | Biosafe <sup>®</sup> 110 bottle-shaped bag gamma sterilizable with rigid collar and protective cover | 20        |

### Library

Further documentation is available upon request:

- Biosafe® 110 bottle-shaped bags validation guide
- Biosafe® 110 user manual
- Biosafe® 110 ports datasheet

### Germany

Sartorius Stedim Biotech GmbH August-Spindler-Strasse 11 37079 Goettingen Phone +49 551 308 0

For further contacts, visit www.sartorius.com

### **USA**

Sartorius Stedim North America Inc. 565 Johnson Avenue Bohemia, NY 11716 Toll-Free +1 800 368 7178