



**DPTe-BetaBag<sup>®</sup> Ø 190 30L REF. 6007014656**  
**PE/EVOH/PE Bag**  
**DPTe-BetaBag<sup>®</sup> with open bottom side**  
**Standard Gamma Sterilization Range**

Product Sheet – FP 238 | 000

## Product overview

### Application

The DPTE-BetaBag® is a single use solution for safe, fast, contamination free transfer in and out of an isolator or filling line.

The DPTE-BetaBag® with a PE/EVOH/PE film bag is mainly used for component inlet, such as plungers, stoppers, caps and other small rigid components compatible with gamma sterilization.



### Key features

DPTE-BetaBag® Part Number	DPTE® BETA Type	Useful Volume	Bag size mm (LxW)	Drawing number
6007014656	190	30 L	1004x400	DC 4090-22-16

## Product description

### Main components and materials

DPTE-BetaBag® = DPTE® Beta part + Bag

- **DPTE® Beta part**
  - DPTE® Beta flange: HDPE material
  - DPTE® Beta door: HDPE material
  - J3L Silicone gasket
  - Protective cover (J3L gasket protection against damage and dirt): PC material
- **Bag**
  - Body: Multilayer film PE/EVOH/PE 120 µm.
  - Inner chute: LDPE film 80 µm.
  - Designed to provide strength and excellent gas barrier performance.
  - Cylindrical tight sealing onto DPTE® Beta part.

### Product specificities

- An inner chute for:
  - seal protection during unloading,
  - easy flow of components.
- Compatible for gamma sterilization.
- Sterilization indicator located on each DPTE® Beta door.
- Single use DPTE-BetaBag® (designed to be gamma sterilized once).
- Multi-connection on DPTE® system (qualified to be connected/disconnected 5 times).

### Loading

- Loading of the DPTE-BetaBag® through the open bottom.  
Heat sealing of the bag after loading.
- Maximum load: 10 kg.
- We suggest using a trolley when handling loaded bags.

### Properties

#### DPTE-BetaBag® properties

PROPERTIES	TEST METHOD OR STANDARD	UNITS	ACCEPTANCE CRITERIA
<b>Leaktightness</b>			
• DPTE® Beta Part 190	Pressure differential at P=-4000 Pa	Pa/min	According to Getinge specification
• DPTE-BetaBag®	Pressure differential at P=1000 Pa	Pa/min	
<b>Seal strength</b>	ISO 527-3	N/15 mm	≥ 15

## PE/EVOH/PE film properties

PROPERTIES	TEST METHOD	UNITS	TYPICAL VALUES
<b>Mechanical properties</b> <ul style="list-style-type: none"> <li>Tensile strength MD</li> <li>Tensile strength CD</li> <li>Tensile strain at break MD</li> <li>Tensile strain at break CD</li> </ul>	DIN EN ISO 527/3 (23 °C/50 % r.h.)	MPa	> 23
		MPa	> 15
		%	> 320
		%	> 400
<ul style="list-style-type: none"> <li>Puncture Resistance</li> </ul>	ASTM F 1306-90 (23 °C/50 % r.h.)	N	> 24
<b>Permeation</b> <ul style="list-style-type: none"> <li>Oxygen</li> <li>Water vapour</li> </ul>	ASTM D3985 / DIN 53380-3 (23 °C / 50 % r.h.)	cm <sup>3</sup> /m <sup>2</sup> .d.bar	< 2
	ASTM F1249 (23 °C/85 % r.h.)	g/m <sup>2</sup> .d	< 1

## Manufacturing process

Cleanroom classification is according to ISO 14644-1 standard.

- Extrusion of the film with filtered air HEPA H13 according to EN 1822.
- Shaping of the liner in ISO 7 cleanroom.
- Tight assembly of the bag onto the DPTE® Beta flange in ISO 5 cleanroom.
- Assembly of the J3L gasket and DPTE® Beta door in ISO 5 cleanroom.
- Packaging in double bag in ISO 5 cleanroom.

## Product compliance

- DPTE® Beta flange, door**
  - Meets the FDA 21 CFR 177.1520 regulation
  - BSE/TSE: EMEA 410/01 compliant
- J3L silicone gasket Ø190**
  - Meets the biocompatibility USP <88> Class VI
  - Meets the FDA 21 CFR 177.2600 regulation
  - BSE/TSE: the material contains no substances of animal origin.

## Routine tests

- Tests 100 % performed in ISO 5 cleanroom.**
  - Pressure differential test of the DPTE® Beta Part.
  - Pressure differential test of the DPTE-BetaBag®.
- Sampling test** (based on Standard NF ISO 2859-1) performed in ISO 5 cleanroom.
  - Dimensional and visual check.

## Traceability

- Each DPTE-BetaBag® is identified by a batch number. Each batch number is associated with a manufacturing batch record.

## Safety features

- The design of the DPTE-BetaBag® ensures that it cannot be connected to the DPTE® Alpha part if the DPTE® Beta door is not properly closed.

## Documentation

A statement of conformity is delivered with each manufacturing batch.

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## Use

### Service conditions

- Operating temperature for loading and unloading: between 16-24 °C.
- Gamma sterilization dose validated between 25-50 KGrays.

### Limits of resistance

Pressure: Maximum + 1000 Pa (relative pressure).

### Guarantee and shelf life

Under normal conditions of use and storage:

- 36-month shelf life after manufacturing date.

### Accessories for use (handles)

- DPTE-BetaBag® 190: Set of 2 handles.

P/N 35502 C



### Compatible type of DPTE® Alpha

- DPTE®-XS with safety interlocks (FP 211).

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## Packaging & Storage

### Packaging

DPTE BetaBag® type	190
Double over packaging	By 3 units
Cardboard box (780x420x360 mm)	3 packs of 3 units
Bag per box	9 units
Boxes per pallet	12 boxes
Pallet size over all (mm)	1200 x 1000 x 1580
Bag per pallet	108 units

### Packaging identification

- Item designation
- Item reference number
- Batch number
- Quantity

### Storage conditions

- Store the DPTE-BetaBag® in its original packaging between 16 and 24 °C and at relative humidity < 70 %.
- Protect the DPTE-BetaBag® against the effects of strong light (sun, electric lighting) and strong heat (radiators, electrical heaters).
- Use the DPTE-BetaBag® on first-in, first-out basis.

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## Glossary

### DPTE®

“Double Porte de Transfert Etanche” Double door for leaktight transfer

### DPTE®-XS

eXtra Secure Double door for leaktight transfer

### J3L

“3-effect” lip seal

### HDPE

High Density Polyethylene

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