



DPTE-BetaBag® PE/EVOH/PE Bag

Standard Gamma and X-Ray Sterilization Range

Product Sheet – FP 215 | 009

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 and X-Ray sterilization.



Key features

DPTE-BetaBag® Part Number	DPTE® BETA Type	Useful Volume	Bag size mm (LxW)	Drawing number
6007001825	105	10 L	570x400	DC 4090-16-01
6007001827	105	30 L	900x400	DC 4090-12-02
6007001927	190	10 L	690x400	DC 4090-26-02
6007011498	190	30 L	1020x400	DC 4090-22-17
6007006979	190	100 L	1315x650	DC 4090-26-03
6007008010	190	150 L	1635x650	DC 4090-26-07

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 and X-Ray sterilization.
- Sterilization indicator located on each DPTE® Beta door.
- Single use DPTE-BetaBag® (designed to be gamma or X-Ray sterilized once).
- Multi-connection on DPTE® system (qualified to be connected/disconnected 5 times).

Loading

- Loading of the DPTE-BetaBag® has to be performed through the DPTE® Beta Part connected onto a DPTE® Alpha Part.

- Maximum recommended load: 5 kg for 10L bag and 10 kg for 30L to 150L bag (depending on type of components).
- We suggest using a trolley when handling loaded bags.

Properties

DPTE-BetaBag® properties

PROPERTIES	TEST METHOD OR STANDARD	UNITS	ACCEPTANCE CRITERIA
Leaktightness <ul style="list-style-type: none">DPTE® Beta Part 105DPTE® Beta Part 190DPTE-BetaBag®	<ul style="list-style-type: none">Pressure differential at P=4000 PaPressure differential at P=1000 Pa	<ul style="list-style-type: none">Pa/minPa/min	According to Getinge specification
Seal strength	ASTM F88	N/15 mm	≥ 15
Cleanliness level	Getinge method	N/A	According to Getinge specification
Bioburden	NF EN ISO 11737-1	CFU/bag	
Endotoxin	European Pharmacopeia 2.6.14	EU/bag	

PE/EVOH/PE film properties

PROPERTIES	TEST METHOD	UNITS	TYPICAL VALUES
Mechanical properties			
• Tensile strength MD	DIN EN ISO 527/3 (23 °C/50 % r.h.)	MPa	> 23
• Tensile strength CD		MPa	> 15
• Tensile strain at break MD		%	> 320
• Tensile strain at break CD		%	> 400
• Puncture Resistance	ASTM F 1306-90 (23 °C/50 % r.h.)	N	> 24
Permeation			
• Oxygen	ASTM D3985 / DIN 53380-3 (23 °C / 50 % r.h.)	cm ³ /m ² .d.bar	< 2
• Water vapour	ASTM F1249 (23 °C/85 % r.h.)	g/m ² .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 5 cleanroom.
- Tight assembly of the bag onto the DPTE® Beta flange in ISO 5 cleanroom.
- In ISO 5 cleanroom for DPTE-BetaBag® 10 L and 30 L:
 - Assembly of the J3L gasket and DPTE® Beta door.
 - Packaging in double bag.
- In ISO 7 cleanroom for DPTE-BetaBag® 100 L and 150 L:
 - Assembly of the J3L gasket and DPTE® Beta door.
 - Packaging in double bag.

Routine tests

- **Tests 100 % performed in cleanroom.**
 - In ISO 5 cleanroom for DPTE-BetaBag® 10 L and 30 L :
 - Pressure differential test of the DPTE® Beta Part.
 - Pressure differential test of the DPTE-BetaBag®.
 - In ISO 7 cleanroom for DPTE-BetaBag® 100 L and 150 L :
 - 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.

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.
- **J3L silicone gasket Ø105**
 - Meets the FDA 21 CFR 177.2600 regulation

- **PE-EVOH-PE film**

PE-Layer which is in contact with the product is in compliance with:

- FDA 21 CFR 177.1520
- Ph. Eur. 3.1.3 / 3.1.5 / 3.2.2
- USP <661>

Additionally, we confirm that:

The film does not contain substances of animal sources (Risk. BSE/TSE, HALAL, KOSHER).

Documentation

A statement of conformity is delivered with each manufacturing batch.

Use

Service conditions

- Operating temperature for loading and unloading: between 16-24 °C.
- Gamma and X-Ray 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.

- DPTE-BetaBag® Ø 190: 36-month shelf life after manufacturing date.
- DPTE-BetaBag® Ø 105: 18-month shelf life after manufacturing date.

Shelf life validation ongoing for X-Ray range.

Accessories for use (handles)

- DPTE-BetaBag® 105: manual handling (no tool required).
- DPTE-BetaBag® 190: Set of 2 handles.

P/N 35502 C



Compatible type of DPTE® Alpha

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

Packaging & Storage

Packaging

DPTE BetaBag® type	105	190	
Volume	10 L and 30 L	10 L and 30 L	100 L and 150 L
Double over packaging	By 4 units	By 3 units	By 2 units
Cardboard box (780x420x360 mm)	6 packs of 4 units	3 packs of 3 units	3 packs of 2 units
Bags per box	24 units	9 units	6 units
Boxes per pallet	10 boxes	15 boxes	
Pallet size over all (mm)	1200 x 1000 x 1580	1200 x 1000 x 1940	
Bags per pallet	240 units	135 units	90 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.

Glossary

DPTE®

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

DPTE®-XS

eXtra Secure Double door for leaktight transfer

HDPE

High Density PolyEthylene

J3L

Triple effect lip seal

LDPE

Low Density PolyEthylene

PC

PolyCarbonate



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