



DPTE-BetaBag[®] Ø 105 30L REF. 6007001904
PE/EVOH/PE Bag

DPTE-BetaBag[®] with open bottom side for
liquid transfer

Specific Gamma and X-Ray Sterilization Range

Product Sheet – FP 237 | 001

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® REF. 6007001904 is mainly used for single use liquid transfer solutions compatible with gamma and X-Ray sterilization.



Key features

DPTE-BetaBag® Part Number	DPTE® BETA Type	Useful Volume	Bag size mm (LxW)	Drawing number
6007001904	105	30 L	900x400	DC 4090-12-01

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): PVC 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.
- Open bottom.
- 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

- Maximum recommended load: 10 kg.
- We suggest using a trolley when handling loaded bags.

Properties

DPTE-BetaBag® properties

PROPERTIES	TEST METHOD OR STANDARD	UNITS	ACCEPTANCE CRITERIA
Leaktightness	• DPTE® Beta Part 105	Pa/min	According to Getinge specification
	• DPTE-BetaBag®	Pa/min	
Seal strength	ASTM F88	N/15 mm	≥ 15

PE/EVOH/PE film properties

PROPERTIES	TEST METHOD	UNITS	TYPICAL VALUES
Mechanical properties <ul style="list-style-type: none"> Tensile strength MD Tensile strength CD Tensile strain at break MD Tensile strain at break CD 	DIN EN ISO 527/3 (23 °C/50 % r.h.)	MPa	> 23
		MPa	> 15
		%	> 320
		%	> 400
<ul style="list-style-type: none"> Puncture Resistance 	ASTM F 1306-90 (23 °C/50 % r.h.)	N	> 24
Permeation <ul style="list-style-type: none"> Oxygen Water vapour 	ASTM D3985 / DIN 53380-3 (23 °C / 50 % r.h.)	cm ³ /m ² .d.bar	< 2
	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.
- 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 Ø105**
 - Meets the FDA 21 CFR 177.2600 regulation

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.

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:

- 18-month shelf life after manufacturing date.
- Shelf life validation ongoing for X-Ray range.
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Accessories for use (handles)

- Manual handling (no tool required).

Compatible type of DPTE® Alpha

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

Packaging & Storage

Packaging

DPTE BetaBag® type	105
Double over packaging	By 4 units
Cardboard box (780x420x360 mm)	6 packs of 4 units
Bag per box	24 units
Boxes per pallet	10 boxes
Pallet size over all (mm)	1200 x 1000 x 1580
Bag per pallet	240 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

Triple effect lip seal

HDPE

High Density PolyEthylene

PVC

PolyVinyl Chloride



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