



DPTE-BetaBag®
Standard Range PU Bag
Gamma and X-Ray Sterilization Range

Product Sheet – FP 213 | 006

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 PU film bag is mainly used for waste disposal, but in some cases inlets compatible with gamma and X-Ray sterilization, are possible.



Key features

DPTE-BetaBag® Part Number	DPTE® BETA Type	Useful Volume	Bag size mm (LxW)	Drawing number	Sterile	
					YES	NO
6007001617	105	30 L	930 x 400	4090-13-01	X	
6007001925	190	10 L	550 x 310	4090-23-28	X	
6007001926	190	10 L	550 x 310	4090-23-28		X
6007001989	190	30 L	1000 x 400	4090-23-26	X	
6007001990	190	30 L	1000 x 400	4090-23-26		X
6007002098	190	100 L	1150 x 740	4090-23-27	X	
6007002097	190	100 L	1150 x 740	4090-23-27		X
6007001829	190	150 L	1400 x 740	4090-23-24	X	
6007001624	190	150 L	1400 x 740	4090-23-24		X
6007002345	270	35 L	730 x 558	4090-33-10	X	
6007002344	270	35 L	730 x 558	4090-33-10		X
6007001105	270	100 L	1150 x 815	4090-33-09	X	
6007002346	270	100 L	1150 x 815	4090-33-09		X
6007002348	270	150 L	1300 x 740	4090-33-08	X	
6007002347	270	150 L	1300 x 740	4090-33-08		X

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) made with:
 - PVC material for Ø 105 and Ø 270.
 - PC material for Ø 190.
- **Bag**
 - Body: Polyurethane film 200 µm.
 - No inner sleeve.
 - Cylindrical tight sealing onto DPTE® Beta part.

Product specificities

- Sterilization indicator located onto the first packing and on the cardboard box for sterile products.
- Single use DPTE-BetaBag®.
- Multi-connection on DPTE® system (qualified to be connected/disconnected 5 times).
- For non sterile product:
 - Compatible for gamma and X-Ray sterilization.
 - Designed to be gamma or X-Ray sterilized once.

Loading

- Loading of the DPTE-BetaBag® has to be performed through the DPTE® Beta Part connected onto a DPTE® Alpha Part.
- Maximum recommended load: 10 kg (depending on type of components).
- We suggest using a trolley when handling loaded bags.

Sterility

Sterile products, packed according the table “packaging” have been qualified according to standards ISO 11137-1 and 2 and ISO 11737-2 for a gamma sterilization cycle between 25 and 50 kGrays.

Properties

DPTE-BetaBag® PROPERTIES

PROPERTIES	TEST METHOD	UNITS	ACCEPTANCE CRITERIA
Leaktightness • DPTE® Beta Part 105 • DPTE® Beta Part 190 • DPTE® Beta Part 270 • DPTE-BetaBag®	Pressure differential at P= -4000 Pa Pressure differential at P=1000 Pa	Pa/min Pa/min	According to Getinge specification
Seal strength	ASTM F88	N/15 mm	≥ 15

PU FILM PROPERTIES

Refer to FT 096 – PU film data sheet

Manufacturing process

Cleanroom classification is according to ISO 14644-1 standard.

- Shaping of the liner in ISO 7 cleanroom.
- Tight assembly of the bag onto the DPTE® Beta flange in ISO 7 cleanroom.
- Assembly of the J3L gasket and DPTE® Beta door in ISO 7 cleanroom.
- Packaging in double bag in ISO 7 cleanroom.

Routine tests

- **Tests performed 100 % in ISO 7 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 7 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
- **PU film**
 - Meets the FDA 21 CFR 177.2600
- **J3L silicone gasket Ø 105**
 - Meets the FDA 21 CFR 177.2600 regulation
- **J3L silicone gasket Ø 190**
 - 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 Ø 270**
 - Meets the biocompatibility USP Class VI
 - Meets the FDA 21 CFR 177.2600 regulation

Documentation

A statement of conformity is delivered with each manufacturing batch.

A gamma irradiation treatment certificate is delivered with each sterile manufacturing batch.

Use

Service conditions

- Operating temperature for loading and unloading: between 16 and 24 °C.
- Gamma and X-Ray sterilization dose validated between 25 and 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: 30-month shelf life after manufacturing date.
- DPTE-BetaBag® Ø 105 and Ø 270: 24-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 and 270: 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	270
Double over packaging	By 4 units	By 3 units	By 1 unit
Cardboard box	6 packs of 4 units	3 packs of 3 units	6 packs of 1 unit
Cardboard dimensions (mm)	780x420x360	780x420x360	550x385x570
Bag per box	24 units	9 units	6 units
Boxes per pallet	15 boxes		
Pallet size over all (mm)	1200x1000x1950		
Bag per pallet	360 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

PC

PolyCarbonate

PVC

PolyVinyl Chloride



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Manufacturer:

Getinge Life Science France – Vendôme site

1 rue du Comté de Donegal – 41102 Vendôme cedex, France
Phone: +33 [0] 254 734 747 / Fax: +33 [0] 254 734 748

www.getinge.com