

Data sheet

Medical Device

1.500 ml 2.000 ml

Qufora® Bed Bags | Drainable

Free-flow T-Valve or Lever Valve | Single Packed

Hygienic. Easy-to-use.

The **Qufora®** drainable bed bags can be attached to either a urinary catheter or a urisheath. They are designed to provide additional drainage capacity overnight or for people who are permanently bedridden.

PRODUCT BENEFITS

- ► The Qufora® bed bags have a universal **conical inlet connector** (X-mas tree or step connector) making it easy to attach a urinary catheter or urisheath. The **protection cap** prevents contamination before connecting the tube to the catheter or urisheath. In addition, the cap prevents urine from dropping from the inlet tube during the exchange of the bag.
- ► The **flexible connection tubes** provide for safe drainage and allow the bag to be placed below the bladder level.
- A **non-return valve** ensures that urine will not flow back into the tube, preventing the risk of infection.
- The Qufora® bed bag (REF 13851202) comes with a fixed and easy-to clean sampling port which allows for needle-free inspection and eliminates the risk of needle stick injuries. Additionally, there is an integrated bacteria-proof and liquid-tight ventilation filter for optimal pressure balance. A separate needle-free sampling port connector/protection cap and the Qufora® hanger are also included.
- ► The **T-Valves** and **Lever valves** have **free-flow** outlets ensuring that clots can freely pass.
- ► The Qufora® bed bags can be emptied in a hygienic and safe way.
- The front has a **scale** for quick estimation of the urine volume.
- ▶ The Qufora® bed bags have **holes** for the Qufora® hangers or Qufora® floor stands.
- ► The Qufora® bed bags are **single packed** with the REF number, lot number and expiration year/month printed on the protective bag.

Qufora® Accessories (not included):

- The Qufora® hangers are durable and fit most beds.
- ► The Qufora® **floor stands** come with four small hooks, making it easy to hang the bed bag.



Connector with needle-free sample port



T-Valve



Lever valve



Scale



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Free-flow T-Valve or Lever Valve | Single Packed

Product description

- Qufora® bed bags are available in several versions with different bag volumes or lengths of the inlet tube.
- The Qufora® bed bags are single-use medical devices.

 All materials are 100% latex- and DEHP-free.

QUFORA® NON-STERILE BED BAGS FEATURES

- Inlet tube: Inner diameter for all bags 4.5mm
 except 13853402/13853403: 6.6mm and 13851202: 7.6mm
- Non-return valve
- Conical inlet connector (X-mas tree or step)
- T-Valve with white "stopper" (except 13853401)
- Lever valve on 13851202
- Free-flow outlet tube: inner diameter 9.7mm (13853101/13853403: 8.7mm)
- · Translucent and white films
- Scale on the front
- Single packed
- Holes for Qufora® hanger or Qufora® floor stand
- 13851202: refer to details on page 3

MATERIALS

Films PVC (plasticizer: DOTP/DEHT)
 Inlet tube PVC (plasticizer: DOTP/DEHT)

 Needle-free sample port and connector

Connector PVC Connector cap PE

Non-return valve
 PVC (plasticizer: DOTP/DEHT)

T-Valve/inlet tube PP/PE; inlet tube: PVC (plasticizer: DOTP/DEHT)

PVC; Port: TPE

Lever valve LDPE/ABS

Hanger PP
Single bag (product) LDPE
Single bag (hanger) LDPE
Poly bag (outer) PE

PACKAGING

Retail box Cardboard

Shipper box Corrugated cardboard IFU One (1) per retail box

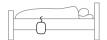
Shelf-life Five (5) years

 Storage Dry in temperatures between 0°C and 35°C; protected from direct sunlight; humidity level max 80%; not to be exposed to heavy pressure









QUFORA® BED BAGS - DRAINABLE NON-STERILE - T-VALVE - SINGLE PACKED

REF	Volume	Tube length	Free-flow outlet tube ³	White "stopper"	Quantity retail box	Quantity shipper box	GTIN-14 ⁴
13753101	1.500 ml	90 cm	Yes	Yes	25	100	15710187004600
13850301	2.000 ml	130 cm	Yes	Yes	10	100	15710187001623
13853101	2.000 ml	90 cm	Yes	Yes	25	100	15710187001562
13853401	2.000 ml	110 cm	Yes	No	25	100	15710187001593
13853402	2.000 ml	110 cm ²	Yes	Yes	-	100	157101870036345
13853403¹	2.000 ml	110 cm ²	Yes	Yes	-	100	157101870073115

All products with X-mas connector (except 13853401: Step connector)

¹Fixed needle-free sample port connector (X-mas tree connector); ²Wide inlet tube (X-mas tree connector): Inner diameter: 6.6 mm;

QUFORA® BED BAGS - DRAINABLE NON-STERILE - LEVER VALVE - ADJUSTABLE TUBE LENGTH - NEEDLE-FREE SAMPLE PORT - SINGLE PACKED

REF	Volume	Tube length		Separate sample port	Quantity poly bag	Quantity shipper box	GTIN-14 ⁵
13851202 ¹	2.000 ml	130 cm ²	Yes ³	Yes ⁴	10	80	15710187013558

Needle-free sample port, ventilation filter, sheet clip, sliding clamp, hanger and holes for the Qufora® hangers or Qufora® floor stands.

¹Dog-house for the outlet valve; ²Wide inlet tube (X-mas tree connector): Inner diameter: 7.6 mm; adjustable tube length; ³Inner diameter: 8.7mm; ⁴Extra/separate needle-free sample port connector (X-mas connector) and protection cap; ⁵GTIN barcode number for poly bag

PRODUCT CLASSIFICATION

 Medical Devices conforming to MDR 2017/745 in Class I

APPLIED STANDARDS

• ISO 13485 Quality Management System

• ISO 8669-2 Urine collection bags

- Part 2: Requirements and test methods

• GMDN 58922

³Inner diameter: 9.7mm; ⁴GTIN barcode number for retail box; ⁵GTIN barcode number for shipper box

Qufora® Accessories (not included)

QUFORA® BED HANGER



REF	Description	Single packed	Quantity retail box	Quantity shipper box	GTIN-14 ¹
21100101	Bed hanger - fits all beds - easy to opera- te with one hand	Yes	5	50	15710187001777

QUFORA® FLOOR STAND



REF	Description	Single packed		Quantity shipper box	GTIN-14 ¹
99910003	Floor stand	Yes	1	20	15710187013589

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¹GTIN barcode number for retail box

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Medical Devices conforming to MDR 2017/745 in Class I

APPLIED STANDARDS

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ISO 13485 **Quality Management System**

Bed hanger: 41052; Floor stand: 41052 **GMDN**