

Data sheet

Medical Device

2.000 ml

Sterile

Qufora® Bed Bags | Drainable

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

Hygienic. Easy-to-use.

The sterile **Qufora® drainable bed bags** with a needle-free sample port and integrated ventilation filter 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 **flexible inlet tube is kink-resistant** and ensures a steady drainage even when the tube turns softer due to, for example, body heat. The inlet tube can be securely fixed with the enclosed **sheet clip** and the tube length allows the bag to be placed below the bladder level. The **sliding clamp** on the inlet tubing facilitate urine sampling.
- ► The **flow rate** of the inlet tube is more than 10 ml/second, which ensures a secure and stable flow from the bladder.
- A **non-return valve** ensures that urine will not flow back into the tube, preventing the risk of infection.
- The sterile Qufora® bed bags come with an easy to clean **sampling port** which allows for needle-free inspection and eliminates the risk of needle stick injuries. The conical inlet connector (X-mas tree) makes 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 sterile Qufora® bed bags have an **integrated bacteria-proof** and **liquid-tight ventilation** filter for optimal pressure balance.
- ► The **T-Valves** and **Lever valves** have **free-flow** outlets ensuring that clots can freely pass.
- ► The **Fold-away**, or **Doghouse**, fixates the outlet tube. This keeps the bed clean of urine, achieves additional distance to the floor and prevents contamination.
- ► 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



Qufora® Bed Bags | Drainable

Free-flow T-Valve or Lever Valve

Product description

- Qufora® sterile bed bags are available in three different models: U4, S4 and Q4, all with a needle-free sample port and integrated ventilation filter.
- The Qufora® bed bags are single-use medical devices.

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

OUFORA® STERILE BED BAGS FEATURES

- Inlet tube: Inner diameter: 7.6mm
- Non-return valve
- Lever valve or T-Valve with white "stopper"
- Free-flow outlet tube: Inner diameter 8.7mm
- Needle-free sampling port with X-mas connector/cap
- · Translucent and white films
- Integrated ventilation and bacteria-proof filter
- Fold-away or Doghouse for outlet tube fixation
- Scale on the front
- Single packed
- Eyelets for Qufora® hanger or Qufora® floor stand

MATERIALS

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

 Needle-free port and connector

Doghouse

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

Lever valve/inlet tube

LDPE/ABS inlet tube: PVC (plasticizer: DOTP/DEHT)

T-Valve/inlet tube PE/PI

PE/PPE

inlet tube: PVC (plasticizer: DOTP/DEHT) PVC (plasticizer: DOTP/DEHT)

PVC; Port: TPE

Sheet clip ABS Sliding clamp ABS

Ventilation filter PA

Single bag (product) HDPE & PE/PET

Poly bag (outer) PE

PACKAGING

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

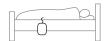
Shelf-life Five (5) years

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









Sterile

Needle-free sample port connector

QUFORA® BED BAGS - DRAINABLE STERILE - NEEDLE FREE SAMPLE PORT - T-VALVE OR LEVER VALVE - SINGLE PACKED



REF	Volume	Tube length ³	Free-flow outlet tube ⁴	Valve	Quantity poly bag	Quantity shipper box	GTIN-14 ⁶
14823202¹: U4	2.000 ml	120 cm	Yes	Lever	25	25	15710187002613
14851201 ² : S4	2.000 ml	120 cm	Yes	Lever	25	25	15710187001692
14853202¹: Q4	2.000 ml	120 cm	Yes	T-valve⁵	25	25	15710187001661

All products have a needle-free sample port, ventilation filter, sheet clip, sliding clamp and holes for the Qufora® hangers or Qufora® floor stands.

¹Fold-away for the outlet valve; ²Doghouse for the outlet valve; ³Wide inlet tube (X-mas connector): Inner diameter: 7.6 mm; ⁴Inner diameter: 9.0mm; ⁵White "stopper" on the T-valve; ⁶GTIN barcode number for poly bag

STERILIZATION

Gas sterilized with ethylene oxide (EtO)

PRODUCT CLASSIFICATION

 Medical Devices conforming to MDR 2017/745 in Class I sterile (Is)

APPLIED STANDARDS

• ISO 13485 Quality Management System

• ISO 8669-2 Urine collection bags

- Part 2: Requirements and test methods

GMDN 58921

Qufora® Accessories (not included)

Non-sterile

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

¹GTIN barcode number for retail box

PRODUCT CLASSIFICATION

 Medical Devices conforming to MDR 2017/745 in Class I

APPLIED STANDARDS

• ISO 13485 Quality Management System

• GMDN Bed hanger: 41052; Floor stand: 41052