

Data sheet

Medical Device

350 ml

600 ml

750 ml

800 ml

Non-sterile

Sterile

Qufora® Leg Bags | Single Chamber | Drainable

Q-Flow Valve or T-Valve | Adjustable or Fixed Tube Length | Single Packed

Discreet. Comfortable. Easy-to-use.

The sterile **Qufora® leg bags** are designed to be worn discreetly under clothing and can be attached to either a urinary catheter or a urisheath. The Qufora® leg bags come with rounded corners for added comfort and are easily fixed to the leg using the Qufora® leg straps.

PRODUCT BENEFITS

- ▶ The **single chamber** bags come with different tube lengths or volumes.
- ▶ The Qufora® leg bags have a soft **adjustable or fixed inlet tube**. The adjustable tube makes it possible to personalize the tube's length. One sterile leg bags also come with a separate connector/cap.
- ▶ A **non-return valve** ensures that urine will not flow back into the tube, reducing the risk of infection.
- ▶ The Qufora® leg bags have a universal **conical inlet connector** (X-mas tree), making it easy to attach a urinary catheter or urisheath to the bag.
- ▶ The front has a **scale** for quick estimation of the urine volume in the bag and the back has a skin friendly **soft backing** for increased comfort, even in warm conditions.
- ▶ The patented **Q-Flow valve** is easy, ergonomic and safe to operate with one hand - also for people with reduced finger dexterity. When turning it 90°, the valve is fully open. At 180° the valve is still fully open and now placed in a safe position without any risk of closing unexpectedly during the night.
- ▶ The **Q-Flow valve** has a silicone tube for easy connection to a urine bag for the night, decreasing the risk of infection when changing the bag.
- ▶ The **Q-Flow valve** provides for a **free-flow** drainage of urine in a **hygienic and safe** manner.
- ▶ The **T-Valve**, with a white "stopper", is easy and safe to operate with one hand. It has a silicone tube for easy connection to a urine bag for the night, decreasing the risk of infection when changing the bag.
- ▶ The sterile Qufora® leg bags come with a **needle-free sample port** for easy urine sampling. The sample port is specially designed for easy cleaning.
- ▶ The Qufora® leg 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® **leg straps** are designed for the Qufora® leg bags. The straps (with two buttons and silicone anti-slip) are adjustable for individual needs and the bags include **holes** for the straps.

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Connector (X-mas tree) with needle-free sample-port (sterile bags)



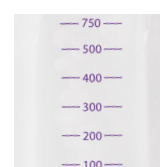
Q-Flow valve



T-Valve



Scale



Soft backing



Qufora® Leg Bags | Single Chamber | Drainable

Q-Flow Valve or T-Valve | Adjustable or Fixed Tube Length | Single Packed

Product description

- ▶ Qufora® leg bags are available in several versions with different bag volumes or lengths of the inlet tube.
- ▶ The Qufora® leg bags are single-use medical devices.
All materials are 100% latex- and DEHP-free.

QUFORA® LEG BAG FEATURES

- Single chamber
- Adjustable or fixed inlet tube length with a frosted surface (inner diameter: 5.5mm) (11451503, 11451803, 11401803: inner diameter: 5.0mm)
- Separate or fixed connector with protective cap
- Non-return valve
- Conical inlet connector (X-mas tree)
- Non-woven soft backing
- Q-Flow valve with soft silicone outlet tube and free flow (outlet tube: inner diameter: 8.0mm)
- T-Valve with white "stopper" and soft silicone outlet tube (outlet tube: inner diameter: 8.0mm)
- Translucent and white films
- Scale on the front
- Single packed
- Eyelets for straps

MATERIALS

- | | |
|---------------------------|--|
| • Films | PVC (plasticizer: DOTP/DEHT) |
| • Inlet tube | PVC (plasticizer: DOTP/DEHT) |
| • Connector | PP (bags with adjustable tube length) |
| • Connector (sample port) | PVC; Port: TPE (bags with fixed tube length) |
| • Connector cap | PE |
| • Non-return valve | PVC (plasticizer: DOTP/DEHT) |
| • Soft backing | Non-woven PET |
| • Q-Flow valve | LLDPE/POM; |
| • T-Valve/white "stopper" | Inlet tube: PVC (plasticizer: DOTP/DEHT)
PP/PE |
| • Outlet tube | Inlet tube: PVC (plasticizer: DOTP/DEHT)
Silicone |
| • Single bag (product) | LDPE (non-sterile products) |
| • Single bag (product) | HDPE & PE/PET (sterile products) |
| • Poly bags | LDPE (inner and outer bag) |

PACKAGING

- | | |
|---------------|---|
| • Retail box | Cardboard |
| • Shipper box | Corrugated cardboard |
| • IFU | One (1) per retail box or inner poly bag |
| • 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 |

11221502





Non-sterile

**QUFORA® LEG BAGS - SINGLE CHAMBER - DRAINABLE
NON-STERILE - Q-FLOW VALVE - ADJUSTABLE OR FIXED TUBE LENGTH - SINGLE PACKED**

REF	Volume	Tube length	Connector	Soft backing	Quantity poly bag	Quantity shipper box	GTIN-14 ⁵
11061901	350 ml	30 cm ²	X-mas	Yes	10 ⁴	100	15710187005850
11223802 ¹	600 ml	10 cm ³	X-mas	No	25	100	15710187001203
11221902	600 ml	30 cm ³	X-mas	Yes	25	100	15710187001234
11221502	600 ml	50 cm ²	X-mas	Yes	25	100	15710187004181
11421502	800 ml	50 cm ²	X-mas	Yes	25	100	15710187004167

¹Slanting outlet tube; ²Adjustable tube length; ³Fixed tube length; ⁴Retail box; ⁵GTIN barcode number for retail box or poly bag

Non-sterile

**QUFORA® LEG BAGS - SINGLE CHAMBER - DRAINABLE - NON-DRAINABLE
NON-STERILE - T-VALVE - ADJUSTABLE OR FIXED TUBE LENGTH - SINGLE PACKED**

REF	Volume	Tube length	White "stopper"	Soft backing	Quantity poly bag	Quantity shipper box	GTIN-14 ⁵
11251502	600 ml	50 cm ³	Yes	Yes	25	100	15710187001173
11251902	600 ml	30 cm ⁴	Yes	Yes	25	100	15710187001142
11259802 ¹	600 ml	10 cm ⁴	Yes	No	25	100	15710187001111
11451503	750 ml	50 cm ⁴	Yes	No	25	100	15710187004631
11451803	750 ml	10 cm ⁴	Yes	No	25	100	15710187004662
11401803 ²	750 ml	10 cm ⁴	No	No	25	100	15710187004693

All bags with X-mas tree connector

¹Slanting outlet tube; ²Non-drainable bag with tear mark; ³Adjustable tube length (loose connector/cap); ⁴Fixed tube length; ⁵GTIN barcode number for poly bag

Sterile

Needle-free sample port connector

**QUFORA® LEG BAGS - SINGLE CHAMBER - DRAINABLE
STERILE - Q-FLOW VALVE OR T-VALVE - ADJUSTABLE OR FIXED TUBE LENGTH - SINGLE PACKED**

REF	Volume	Tube length	Needle free sample port	Soft backing	Quantity retail box	Quantity shipper box	GTIN-14 ⁶
12061901 ¹	350 ml	30 cm ³	Yes ⁵	Yes	10	100	15710187007038
12251902 ²	600 ml	30 cm ⁴	No ⁵	Yes	10	100	15710187003078

¹Q-Flow Valve; ²T-Valve with white "stopper"; ³Fixed length and adjustable option with separate connector/cap; ⁴Fixed tube length; ⁵X-mas tree connector; ⁶GTIN barcode number for retail box

Non-sterile

QUFORA® LEG STRAPS



REF	Description	Width / length	Quantity retail box	Quantity shipper box	GTIN-14 ¹
21100301	Velcro® leg straps 1 pair with silicone anti-slip and buttons	3 cm / 60 cm	10 pairs	100 pairs	15710187001715

Sterile

QUFORA® Q-FLOW VALVE



REF	Description	Quantity retail box	Quantity shipper box	GTIN-14 ¹
21104201	Q-Flow valve with 5 cm soft silicone tube	30	300	15710187004754

QUFORA® T-VALVE



REF	Description	Quantity retail box	Quantity shipper box	GTIN-14 ¹
21104101	T-Valve with 5 cm soft silicone tube	30	300	15710187001807

QUFORA® LEVER VALVE



REF	Description	Quantity retail box	Quantity shipper box	GTIN-14 ¹
21104301	Lever valve with 5 cm soft silicone tube	30	300	15710187001838

¹GTIN barcode number for retail box

PRODUCT CLASSIFICATION

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

APPLIED STANDARDS

- ISO 13485 Quality Management System
- ISO 8669-2 Urine collection bags
- Part 2: Requirements and test methods
- GMDN Urinebags: Non-sterile: 58924; Sterile: 58923
Straps: 38861; Valves (sterile): 31975

STERILIZATION

- Gas sterilized with ethylene oxide (EtO)

Importer

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