

### Data sheet

Medical Device

500 m

Non-sterile

Sterile

# **Qufora**® Leg Bags | Multi 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 **multi chamber** system ensures that the Qufora® leg bags are almost invisible and noiseless under clothing, even when full.
- ► The Qufora® leg bags have a soft **adjustable or fixed inlet tube**. The adjustable tube makes it possible to personalize the tube's length. Two 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.



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



Q-Flow valve



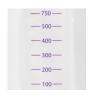


T-Valve



Scale

Soft backing





# Qufora® Leg Bags | Multi 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**

- Multi chamber (3 chambers)
- Adjustable inlet tube length (non-sterile) with a frosted surface (inner diameter: 5.5mm)
- Fixed and adjustable inlet tube length (sterile) with a frosted surface (inner diameter: 5.5mm)
- Separate or fixed connector with protective cap
- Non-return valve
- Conical inlet connector
- 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: Non-sterile products & separate connector for sterile

products: 12161502 & 12361502 (x-mas connector)

Connector (sample port)
 PVC; Port: TPE (sterile products)

Connector cap Pl

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

Soft backing Non-woven PETQ-Flow valve LLDPE/POM;

Inlet tube: PVC (plasticizer: DOTP/DEHT)

T-Valve/white "stopper" PP/P

PP/PE Inlet tube: PVC (plasticizer: DOTP/DEHT)

Outlet tube Silicone

Single bag (product)
 LDPE (non-sterile products)
 HDPE & PE/PET (sterile products)



Retail box
 Cardboard

Shipper 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





#### Non-sterile

## QUFORA® LEG BAGS – MULTI CHAMBER - DRAINABLE NON-STERILE - Q-FLOW VALVE OR T-VALVE - ADJUSTABLE TUBE LENGTH - SINGLE PACKED

REF	Volume	Tube length <sup>3</sup>	White "stopper"	Soft backing	Quantity retail box	Quantity shipper box	GTIN-14 <sup>4</sup>
11121501 <sup>1</sup>	500 ml	50 cm	Yes	Yes	10	100	15710187001296
11161502 <sup>2</sup>	500 ml	50 cm	No	Yes	10	100	15710187004402
11321501 <sup>1</sup>	750 ml	50 cm	Yes	Yes	10	100	15710187001326
11361502 <sup>2</sup>	750 ml	50 cm	No	Yes	10	100	15710187004518

All bags with seperate X-mas tree connector/cap

<sup>1</sup>T-Valve; <sup>2</sup>Q-Flow Valve; <sup>3</sup>Adjustable tube length; <sup>4</sup>GTIN barcode number for retail box

### Sterile

## QUFORA® LEG BAGS – MULTI CHAMBER - DRAINABLE STERILE - Q-FLOW VALVE - ADJUSTABLE OR FIXED TUBE LENGTH - SINGLE PACKED

Needle-free sample port connector



REF	Volume	Tube length	Needle-free sample port <sup>3</sup>	Soft backing	Quantity retail box	Quantity shipper box	GTIN-14 <sup>4</sup>
12161802*	500 ml	10 cm <sup>1</sup>	Yes	Yes	10	100	15710187005829
12161602	500 ml	25 cm <sup>1</sup>	Yes	Yes	10	100	15710187005096
12161502	500 ml	50 cm <sup>2</sup>	Yes	Yes	10	100	15710187004433
12361802	750 ml	10 cm <sup>1</sup>	Yes	Yes	10	100	15710187012346
12361902	750 ml	25 cm <sup>1</sup>	Yes	Yes	10	100	15710187012377
12361502	750 ml	50 cm <sup>2</sup>	Yes	Yes	10	100	15710187004723

<sup>\*</sup> Wide inlet tube (inner diameter 7.6mm)

<sup>1</sup>Fixed tube length; <sup>2</sup>Fixed tube length and adjustable option with separate connector/cap (no needle-free sample port); <sup>3</sup>X-mas tree connector; <sup>4</sup>GTIN barcode number for retail box

#### **PRODUCT CLASSIFICATION**

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

## **STERILIZATION**

Gas sterilized with ethylene oxide (EtO)

### **APPLIED STANDARDS**

- ISO 13485 Quality Management System
- ISO 8669-2 Urine collection bags
  - Part 2: Requirements and test methods
- GMDN Non-sterile: 58924; Sterile: 58923

# **Qufora**® Accessories (not included)

#### Non-sterile

## **QUFORA® LEG STRAPS**



REF	Description	Width / length	Quantity retail box	Quantity shipper box	GTIN-14 <sup>1</sup>
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**

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

### **QUFORA® LEVER VALVE**



REF	Description	- ,	Quantity shipper box	GTIN-14 <sup>1</sup>
21104301	Lever valve with 5 cm soft silicone tube	30	300	15710187001838

<sup>&</sup>lt;sup>1</sup>GTIN barcode number for retail box

## **PRODUCT CLASSIFICATION**

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

### **APPLIED STANDARDS**

**GMDN** 

ISO 13485 Quality Management System

• ISO 8669-2 Urine collection bags

- Part 2: Requirements and test methods Urinebags: Non-sterile: 58924; Sterile: 58923

Straps: 38861; Valves (sterile): 31975

## STERILIZATION

• Gas sterilized with ethylene oxide (EtO)

Denmark