



POLY MEDICURE LIMITED

TECHNICAL DATA SHEET **Urine Collection Bag**

**POLY MEDICURE LIMITED****TECHNICAL DATA SHEET
Urine Collection Bag**Page No.
1 of 5

Product Code	Description Of Product
30101	Polyuro- Premium with 100cm tube-9.0mmx6.6mm
30102	Polyuro- Premium with 100cm tube-9.0mmx6.6mm, with sampling port
30103	Polyuro with 100 cm tube-8.0mmx5.7mm, Bag capacity-2000ml (Polyuro Deluxe)
30104	Poly Echo with 90cm tube-6.8mmx5.0mm
30105	POLYMED Urine Collection Bag with Bottom outlet with tube-6.8mmx5.0mm, length 100 cm
30106	POLYMED Urine Collection Bag with Bottom outlet with tube-6.8mmx5.0mm, length 90 cm
30107	Urine collection bag with Top outlet & Rod for hanging with tube-8.0mmx5.9mm, length 100 cm (Polyuro Standard)
30108	POLYMED Leg Bag set with tube-9.1mmx6.5mm, length 50 cm, Bag capacity-800ml
30109	POLYMED Leg Bag set with tube-9.1mmx6.5mm, length 75 cm, Bag capacity-800ml
30110	POLYMED Urine collection bag with T-Type Bottom Outlet and Sampling Port, with tube-9.0mmx6.6mm, length 100 cm
30111	POLYMED Urine collection bag with T-Type Bottom Outlet, with tube-9.0mmx6.6mm, length 100 cm
30112	POLYMED Paediatric Urine Collection Bag
30113	Polyurimeter - 250 ml- WITH SAMPLING PORT, tube-9.1mmx6.5mm, length 130cm
30114	Polyurimeter - 500 ml- WITH SAMPLING PORT, tube-9.1mmx6.5mm, length 130cm
30115	Polyurimeter - 250 ml- WITHOUT SAMPLING PORT, tube-9.1mmx6.5mm, length 130cm
30116	Polyurimeter - 500 ml - WITHOUT SAMPLING PORT, tube-9.1mmx6.5mm, length 130cm
30117	Polyuro- ULTRA with 150cm tube-9.0mmx6.6mm
30118	Polyuro- ULTRA with 150cm tube-9.0mmx6.6mm, with sampling port
30119	Polyurimeter - 250 ml- WITHOUT SAMPLING PORT, tube-9.1mmx6.5mm, length 160cm
30120	POLYMED Urine collection bag with T-Type Bottom Outlet and Sampling Port, R4 hanger, with tube-9.0mm x 6.6mm, length 100 cm
30121	Polyurimeter - 250 ml- with Needle free SAMPLING PORT, Tube-9.1mmx6.5mm, length 130cm
30122	Polyurimeter - 500 ml- with Needle free SAMPLING PORT, Tube-9.1mmx6.5mm, length 130cm
30123	Poly Uro Premium With Air Filter - Urine Collection Bag With T-Type Bottom Outlet, NRV & Air Filter
30124	Urine bag with T-type bottom outlet 2000ml with Needle Free Sampling Port
30125	Urine bag with T-type bottom outlet 2000ml with Air Filter with Needle Free Sampling Port
30126	Polyurimeter - 250 ml- without sampling port tube-9.0mmx6.6mm, length 120cm
30127	Polyuro-2 , with 110 cm tube-8.0mmx5.7mm, top outlet with hanger, Bag capacity-2000ml Ribbon pack

Product Image



General Information:

Intended Use

The Urine Collection Bag is used to collect urine from a patient in short term by connecting to a Foley's or Nelaton Catheter.

Legal Manufacturer-

POLY MEDICURE LIMITED

Plot No.: 104-105, Sector 59, HSIIDC Industrial Area, Ballabhgarh,
Faridabad, HARYANA, INDIA - 121004

Manufacturing Site-

POLY MEDICURE LIMITED

Plot No.:104-105, Sector 59, HSIIDC Industrial Area, Ballabhgarh,
Faridabad, HARYANA, INDIA – 121004

European Authorized Representative- Name and address

OBELIS S.A.

Boulevard Général Wahis 53,
B-1030, Brussels,
Belgium

Certification:

Certification	Notified Body
CE Certificate Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III <u>CE Certificate No.: G11 041938 0012</u>	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany <u>Notified Body Number: 0123</u>
EN ISO 13485:2016/DIN-EN ISO 13485:2016 <u>Certificate No.: Q5 041938 0001 Rev.03</u>	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany

Device Classification:

- As per "Classification Criteria" in Annexure- VIII of Regulation (EU) 2017/745 Urine Collection Bags are normally intended for continuous use for between 60 minutes and 30 days. Hence, these are for short-term device as per description in 1.2 of Annexure- VIII.
- As Urine bag does not penetrate into body hence this device is "Non-invasive device".
- As per Rule- 1 of Classification, Urine Collection Bags are classified as Class- I Medical devices.

Device Description:

Urine collection Bag made from medical grade soft, Semi-transparent PVC sheet. It consists of a bag with connecting tube with a universal taper connector compatible to fit with Foley or Nelaton Catheter and **an outlet port towards bottom side**. A non-return valve has been provided in Urine Bag which prevents back flow thus offering added protection. The sampling port helps to avoid needle-stick injuries and reduces the risk of infection.

Urine collection bag is used to collect urine from a patient in short term. It is connected to a urinary Catheter for collection and temporary storage of urine.

The urine bag is provided with an easily readable scale with graduations to measure the volume of urine. Urine is collected in bag via PVC collection tubing & excess urine is drained through outlet connector. The Outlet connector is cylindrical in shape with a stopper. Flexible PVC tubing connects to NRV at proximal end and connects to inlet connector at the distal end. The urine collected from distal end passes through the collection tube and collected in the bag. Urine collection bag with measure volume meter is provided with a rigid measuring chamber.

Technical Specification:

*A non-return valve has been provided in Urine Bag which prevents back flow thus offering added protection. **The sampling port helps to avoid needle-stick injuries and reduces the risk of infection.***

- Soft & kink resistant **PVC Tubing with Non-Return Valve.***
- Bag graduated in ml to indicate the quantity of urine collected.*
- The capacity of urine bag varies from 100 ml to 2000 ml.***
- The bag is made of non-toxic & medical grade PVC Sheet suitable for short term urine collection.*
- Options of different tube length e.g. 50, 75, 90, 100, 110, 120, 130, 150 & 160 cm are available as per variants.*
- Available with specially molded **handle for easy handling** or Reinforced hole for hanging or Rod at the top for hanging the bag.*
- Urine collection Leg bag provides freedom of mobility as the bag is attached to the leg of the patient. The soft non-woven backing material allows the skin to breathe, making it comfortable and almost noiseless in use.*
- Urine collection bag is available with T-type bottom outlet and sampling port for clean single hand operation and efficient emptying of the bag.***
- Urine collection bag graduated in ml with measured volume meter offers accurate measurement of urine.***
- Sampling port provided** for samples collections maintains closed system, reduces the risk of contamination and the chance of Urinary Tract Infection.*
- Pediatric urine bag provided with special adhesive paper on one end for better grip and easy removal from soft skin of the male or female infants.*

Approved Materials of Constructions:

S. No.	Parts Where Material is used	Base Material	CAS No.
1	PVC Tubing	PVC Compound	9002-86-2
2	Non-Return Valve	PVC	9002-86-2
3	Inlet Connector	ABS	9003-56-9

**POLY MEDICURE LIMITED****TECHNICAL DATA SHEET
Urine Collection Bag**Page No.
4 of 5

S. No.	Parts Where Material is used	Base Material	CAS No.
		PVC	9002-86-2
4	PVC Sheet for Bag	PVC	9002-86-2
5	Hanger	HDPE	9002-88-4
6	Inlet Cap without Hole	Polypropylene	9003-07-0
7	Inlet Cap with Hole	Polypropylene	9003-07-0
8	Hook	ABS	9003-56-9
9	U-Hanger	Polypropylene	9003-07-0
10	R-4 Hanger	Polypropylene	9003-07-0
11	T-Type Bottom outlet Pin	HDPE	9002-88-4
12	T-Type Bottom outlet Barrel	Polypropylene	9003-07-0
13	Bottom Cap	HDPE	9002-88-4
14	Straight Connector	PVC	9002-86-2
15	Outlet Connector Big/small	PVC	9002-86-2
16	Nylon Dori	Nylon	25038-54-4
18	Sampling port connector	RPVC	9002-86-2
		ABS	9003-56-9
19	Valve	Polyisoprene rubber / Silicone	102782-809/78-79-5
20	Tube Clamp	ABS	9003-56-9
21	Tube Hanger Rod	PVC	9002-86-2
22	Tube Sleeve	PVC	9002-86-2
23	Flaper	PVC	9002-86-2
24	Bottle Urimeter	PVC	9002-86-2
25	Bottle Connector+	PVC	9002-86-2
26	Pediatric Urine Collection Bag	LDPE + 80GSM paper + Acrylic adhesive	NA
27	Elastic String With Button	Elastic Rubber	NA
28	Protective cap for T-type connector	LDPE	9002-88-4
29	Hydrophobic filter 3 micron width 16mm	BOP	NA

Sterilization Method:

Sterilized using Ethylene Oxide

Shelf Life:

Five years from the date of manufacturing

Standards Compliance:

Document Code	Document Description
EN ISO 13485:2016+ A11:2021	Quality system - Medical Devices - Requirements for the Regulatory Purposes
EN ISO 14971:2019/ A11:2021	Application of risk management to medical devices
IEC 62366-1:2015 / Amd 1:2020	Medical Devices – Application of usability engineering to medical devices
EN ISO 11135:2014 /A1:2019	Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 11737-1:2018/A1:2021	Sterilization of health care products -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products.
EN ISO 11737-2:2020	Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.

**POLY MEDICURE LIMITED****TECHNICAL DATA SHEET
Urine Collection Bag**Page No.
5 of 5

Document Code	Document Description
EN ISO 11607-1:2020/ A1:2023	Packaging for terminally sterilized medical devices – requirements for materials, sterile barrier & packaging systems.
EN ISO 11607-2:2020/ A1:2023	Packaging for terminally sterilized medical devices – Validation requirements for forming, sealing and assembly process.
EN ISO 15223-1:2021	Symbols to be used with medical devices labels, labeling and information to be supplies
ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
EN ISO 10993-1:2020	Biological evaluation of medical devices – Evaluation and testing within a risk management process.
EN ISO 8669-2:1996	Urine collection bags - Part 2: Requirements and test methods

Reference to QMDS Documents:

Document Title	Polymed Internal Document Reference
Technical File	PML/MD/TF/20
Product Specification	FP/QA/214
Risk Management	PML/MD/RA/20
Clinical Evaluation	PML/MD/CER/20
DOC	F/QA/176

Packaging Characteristics:

The urine collection bag is individually packed in ribbon pouches. These pouches are designed to ensure product protection and maintain hygiene during handling, storage, and transportation.

- One (1) unit package shall be packed into one inner duplex printed cardboard box.
- Twenty (20) duplex boxes shall be packed into one corrugated shipper box.

This packaging system—comprising the unit package, duplex box, and shipper box—shall provide adequate protection during standard shipping, handling, and storage, ensuring the product reaches the end user in optimal condition.

Storage Conditions:

Store in between 5°C to 35°C, avoid excessive heat, protect from direct sunlight and moisture.

Materials of Concern:

- Not made with natural rubber latex or DEHP plasticizer.
- Any substances of animal origin e.g., BSE/TSE are not used during manufacturing.