

Fig.1: Urine Bag

1. PRODUCT DESCRIPTION:

Device for urine collection or waste are made of flexible plastic sheet welded together to form a bag. On the top there is a tube which is attached to urinary catheter and a drain tub is also attached with bag . Sold only sterile condition in order to protect the patient from any contamination. Material of composition: PVC, ABS, PP. Duration of Use: Short Term.

2. DEVICE CLASSIFICATION AND RULE:

The device is classified as Class Is/Rule 1, medical device (classification as per MDR Annex II Section 1.1(f); Annex VIII.)

3. PRODUCT CHARACTERISTICS & INTENDED USE:

Intended use: Urine bag is intended for collection of urine of a patient during the surgery and post-surgery. It is attached to a Foley's catheter recovery.

Features:

- Drainage and monitoring of urine from an indwelling catheter
- Tapered and corrugated connector design ensures secure fixation to the catheter.
- Each bag includes a dedicated sampling port.
- Integrated non-return (anti-reflux) valve at the tubing-to-bag connection which prevents backflow of urine and supports infection control.
- Front surface provided with clear and legible graduations with markings available in 50–100 mL increments for volume estimation.
- Space for recording date of change included.
- Reinforced eyelets provided for suspension designed to support the weight of a fully filled bag without tearing.
- Flip-type drainage valve with 180° rotation for full opening and closing.

- Wide bore design (~1 cm diameter) allows smooth drainage of viscous urine.
- Leak-resistant performance in closed position.

4. PRODUCT VARIANTS:

Following variants are available for the products:

S.No.	Product	Type	Gauge/Size (FG)	GMDN Code	Classification
1.	**Urine CollectionBag**	With T Hanger, Without T hanger, with Urimeter	100ml, 500ml, 1000ml,1500ml, 2000ml	31086	Is/1

5. MATERIAL OF CONSTRUCTION:

Component Functionality:

S. No.	Components	Material Used
1.	Hanger	Used to hang the urine bag securely to a fixed location (e.g., bedpost or IV pole) to allow gravity flow of urine.
2.	Bag	Holds the collected urine, designed to be flexible and durable for easy storage and disposal.
3.	PVC Tube	Transports urine from the catheter or drainage point to the bag, made of flexible, medical-grade PVC.
4.	Top Connector	Connects the PVC tube to the catheter or drainage point, ensuring a secure and leak-proof connection.
5.	Bottom Connector	Connects the bag's drainage valve to the PVC tube, allowing for the urine to flow into the bag.
6.	Top Connector Cap	Seals the top connector when not in use, maintaining sterility and preventing leaks or contamination.
7.	Bottom Connector Cap	Seals the bottom connector when not in use, ensuring hygienic storage and preventing leaks.

Description of the Raw Materials:

S. No.	Components	Material Used
1	Hanger	LDPE
2	Bag	PVC Sheet
3	PVC Tube	PVC
4	Top Connector	Soft PVC
5	Bottom Connector	Soft PVC
6	Top Connector Cap	Rigid PVC
7	Bottom Connector Cap	Rigid PVC

Table- Components and their raw materials

6. PRODUCT SPECIFICATION:

- Tubing length: minimum 90 cm.
- Internal diameter: approximately 1 cm.
- Soft and flexible material helps prevent patient discomfort and reduces tension on the catheter.

S. No.	Characteristic	Criteria/Limit/Value
i.	Visual	Should be free from foreign particle
ii.	Mould Defect	Should be no defect
iii.	Length of Tube	90, 100, 120, 150 (CM)
iv.	O.D. of Tube	6.9 ± 0.2mm
v.	Tube Kink	Should be no Kink
vi.	Capacity of Urine Bag (Size)	500ml, 1000ml, 1500ml, 2000ml
vii.	Working of bottom connector cap	Should be no leakage at gravity feed
viii.	Functional of Non-Returnable Valve	Should be no Return Urine in Opposite Direction
ix.	Working of Outlet Cap	Should be no leakage at gravity feed
x.	Printing matter	Should Legible
xi.	Tear Mark	Should be printed on Pouch
xii.	Sterility	Should be Comply
xiii.	Bacterial Endotoxin Test	Should be Comply
xiv.	Physico Chemical Test	Should be Comply
xv.	Liquid Leakage	Should be no leakage at gravity feed
xvi.	Additional test	- - - - - - - - - - -

7. REFERENCE COMPLIANCE STANDARD:

S. No.	Name of Standard	Standard Number
ISO Standards for Urine Bag		
1.	Urine collection bags Part 2: Requirements and test methods	ISO 8669-2:1996
2.	6% Luer- Small-bore connectors for liquids and gases in health care applications	EN ISO 80369-7:2017
3.	Sampling Procedure For Inspection By attributes	ISO 2859-1:1999
4.	Clean Rooms And Associated Controlled Environments: Classification of air cleanliness by particle concentration	EN ISO 14644-1:2015
5.	Clean Rooms And Associated Controlled Environments : Monitoring to provide evidence of clean room performance related to air cleanliness by particle concentration	EN ISO 14644-2:2015

6.	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements	EN ISO 15223-1:2021
7.	Sterilization of Health-care products - Ethylene Oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices	EN ISO 11135:2014/ Amd 1:2018
8.	Sterilization of health care products - Biological Indicators - Part 1: General requirements	EN ISO 11138-1:2017
9.	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	EN ISO 11607-1:2019
10.	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	EN ISO 11607-2:2019
11.	Sterilization of health care products - Biological indicators for ethylene oxide sterilization processes	EN ISO 11138-2:2017
12.	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1:2020
13.	Biological evaluation of medical devices - Part 3: Tests for Genotoxicity, carcinogenicity and reproductive toxicity	EN ISO 10993-3:2014
14.	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood	EN ISO 10993-4:2017
15.	Biological evaluation of medical devices - Part 5: Tests for in vitro Cytotoxicity	EN ISO 10993-5:2009
16.	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	EN ISO 10993-10:2021
17.	Biological evaluation of medical devices - Part 11 : Tests for systemic toxicity	EN ISO 10993-11:2017
18.	Medical devices - Quality management systems - Requirements for regulatory purposes	EN ISO 13485:2016
19.	Medical devices - Application of risk management to medical devices	EN ISO 14971:2019
20.	Clean rooms and associated controlled environments - bio-contamination control- general principles and methods	EN ISO 14698-1:2003
21.	Medical devices - Part -1: Applications of Usability engineering to the medical devices.	IEC 62366-1:2015/Amd 1:2020
22.	Clinical Investigations of medical devices for human subjects - Good Clinical Practices	ISO 14155:2020,
23.	Medical Devices- Post market Surveillance for manufacturers	ISO 20416:2020

24.	General Specifications & Validation methods for non- sterile medical device packages in good distribution practice principles	ISO 23417:2020
25.	Clinical Evaluation Assessment Report Template	MDCG 2020-13
26.	Medical Devices Regulations Clinical Evidence Requirements	MEDDEV 2.7.1 Rev 4,

8. PACKAGING DETAILS:

Packaging specifications		
1.	Primary packaging (Paper Pouch)	01 Nos.
2.	Outer / Master Carton (Corrugated box)	100 Nos.

9. COMPLIANCE INFORMATION:

Manufacturer Information: Disposafe Health and Life Care Ltd., Plot No. 1 & 2, Phase-II, Sec-59, Ballabgarh, Faridabad-121004, Haryana (INDIA)
Drug Manufacturing License No.: MFG/MD/2019/000106
QMS Certification: EN ISO 13485:2016, TUV SUD Product Service GmbH CE Marking: **TUV SUD Product Service**: GmbH, EC Notified body No. 0123 GMDN Code: 32172

10. ABBREVIATIONS:

QMS – Quality Management System
GMDN – Global Medical Device Nomenclature
P.V.C – Poly-vinyl Chloride
L.D.P.E – Low-density polyethylene