

ZIBO EASTMED HEALTHCARE PRODUCTS CO., LTD

Add: No. 99 Lutai Road, Gaoxin District, Zibo City 255086, Shandong, China

Website: www.eastmedcn.com Tel: +86-533-5201297 Fax: +86-533-5201298

Email: ruth@eastmedcn.com

TECHNICAL DATA OF DISPOSABLE URINE BAG

A. Registration Certificate of Disposable Urine Bag

1.) Certificate of ISO13485:2003 issued by TUV (No.: Q2N 13 09 34827 017)

2.) Certificate of CE Issued by TUV (No.: G2S 14 05 34827 019)

B. Type & Chemical Composition of Raw Material:

Name of Parts	Name of Code of Raw Material	
(1) . Urine Collection Bag	Polyvinyl Chloride	P.V.C.
(2) . Inlet Tubing (90CM)	Polyvinyl Chloride	P.V.C.
(3) . Connector	Polyvinyl Chloride	P.V.C.
(4) . Non-return Valve	Polyvinyl Chloride	P.V.C.
(5) . Outlet tubing	Polyvinyl Chloride	P.V.C.
(6) . Cap	Polyethlyene	P. E.

Microbiologic, Toxical, Chemical and Mechanical Properties:

1. Microbiologic, Toxically and Chemical:

a. Non-toxic: Non-toxic

b. Allergy : Hypoallergenic

c. Pyrogenic: Non-pyrogenic

d. Abnormal Poisonousness: No abnormal poisonousness in accordance with the Pharm.of P.R. China and B.P.

e. Acidity-alkali Degree: The difference of solution through a hypodermic needle comparison P.H. with comparative liquid is less than 1.0.

f. Heavy Metal: The color of solution through a hypodermic needle is no deeper than the color of standard liquid. (Contents of Pb; Zn; Sn and Fe are not more than 5 μ g/ml.

(Content of Cd is less than 0.1 μ g/ml.)

3. Mechanical Properties:

a. Tightly Connecting of Circular Cone in Conical Fitting: There is not any water-drop from the combination between circular and standard cone when axial

- pressure force of 27.5N acts on it for 5 seconds and it is rotated at less than twisting force of 0.1 N° m at angle of 90° under hydro-pressure of 300Kpa.
- b. Security between Hub and Cannula: Jointer between hub and cannula should not be slit and separated at 15N static axial force.
 - c. Fragmentation rate of needle(according to DIN13097)----Measurement of Inclination
 - d. Tensile strength between metal tube and handle, minimum 20N.
 - e. Stress bread Test: Carry out according to Clause 12 of ISO7864 and its Annex B(B2.1; B2.2; B2.3)
 - f. Needle Sharpness: The needle should be sharp, no burr, no other defects through magnifying glass(2.5times).The bevel of the needle point and the needle handle should be in the same direction, and their gradient force should not exceed 30°C. All the inspection requirements should be in accordance with the Clause 4.15 and 4.20 of GB15811-1995.

1. Method of Analysis

- a. Non-toxic: W test by using white mouse.
- b. Pyrogenic: We test by using rabbit.
- c. Abnormal Poisonououeness: We test by using white mouse.
- d. Hemolysis: We test by measuring the quantities of hemoplobin released by red cell.
- e. Reducing Matter: We test by colourimetric analysis.
- f. Heavy Metal: We test by colourimetric analysis.
- g. Acidity-alkali Degree: We use PH meter to measure PH value of both extract prepared and control fluid.
- h. Non-volatidity: We use vapouring and weighting method.
- i. Chloride: We test by colourmetric analysis.

2. Details and Process of the Sterilization by ETO

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|--------------------------------|-------------------------|
| a. Type of Sterilization Cycle | Overkill Cycle |
| b. Gas Mixture | 100% Ethylene Oxide Gas |
| c. Maximum Level of Gas Reside | < 10ppm |
- d. Sterilization process:
 - i. Load the products in sterilizer;
 - ii. Load and place 10 pieces of biological indicators in sterilizer for proving and checking the result of sterility;
 - iii. Precondition at 50°C ±5°C temperature and 40% humidity for 30 minutes;
 - iv. Initial Vacuum: 22±2HG;
 - v. Inject the 30/70 ETO Gas /CO into the sterilizer and operate sterilization cycle at 55°C ± 5 °C temperature and 50%humidity with exposure pressure 12PSIG for 12Hrs.
 - vi. Evacuate the mixture gas with the 15HG evacuation for 30 minutes.

- vii. In bleed the fresh air into the sterilizer;
- viii. Repeat the procedure of above-mentioned vi. and vii.
- e. Expiry Period: 3 years.

B. Package:

- 1. Carton: Double-layer corrugated carton
 - a. Outer Surface: 300g kraft
 - b. Middle: 127g high strength corrugated paper
 - c. Inner surface: 300g kraft
 - d. Printing on Carton

Front	Side
SHANCHUAN CE0123 DISPOSABLE URINE BAG LOT NO. MFG. DATE: EXP. DATE:	QTY.: PCS G.W.: KGS N.W.: PCS MEAS.: CM

- 2.Inner Packing: PE Bag
- 3.Individual Packing: small PE bag

Remarks: All the printings on carton, secondary & primary package could be printed as the clients requested.

For and on behalf of
ZIBO EASTVED HEALTHCARE PRODUCTS CO., LIMITED