

# DECLARATION OF CONFORMITY MEDICAL DEVICE REGULATION 2017/745 CONCERNING MEDICAL DEVICES

**SYC/JY-CE19-0001**

**Edition: A/0**



**MANUFACTURER:**

NAME: JIANGSU SUYUN MEDICAL MATERIALS CO., LTD.  
ADDRESS: NO.18 JIN QIAO ROAD, DAPU INDUSTRIAL PARK,  
LIANYUNGANG, JIANGSU PROVINCE, PEOPLE'S REPUBLIC OF CHINA  
POSTAL CODE:222002  
SRN:CN-MF-000021132

**MEDICAL DEVICE:**

NAME: *STERILE URINE DRAINAGE BAG FOR SINGLE USE*

TYPE AND SIZE: Paediatric 100ml general , Paediatric 100ml boy use, Paediatric 100ml girl use, Paediatric 150ml general type ,Paediatric 150ml boy use,Paediatric 150ml girl use, 200ml general type, 200ml boy use,200ml girl use,750ml, Adult 1000ml,without outlet,Adult 1000ml,with cross valve /T-valve, Adult 1000ml,with pull/push valve, Adult 1000ml,with twist/ screw valve, Adult 1500ml,without outlet, Adult 1500ml,with cross valve /T-valve, Adult 1500ml,with pull/push valve, Adult 1500ml,with twist/ screw valve, Adult 2000ml,without outlet, Adult 2000ml,with cross valve /T-valve, Adult 2000ml,with pull/push valve, Adult 2000ml,with twist /screw valve, Luxury 2000ml.

CODE:714111, 714112,714113,71111,71102,71103,71114,71450

*Intended purpose: THE MAIN CLINICAL USAGE IS TO COLLECT URINE FOR THOSE INCONTINENCE PATIENTS, BEDRIDDEN PATIENTS AND OTHER LOWER LIMBS PARALYSED PATIENTS.*

BASIC UDI-DI:69332982019

CLASSIFICATION - ANNEX VIII: RULE 1: CLASS I , STERILE

CONFORMITY ASSESSMENT ROUTE: ANNEX IX (CHAPTER I + III)

WE, JIANGSU SUYUN MEDICAL MATERIALS CO.,LTD., HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE MEDICAL DEVICE REGULATION RUGULATION 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 APRIL 2017.WE STATED THAT THE EU DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF OUR COMPANY.

STANDARDS APPLIED: **EN ISO 13485:2016/A11:2021, EN ISO 14971:2019/A11:2021, EN ISO 11135:2014/A1:2019, EN ISO 11607-1:2020/A1:2023,EN ISO 11607-2:2020/A1:2023, EN ISO 10993-1:2020, EN1422:2014, EN ISO 11737-1:2018/A1:2021, EN ISO 11737-2:2020, MEDDEV2.7.1 Rev 4, EN ISO15223-1:2021,EN ISO 8669-2:1996.**

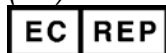
**NOTIFIED BODY:**

TÜV SÜD PRODUCT SERVICE GMBH  
RIDLERSTRASSE 65, 80339 MUNICH, GERMANY

**IDENTIFICATION NUMBER**

**CE** 0123

**(EC) CERTIFICATE(S):**



**EUROPEAN REPRESENTATIVE:**

**Shanghai International Holding Corp. GmbH (Europe)**  
**Eiffestraße 80, 20537 Hamburg, Germany**  
**Tel: 0049-40-255726**

**PLACE, DATE OF DECLARATION:**

LIANYUNGANG, JIANGSU

DATE: 2025-05-22

**SIGNATURE:**

江苏苏云医疗器材有限公司

NAME: ZHANG QINGJUN

POSITION: GENERAL MANAGER

张宏平