

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

SYC/JY-CE19-0001

Edition: C/1



MANUFACTURER:

< Jiangsu Suyun Medical Materials Co., Ltd >
< Site 1: Jiangsu Suyun Medical Materials Co., Ltd., No.1 Medicine Lane, Renmin Rd., 222002 Lianyungang, PEOPLE'S REPUBLIC OF CHINA
Site 2: No.18 Jin Qiao Road, Dapu Industrial Park, 222002 Lianyungang, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA >

MEDICAL DEVICE:

< Sterile Urine Drainage Bag for single use >

SPECIFICATION:

<Child type and adult type >

CLASSIFICATION - ANNEX IX:

Class I sterile, Rule 1

CONFORMITY ASSESSMENT ROUTE:

MDD 93/42/EEC Annex V

WE, JIANGSU SUYUN MEDICAL MATERIALS CO., LTD, HERE WITH DECLARE THAT THE STATED MEDICAL DEVICE MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES;

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER, AND THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

NOTIFIED BODY:

**TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR. 65 - 80339 MUNICH, GERMANY**

IDENTIFICATION NUMBER

CE 0123

(EC) CERTIFICATE(S):

No.G2S 043337 0044 Rev.03

EXP. DATE:

<2024-4-13 >



EUROPEAN REPRESENTATIVE:

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START OF CE-MARKING:

<2008.12.09>

PLACE, DATE OF DECLARATION:

<LIANYUNGANG>, 2021-1-10

SIGNATURE:

NAME: MR. QINGJUN ZHANG
POSITION: GENERAL MANAGER

江苏苏云医疗器材有限公司
JIANGSU SUYUN MEDICAL MATERIALS CO., LTD

秦宏平